Draft Screening Assessment

Zinc and Its Compounds

Environment and Climate Change Canada
Health Canada

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Synopsis

Pursuant to sections 68 and 74 of the *Canadian Environmental Protection Act, 1999* (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of zinc and its compounds. Sixty-four of these substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA. Eleven additional substances were identified for further consideration following prioritization of the Revised In Commerce List (R-ICL).

There are both natural and anthropogenic sources of zinc to the environment. Natural sources include weathering, wind and water erosion of zinc-enriched rocks, soils and sediments. Anthropogenic sources include: zinc metal production (e.g., mining and processing); the manufacture, import and use of zinc compounds, products and manufactured items; and industrial activities (e.g., iron and steel manufacturing, pulp and paper manufacturing, wastewater treatment systems, tire and rubber manufacturing). Results of the *Domestic Substances List* Inventory Update (DSL IU) Phase 1, 2 and 3 surveys for 72 zinc compounds indicate that those zinc compounds were reported to be manufactured in Canada in quantities ranging from 0.1 t to more than 500 t and imported into Canada in quantities ranging from 0.1 t to more than 10 000 t.

Activities and uses involving zinc and its compounds reported in Canada and abroad include metal mining, galvanizing, as an intermediate in metallurgical processes, non-ferrous metal smelting and refining processes, fertilizers, hard material tools, paints and coatings, plastics, tires and rubber. In addition, zinc is present in thousands of products available to consumers including supplemented foods and food packaging, drugs, cosmetics, natural health products (e.g., multi-vitamin/mineral supplements), pesticides, paints and coatings, sealants, cleaning products, automotive products, and plant fertilizers.

Zinc species often encountered in the environment include $ZnOH^+$, Zn^{2+}, and $ZnCO_3$. The species typically considered to be the source of toxicity (due to its bioavailability) is the uncomplexed, free ion (Zn^{2+}). However, as zinc interacts with various constituents of water, soil and sediment, it can form many different complexes. Competition with other chemicals at the receptor site in organisms and formation of organic or inorganic metal species can render a significant fraction of dissolved metals non-bioavailable. The predicted no-effect concentration (PNEC) in surface water is based on the recently derived Canadian Council of Ministers of the Environment (CCME) Canadian Water Quality Guideline (CWQG) for zinc for the Protection of Aquatic Life, which allows for the derivation of site-specific PNECs dependant on toxicity modifying factors, namely hardness, pH and dissolved organic carbon.

The ecological exposure assessment focuses on releases of zinc from the main sectors of activity associated with the greatest quantities in commerce or with the largest reported releases to the environment, when enough data was available. These include metal mining, base metal smelting and refining (BMS), iron and steel manufacturing, and

wastewater treatment systems. Predicted environmental concentrations (PECs) derived using measured concentrations of zinc in surface water samples collected at sites receiving metal mining effluent were found to exceed surface water PNECs at certain mining facilities. PECs based on measured zinc concentrations in samples collected from waterbodies near base metal smelters and refineries were generally below PNEC except for one facility, where BMS effluents are combined with mining effluents. PECs derived for the iron and steel sector using average annual releases of zinc calculated using loadings reported to a provincial government, did not exceed PNECs. Similarly, PECs derived for wastewater treatment systems using measured concentrations of zinc in effluents were determined to be lower than PNECs.

Considering all available lines of evidence presented in this draft screening assessment, there is risk of harm to the environment from zinc and soluble zinc compounds. It is proposed to conclude that zinc and soluble zinc compounds meet the criteria under paragraph 64(*a*) of CEPA as they are entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, it is proposed to conclude that zinc and soluble zinc compounds do not meet the criteria under paragraph 64(*b*) of CEPA as they are 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.

Zinc is ubiquitous in air, drinking water, food, soil, and house dust, and it is present in thousands of products available to consumers. Food is the primary source of exposure for the general public. General population exposure was characterized using nationally representative biomonitoring data from the Canadian Health Measures Survey (CHMS), the First Nations Biomonitoring Initiative (FNBI), and the Maternal-Infant Research on Environmental Chemicals Early Childhood Biomonitoring and Neurodevelopment (MIREC-CD Plus) Study. Total concentrations of zinc measured in whole blood and urine provide a biologically relevant, integrated measure of exposure that may occur across multiple routes (e.g., oral ingestion, dermal contact and inhalation) and sources (e.g., natural and anthropogenic, environmental media, diet, and frequent or daily-use products). Whole blood zinc concentrations increase with age, and the highest zinc concentrations in whole blood are found in older adults, while urinary zinc concentrations display a ‘U’ shaped pattern of exposure, with the highest concentrations in 3 to 5 year olds and in older adults. Generally, males have higher blood and urine concentrations of zinc than females. The evidence linking changes in biomarker concentrations to changes in external exposures is stronger for urine than for whole blood. Hence, urine zinc concentration was identified as the most suitable biomarker to quantify population-level zinc exposure.

Although zinc is an essential element to human health, elevated intake may result in adverse health effects. Several international organizations have previously established exposure guidance values (e.g., tolerable upper intake level, reference dose) to protect against toxicity of zinc on the basis of the alteration of copper status observed in human supplementation studies. The alteration of copper status in those studies was considered mild and within the range of natural variation. Thus, to characterize human

health risk, biomonitoring equivalents were developed for the no observed adverse effect level (NOAEL) and lowest observed adverse effect level (LOAEL) associated with headaches, nausea, vomiting, loss of appetite and abdominal cramps reported in the individuals. Median and 95th percentile concentrations of total zinc in urine from the CHMS survey were lower than the urine biomonitoring equivalent values derived for the NOAEL and LOAEL. Therefore, zinc and its compounds are considered to be of low concern to the health of the general population in Canada at current levels of exposure.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that zinc and its compounds do not meet the criteria under paragraph 64(*c*) of CEPA as they are 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.

It is therefore proposed to conclude that zinc and soluble zinc compounds meet one or more of the criteria set out in section 64 of CEPA. It is also proposed that zinc and soluble zinc compounds meet the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

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1. Introduction

Pursuant to sections 68 and 74 of the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of zinc and its compounds to determine whether these substances present or may present a risk to the environment or to human health. Sixty-four substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA ECCC, HC [modified 2007]). Eleven additional substances were identified for further consideration following prioritization of the Revised In Commerce List (R-ICL)[1] (Health Canada [modified 2017a]).

The focus of the ecological and human health screening assessments is on the zinc moiety. The scope of the assessment considers all zinc compounds on the Domestic Substances List (DSL) that may release zinc as well as zinc in its elemental form and zinc released in the environment in dissolved, solid or particulate forms. The risk assessment is therefore not limited to the 75 substances listed in Appendix A. For simplicity, the zinc moiety is referred to as “zinc” in the assessment.

This assessment addresses key pathways and sources of zinc exposure relevant to ecological receptors and human health and therefore considers zinc in environmental compartments (e.g., water, sediments, soil and air), food, or products that may result from natural or anthropogenic sources. Anthropogenic sources include zinc production (e.g., mining), incidental production of zinc (i.e., as a by-product), and the manufacture, import and use of zinc compounds, products or manufactured items. All substances in this group that have the potential to dissolve, dissociate or degrade to release zinc through various transformation pathways can potentially contribute to the exposure of living organisms to bioavailable forms of zinc. This assessment considers the combined exposure to zinc, whether it is present in environmental compartments (e.g., water), food or products.

This assessment only considers effects associated with zinc and does not address other elements or moieties that may be present in certain zinc compounds (such as cadmium or copper). Some of these other elements or moieties have already been addressed through previous assessments conducted as part of the Priority Substances List program under CEPA or may be addressed via other initiatives of the Chemicals Management Plan (CMP). Engineered nanomaterials containing zinc are not explicitly considered in exposure scenarios of this assessment, but measured zinc concentrations in the environment could include engineered nanomaterials containing zinc. However, health effects associated with nano-scale zinc are not considered in this screening

[1] The Revised In Commerce List (R-ICL) is a list of substances that are known to have been authorized for use in commerce in Canada between 1987 and 2001. As the substances are present in Canada, the government is addressing them for potential impact on human health and the environment, in order to risk-manage the substances if required.

assessment. Lastly, zinc is an essential element for human health; this assessment evaluates the potential for harm from elevated zinc exposure rather than deficiency or essentiality.

This draft screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures, including additional information submitted by stakeholders. Relevant data were identified up to December 2017. Empirical data from key studies as well as results from models were used to reach proposed conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

The human health risks of the substances in this assessment were characterized using Biomonitoring-based Approach 2 (Health Canada [modified 2016a]), which compares human biomonitoring data (exposure) against biomonitoring guidance values (health effects), such as biomonitoring equivalents (BEs), to identify substances with low concern for human health.

This draft screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The ecological and human health portions of this assessment have undergone external review and consultation. Comments on the technical portions relevant to the environment were received from Prof. Beverly Hale (University of Guelph), Dr. Claude Fortin (Institut national de la recherche scientifique), and Dr. Jim McGeer (Wilfrid Laurier University). Comments on the technical portions relevant to human health were received from Dr. Judy LaKind (University of Maryland School of Medicine, Maryland/ LaKind Associates), Dr. Harold Sandstead (University of Texas Medical Branch, Galveston, Texas), and Dr. Gunnar Nordberg (Umea University, Sweden/ Department of Public Health and Clinical Medicine Alfred Bernard Louvain Centre, Belgium). In addition, the health portion of this assessment is based on the Biomonitoring-based Approach 2 Science Approach Document (SciAD) (published December 9, 2016) which was externally peer-reviewed and subject to a 60-day public comment period. External peer-review comments were received from Lynne Haber and Andrew Maier from Toxicology Excellence for Risk Assessment (TERA) and Judy LaKind from LaKind Associates. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This draft screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA by examining scientific information and incorporating a weight of evidence approach and precaution.[2] This draft

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

screening assessment presents the critical information and considerations on which the proposed conclusions are based.

2. Identity of substances

Zinc (Zn) is a transition metal belonging to group 12 of the periodic table, and its predominant oxidation state in natural environments is Zn (II) (Zn^{2+}). Zinc compounds considered in this assessment belong to various categories or subgroups, including elemental zinc, inorganic compounds, organic-metal salts, organometallic compounds, and compounds of "unknown or variable composition, complex reaction products, or biological materials". The identities of the 64 substances identified as priorities for assessment and the 11 additional substances on the R-ICL are presented in Appendix A.

3. Physical and chemical properties

A summary of physical and chemical properties of key zinc compounds identified as remaining priorities for assessment is presented in Table B-1 in Appendix B. Zinc is amphoteric (i.e., it can react both as an acid and a base) and a chalcophile (i.e., more often found in sulphide minerals) (Sandstead and Au 2015). In a biological system, zinc is redox neutral (Sandstead and Au 2015) and readily binds to proteins with appropriate amino acid motifs. Its redox properties are therefore not relevant (Krezel and Maret 2016) for this assessment. Zinc metal is stable in dry air, but in moist air it is coated with Zn oxide or basic carbonate (Sandstead and Au 2015). Zinc forms compounds with many organic or inorganic ligands such as oxygen (e.g., zinc oxide ZnO, CAS RN 1314-13-2) or sulphur (e.g., zinc sulphide ZnS, CAS RN 1314-98-3) (WHO 2001) and forms many salts (e.g., zinc chloride ($ZnCl_2$, CAS RN 7646-85-7) (Sandstead and Au 2015). At slightly alkaline pH, zinc forms hydroxides (e.g., $Zn(OH)_2$, CAS RN 20427-58-1) that have lower water solubility, whereas at both extremes of pH, solubility is increased, favouring releases of Zn^{2+} ions at low pH and zincate [tetrahydroxozincate ion, $Zn(OH)_4^{2-}$] at high pH (Sandstead and Au 2015).

In general, most of the zinc compounds on the DSL may dissociate or degrade to release zinc at environmentally and physiologically relevant conditions (e.g., pH and concentration). Metallic zinc is insoluble, while the water solubilities of different zinc compounds range from insoluble (oxides, carbonates, phosphates, and silicates) to soluble (sulphates and chlorides) (CCME 2018a). For example, at temperatures between 20 °C to 25 °C, zinc chloride is highly soluble, zinc distearate is sparingly soluble (i.e., 0.97 mg/L), and other compounds, such as zinc phosphate, are insoluble in water (OECD 2012).

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.

4. Sources and uses

4.1 Natural sources

Natural sources of zinc in the environment include the weathering of zinc-enriched rocks, soils and sediments by wind and water (Clement Associates 1989). Erosion of soils naturally enriched with zinc particularly accounts for a large input of zinc into water (CCME 2018a). Additional sources include forest fires, volcanic activity, and aerosol formation above seas (Singh 2005). Globally, the largest source of natural emissions of zinc to the atmosphere is sea salt spray (Richardson et al. 2001). Mean predicted emission rates from the various natural sources are 4.6×10^6 kg/year for Canada, 3.8×10^7 kg/year for North America, and 5.9×10^9 kg/year globally (Richardson et al. 2001).

4.2 Anthropogenic sources

4.2.1 Zinc production

Canada is the ninth largest mine producer of zinc globally (NRCan 2016). In 2015, zinc was produced from mines in British Columbia, Manitoba, Ontario, Quebec, Yukon, and Newfoundland and Labrador (NRCan 2016). Sphalerite (zinc sulphide) is the most important zinc ore. Canadian mines produced 272 000 tonnes of zinc concentrate in 2015, but production has been steadily declining since 2008 (NRCan 2016). Zinc concentrate is produced from zinc ore, but it is also a by-product/co-product in the mining and production of several other metals, including lead (NRCan 2007). In 2015, Canada was the fourth largest producer of refined zinc (from both mined and recycled sources) with a production of 683 000 tonnes from refineries located in British Columbia, Manitoba, and Quebec (NRCan 2016).

4.2.2 Manufacture and imports

Canadian smelters imported 532 000 tonnes of zinc in concentrates in 2015 (NRCan 2016). Canada exported 513 000 tonnes of unwrought zinc and other zinc metal products in 2015, primarily to the United States (NRCan 2016). Information regarding the manufacture and import into Canada of 72 zinc substances was obtained under three CEPA section 71 DSL Inventory Update (DSL IU) surveys: Phase 1 (53 substances), Phase 2 (10 substances) and Phase 3 (9 substances) (Canada 2009; Canada 2012; Canada 2017). It is presented in Tables C-1 (Appendix C). Three substances (CAS RN 36393-20-1, 68918-69-4, 1434719-44-4) were not surveyed. For the purpose of the notices, “manufacture” was defined as the production or the preparation of a substance, including the incidental production of the substance (Environment Canada 2009a; Environment Canada 2013).

Results of the DSL IU Phase 1 survey indicate that 23 zinc compounds were manufactured in Canada in quantities ranging from 0.1 t to more than 500 t by 28 companies and that 49 zinc compounds were imported into Canada in quantities

ranging from 1 t to more than 10 000 t by 110 companies (Environment Canada 2009a). Of the 53 substances surveyed under DSL IU Phase 1, 16 CAS RNs were either manufactured and/or imported in quantities greater than 500 t (Environment Canada 2009a). The DSL IU Phase 2 survey showed that only 1 of the 10 zinc compounds surveyed was reported to be imported into Canada in quantities ranging from 1 to 10 t and that there were no zinc compounds reported to have been manufactured in Canada (Environment Canada 2013). Two of nine substances surveyed had import quantities reported in the DSL IU Phase 3 survey ranging from 0.1 to 10 t; there were no reports of manufactured quantities (ECCC 2017).

4.3 Uses

Zinc and its compounds have a wide array of industrial, commercial and consumer, applications. The primary use of refined zinc (i.e., 50% of the worldwide production) is in galvanizing iron and steel products (e.g., pipes, wires) to prevent corrosion and rust (NRCan 2016). The remaining uses include 17% in alloys, 17% in brass and bronze and 6% in chemicals (NRCan 2016). Zinc oxide (ZnO, CAS RN 1314-13-2) is the compound most commonly used in industrial applications (Environment Canada 2009a; Environment Canada 2013). Main uses for zinc oxide in the EU include: manufacture of rubber, tires and general rubber goods (36%), glass and ceramics (27%), ferrites and catalysts (12%), animal feed (9%), raw material for the production of zinc chemicals (4.5%), fuel and lubricants additives (4.5%), paints (4.5%) and cosmetics and pharmaceuticals (2%) (EC 2008a). Zinc phosphate ($Zn_3(PO_4)_2 \cdot 2\text{-}4H_2O$, CAS RN 7779-90-0) is used in the EU as an active inorganic anticorrosive pigment in primers and paints for corrosion protection of metal substrates (EC 2006a). Zinc sulphate ($ZnSO_4$, CAS RN7733-02-0) is mainly used in the EU for the production of fertilizers and pesticides (60%) and for agriculture pharmaceutical purposes, such as feedstuff additives (20%), and in the chemical industry (20%) (EC 2006b). Zinc chloride ($Zncl_2$, CAS RN 7646-85-7) is mainly used in the EU in the chemical industry (37%), galvanizing industry (28%), battery industry (15%), agrochemical industry (fungicides) (13%) and printing and dye industry (7%) (EC 2006c). Zinc distearate ($Zn(C_{18}H_{35}O_2)_2$, CAS RN 557-05-1) is mainly used in the EU in the polymers industry as a stabilizer component (e.g., in PVC stabilizers), lubricant, mould release agent and dusting agent for rubber (~55%) (EC 2006d). Zinc distearate is also used in the paints, lacquers and varnishing industry as a sanding and flatting agent (~18%), in the building industry as a waterproofing agent in concrete (5%), in the paper, pulp, board and textile industry as a waterproofing agent (~2%), in the cosmetics and pharmaceutical industry (~1%), in the chemical industry (~1%), in the metal industry (~1%) and in other applications (EC 2006d).

In Canada, the major uses of zinc compounds and the sectors where use occurs were identified from surveys issued pursuant to a CEPA section 71 notice (Canada 2009; Canada 2013; Canada 2017). Some of the major uses of zinc in Canada involve the following sectors: iron and steel mills and ferro-alloy manufacturing; medical health products and veterinary; hardware manufacturing; pulp, paper and paperboard mills; animal food manufacturing and crop production; metal products manufacturing and foundries; and chemical manufacturing. Zinc is used in the metal finishing industry in

Canada for electroplating processes, but data on its use in this sector are limited. Additional uses of zinc in Canada are identified in Table 4-1.

Table 4-1. Additional uses in Canada for zinc

Use	Zinc
Food additive[a]	Y
Incidental additives[b]	Y
Food packaging materials[b]	Y
Mineral nutrients added to foods including supplemented foods[c]	Y
Medicinal or non-medicinal ingredients in disinfectant, human or veterinary drug products[d]	Y
Medicinal or non-medicinal ingredient in licensed natural health products [e,f]	Y
List of Prohibited and Restricted Cosmetic Ingredients[g]	Y
Notified to be present in cosmetics under the *Cosmetic Regulations*[h]	Y
Active ingredient or formulant in registered pest control products[i]	Y

[a] Health Canada [modified 2012], zinc sulfate as a permitted yeast food.

[b] While not defined under the Food and Drugs Act (FDA), incidental additives may be regarded, for administrative purposes, as those substances which are used in food processing plants and which may potentially become adventitious residues in foods (e.g., cleaners, sanitizers). Personal communication, email from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated May 25, 2017; unreferenced.

[c] Zinc is permitted to be added, as a mineral, to breakfast cereals, infant formulas and formulated liquid diets, foods represented for use in a very low energy diet, simulated meat products, meal replacements and supplements, and products simulating whole egg (Canada 1978) Health Canada [modified 2016b].

[d] Personal communication, email from the Therapeutic Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated May 24, 2017; unreferenced.

[e] NHPID [modified 2018], personal communication, emails from the Non-prescription and Natural Health Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated May 10, 2017; unreferenced, Health Canada [modified 2018a].

[f] LNHPD [modified 2018], personal communication, emails from the Non-prescription and Natural Health Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated May 10, 2017; unreferenced.

[g] Health Canada [modified 2018b]; Health Canada's Cosmetic Ingredient Hotlist is an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances may contravene the general prohibition found in section 16 of the Food and Drugs Act (FDA) or may contravene one or more provisions of the Cosmetic Regulations. Zinc borate and zinc peroxide are identified as being restricted on the Cosmetic Ingredient Hotlist.

[h] Personal communication, emails from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated May 26, 2017; unreferenced.

[i] Personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated June 1, 2017; unreferenced, Health Canada [modified 2016c], Health Canada 2010.

5. Releases to the environment

Reporting to the NPRI is mandatory for zinc and its compounds for facilities meeting the reporting threshold[3] (NPRI 2016). Results from 2011 to 2015 for annual releases of zinc and its compounds from reporting Canadian facilities to air, land and water are reported in Table 5-1.

[3] Zinc and its compounds on an elemental basis, manufactured, processed or otherwise used at a facility at a concentration equal to or greater than 1% by weight (except for by-products and mine tailings) and in a quantity of 10 tonnes or more, and where employees worked 20 000 hours or more.

Table 5-1. Quantity of zinc and its compounds released annually to air, soil and water from 2011 to 2015 (t)[a]

Year	Air	Water	Land	Total[b]
2011	444	211	153	808
2012	475	207	159	841
2013	395	257	133	785
2014	346	222[c]	88	656[c]
2015	398	213	72	683
Range of annual releases	346 to 475	207 to 257[c]	72 to 159	656 to 841[c]

[a]Data used for this table is current as of September 29, 2016. Facilities can and do update their information reported to the NPRI at any time. Asa result, similar analysis done with different versions of the data may produce different results. There is a degree of complexity surrounding NPRI data reporting, such as meeting reporting thresholds and the use of various acceptable methods and data sources. Therefore, uncertainties exist in the reported quantities. See the NPRI reporting guidance document for more details NPRI 2016).
[b]Sum of releases from facilities meeting NPRI reporting threshold requirements. Totals are rounded to 1 t.
[c] The total value excludes the spill of 1342.47 tonnes of zinc to water due to the Mount Polley tailings dam failure in 2014.

Releases of zinc and its compounds to each environmental compartment were from various industrial sectors. The total annual quantity of zinc released to air ranged from 346 to 475 t from 2011 to 2015 (Table 5-1). Key sectors that released zinc to the atmosphere in any of those years were involved in non-ferrous metal (except aluminum) production and processing (137 to 209 t), metal mining (32 to 108 t), iron and steel mills and ferro-alloy manufacturing (68 to 83 t), and motor vehicle body and trailer manufacturing (18 to 37 t).

The total annual quantity of zinc released to water ranged from 207 to 257 t from 2011 to 2015 (Table 5-1). Key sectors responsible for zinc released to water in any one of those years are metal mining (10 to 222 t), water sewage and other system (111 to 133 t), pulp, paper and paperboard mills (32 to 54 t), non-ferrous metal (except aluminum) production and processing sector (14 to 18 t), and iron and steel sector (10 to 16 t).

Total yearly quantity of zinc released to land ranged from 72 to 159 t from 2011 to 2015 (Table 5-1) Key sectors responsible for zinc released to land in any one of those years are defence services (51 to 92 t), alumina and aluminum production and processing (21 to 26 t), and pulp, paper and paperboard mills (12 to 47 t).

Other sources in Canada of anthropogenic releases of zinc to the environment include, metal surface finishing industry (electroplating), road surface runoff, corrosion of zinc alloys and galvanized surfaces and erosion of agricultural soils (Weatherley et al. 1980; Mirenda 1986). Since most of the processes employed in these sectors are of an aqueous nature, effluents discharges to rivers and sewers may be of concern (OECD 2004). Quantities of zinc released into the environment by metal surface finishing facilities that may not meet the threshold to report releases to NPRI were monitored by Toronto Water's Environmental Monitoring and Protection Unit in 2016, under the city's sewers and water supply by-laws (Toronto Municipal Code, Chapter 681, Sewers, and Chapter 851, Water Supply). Some electroplating companies were found to have released zinc into the environment in quantities greater than the thresholds of the

sewers and water supply by-laws. Three of these companies were fined for non-compliance under the Sewers By-law and they have since made adjustments to treatment systems to comply with the sewers by-law. With the upgraded systems, no further elevated zinc concentrations were detected as of December 31, 2016, in the facilities that remain active.

6. Environmental fate and behaviour

6.1 Environmental distribution

Zinc can occur in both suspended and dissolved forms, partitioning between the aqueous or dissolved form ($ZnOH^+$, Zn^{2+}, $ZnCO_3$), and in the solid phase (e.g., particulates, colloids) in soils (e.g., clays) and sediments (e.g., sulphides) (ATSDR 2005). Average partition coefficients for zinc between environmental compartments reported by Harvey et al. (2007) were 5.3 for suspended sediments to water (log K_{ssw}), 4.1 for sediment to water (log K_{sdw}), and 3.4 for soil to water (log K_{sw} (see Table E-1).

The speciation of zinc in the aqueous environment depends on the composition of the water (Chaminda et al. 2010), particularly the concentration of organic (humic and fulvic acids) and inorganic species such as CO_3^{2-}, SO_4^{2-}, Cl^- or PO_4^{3-} (Almas et al. 2006). Several abiotic variables influence the speciation of zinc, the most important of which are pH, alkalinity, redox potential (Eh), and dissolved organic matter content (CCME 2018b). At circumneutral pH, zinc carbonate ($ZnCO_3$) is presumed to be the main zinc species in the aquatic ecosystem. Hydroxide-zinc complexes are expected to be the predominant forms at high pH, while the free cation (Zn^{2+}) would predominate in acidic and low alkalinity water. Zinc is most bioavailable under conditions of low pH, low alkalinity, and low dissolved oxygen (Eisler 1993). Under anoxic conditions with low redox potential (Eh), such as sediments, and in the presence of sulphide ions, zinc is most commonly found as zinc sulphide (ZnS) (EC 2007; Hem 1972; Spear 1981; Turner et al. 1981; WHO 2001).

In sediments, free zinc (Zn^{2+}) and zinc species ($ZnOH^+$, $ZnCO_3$) in water are generally transferred from the water column to bottom sediments a few days after their initial introduction to an aquatic medium open to surface sediments (Diamond et al. 1990). Once in sediments, zinc may be found in a variety of fractions: dissolved in pore water; present in exchangeable fractions of clays; bound to carbonates; bound to iron and manganese oxides and hydroxides; bound to particulate organic matter; complexed with sulphides including acid volatile forms; and in the crystal lattice of primary and secondary minerals (Tessier et al. 1979; Förstner and Wittmann 1981; Di Toro et al. 1992). Zinc in bottom sediments may become re-suspended through bioturbation, dredging, seasonal floods or mixing by turnover events.

In the soil, zinc is distributed between five fractions: pore water (dissolved species); soil particles (reversibly bound); organic ligands (reversibly bound); secondary clay minerals and insoluble metal oxides/hydroxides (adsorbed); and primary minerals (adsorbed) (EC 2008b, IPCS 2001, Van Riemsdijk 2001). Zinc is highly reactive in soils where it is

present as part of soluble or insoluble compounds or as the inorganic ion (Zn^{2+}) (CCME 2018a). The concentration of zinc in soil solution is dependent on the amount of zinc present in the soil, solubility of the particular zinc compounds, and the extent of adsorption (CCME 2018a). Zinc may be adsorbed to clay minerals and may also form stable compounds with soil organic matter, hydroxides, oxides, and carbonates (CCME 2018a).

The behaviour of zinc in soils is linked to chemical and physical properties of the soil, such as the effective cation exchange capacity (eCEC), redox potential, mineral composition, moisture content, pH, soil organic matter, clay content and the speciation of zinc (CCME 2018a). According to Shuman (1975), Evans (1989), Duquette and Hendershot (1990), and Davis-Carter and Shuman (1993), soil pH is the main factor influencing the mobility and sorption of zinc in soils. The EU risk assessment for zinc identified pH and eCEC as factors influencing zinc bioavailability in soils (EC 2008b). The solubility and mobility of zinc increases as pH decreases, and zinc is therefore more bioavailable to organisms, especially below pH 5 (Duquette and Hendershot 1990). According to Giordano and Mortvedt (1980), at pH <7.7, zinc occurs as Zn^{2+} in soil solution, whereas at pH >7.7 the dominant form is $Zn(OH)_2$. However, given the complexity of zinc interactions in soil, zinc transport behaviour in soil cannot be predicted accurately (Hinz and Selim 1994), and soil adsorption effects cannot be separated from solution effects such as precipitation (CCME 2018a).

Atmospheric zinc is mostly found in aerosols in the oxidized form. Zinc particles up to 5 mm in diameter occur in industrial areas (Nriagu 1980). Depending on the size of the particulate matter with which zinc is associated, it may travel for a certain distance in air before being deposited to aquatic or terrestrial environments. Zinc is non-volatile at environmentally relevant temperatures.

6.2 Environmental persistence

A metal ion is considered persistent because it cannot degrade, though it can transform into different chemical species and/or partition among different phases within an environmental compartment. Biodegradation and photodegradation are not applicable to inorganic zinc compounds or to the inorganic zinc released upon dissolution, dissociation or degradation (EC 2008b). These processes can, however, be applicable to the organic metal salts and organometallics. The persistence of the parent organic metal salts and organometallics and their organic counter-ions or organic transformation products is not evaluated individually in this assessment.

6.3 Potential for bioaccumulation

The bioaccumulation of zinc depends on its bioavailability. Because zinc interacts with various constituents of water, soil and sediment, it can exist in many different complexes of variable bioavailability. Zinc availability in the water column is controlled by several processes such as sorption, precipitation/co-precipitation, and desorption/dissolution (CCME 2018b). Among these processes, sorption (adsorption,

complexation, and absorption) and precipitation are important in controlling zinc solubility, thus limiting zinc bioavailability in aquatic environments (CCME 2018b).

According to a recent review by the CCME (2018b), internal concentrations of zinc, an essential element, are generally well regulated in aquatic organisms via various mechanisms including homeostatic control of accumulation. Indeed, a negative relationship has been observed between bioconcentration factors (BCFs) or bioaccumulation factors (BAFs) and zinc exposure for aquatic organisms (McGeer et al. 2003; De Schamphelaere et al. 2004). The existence of a regulation mechanism was also suggested by De Schamphelaere et al. (2004) in a zinc dietary exposure study with *Daphnia magna*. The author observed a higher zinc body burden in organisms from the control group versus organisms whose food source, green algae, was exposed to 20 and 30 µg/L of zinc. Zn metabolism may protect or exacerbate the uptake and toxicity of other metals (Lavoie et al. 2012a).

While regulation mechanisms exist in many organisms, a review by CCME (2018c) indicates that zinc may be accumulated in tissues of aquatic plants and animals exposed to high concentrations of zinc, for example, in green algae (McHardy and George 1990), *Daphnia magna* (De Schamphelaere et al. 2004; Muyssen et al. 2006), Indian major carp (Gupta and Sharma 1994) or rainbow trout (McGeer et al. 2000). However, zinc biomagnification was not deemed to be a significant process, based on findings from Cleven et al. (1993), who observed that BCFs and BAFs decreased with increasing trophic level.

7. Potential to cause ecological harm

7.1 Essentiality

According to the review by CCME (2018b), zinc is an essential element needed for a variety of biological functions. It is an essential element for the normal growth of higher plants and animals, and zinc concentrations below the critical concentrations for specific organisms can cause physiological stress due to enzymatic or metabolic dysfunctions (Alloway 2008). Aquatic environments in Canada are not likely to have zinc concentrations sufficiently low to cause deficiency; moreover, organisms from environments with naturally low zinc concentrations are expected to have adapted to such conditions (Spry et al. 1988).

7.2 Mechanisms of toxic action

According to the World Health Organization (WHO) (2001), zinc produces adverse effects on many biological processes in aquatic organisms, including behaviour, reproduction and biochemical and physiochemical reactions. The CCME review (2018b) identified several toxicity mechanisms for zinc in aquatic organisms. Zinc disrupts calcium uptake in fish, causing calcium deficiency (Spry and Wood 1985), and disrupts calcium homeostasis in invertebrates (Muyssen et al. 2006). It also disturbs sodium or chloride fluxes in fish, causing an increase in gill permeability attributed to alteration of ATPase activities (Spry and Wood 1985). At higher concentrations, zinc can cause

destruction of gill tissue (Skidmore 1970; Hiltibran 1971; Skidmore and Tovell 1972 2008), limiting oxygen diffusion in blood. The principal mode of action for acute Zn toxicity to freshwater fish is inhibition of calcium uptake (Hogstrand 2011).

7.3 Ecological Effects Assessment

7.3.1 Aquatic toxicity

There are numerous empirical and field studies on the acute and chronic toxicity of zinc and its compounds to aquatic organisms such as microorganisms, invertebrates, fish, plants and amphibians. The aqueous zinc ion (Zn^{2+}) is often used as the basis of expressing zinc toxicity in the aquatic environment (ANZECC 2000).

CCME recently derived a Canadian water quality guideline (CWQG) for zinc for the protection of aquatic life (CCME 2018b) based on a CCME protocol (CCME 2007). The CWQG (or long term guideline) for freshwater exposure to zinc is based on a species sensitivity distribution (SSD) (Appendix F contains the chronic toxicity data in the SSD) and is presented as a multi-variable equation that is a function of specific water chemistry conditions or parameters that have the most influence on the toxicity of zinc to organisms (CCME 2018b). The long-term exposure guidelines are intended to protect all forms of aquatic life for indefinite exposure periods (greater than or equal to 21-day or longer exposures for adult and juvenile fish, greater than or equal to 7-day exposures for fish larvae and eggs, greater than or equal to 96-h for shorter-lived invertebrates, greater than or equal to 24-hour exposures for aquatic plants and algae) (CCME 2007).

The long-term CWQG is for dissolved zinc and is calculated using the following equation:

$$\boldsymbol{CWQG = e^{\left(0.947\left[\ln\left(hardness\,\frac{mg}{L}\right)\right] - 0.815[pH] + 0.398\left[\ln\left(DOC\,\frac{mg}{L}\right)\right] + 4.625\right)}}$$

This equation is valid between hardness 23.4 and 399 mg $CaCO_3$/L, pH 6.5 and 8.13, and DOC 0.3 to 22.9 mg/L, which are the ranges of data used to derive the hardness, pH and DOC slopes, and therefore the ranges within which the equation should be applied.

The current assessment uses this equation to derive predicted no-effect concentrations (PNEC) of aquatic compartments. For reference, assuming a hardness of 50 mg $CaCO_3$/L, pH of 7.5 and DOC of 0.5 mg/L, the equation yields a PNEC value of 7 µg Zn/L.

Based on water chemistry limits at which the equation can be applied, the highest possible PNEC value would be 516 µg/L dissolved Zn and would be found at the highest hardness (399 mg $CaCO_3$/L), the highest limits of DOC (22.9 mg/L) and the lowest pH (6.5), while the lowest possible PNEC value that is within the equation limits would be 1.7 µg/L dissolved Zn and would be found at the lowest hardness (23.4 mg $CaCO_3$/L), the lowest DOC (0.3 mg/L) and the highest pH value (8.13). Since toxicity

modifying factors are often interrelated, these PNEC values simply represent limits of the validity of the equation.

PNECs for freshwater were derived by the European Union (EU) using similar statistical methods and are equal to 7.8 µg/L for dissolved zinc and 21 µg/L for total zinc, with a hardness value greater than or equal to 24 mg/L, and to 3.1 µg/L for dissolved zinc for freshwater with hardness less than or equal to 24 mg/L.

7.3.2 Benthic organisms

A review of the toxicity of zinc to benthic organisms was conducted by the CCME (1999) to derive an interim sediment quality guideline (ISQG) for freshwater. The review determined that the toxicity of zinc in sediments depends on its bioavailability and can be reduced by various sediment fractions, for example, organic matter and sulphides (Sibley et al. 1996). Once zinc is ingested by benthic organisms, its availability depends on various factors, including enzyme activity and gut pH (CCME 1999). The review indicated that adverse biological effects on benthic organisms resulting from zinc exposure include decreased benthic invertebrate diversity and abundance, increased mortality, and behavioural changes (CCME 1999). The freshwater Interim Sediment Quality Guidelines and the probable effect level (PEL) were determined to be 123 mg Zn/kg and 315 mg Zn/kg dry weight (dw) respectively (CCME 1999).

Additional sediment toxicity testing was recently conducted to assist in the eventual development of a new Canadian Sediment Quality Guideline for zinc. Spiked sediment toxicity tests were conducted with four freshwater aquatic invertebrate species—*Hyalella azteca* (amphipod), *Chironomus riparius* (midge), *Hexagenia* spp. (mayfly), and *Tubifex tubifex* (Oligochaete worm)—and four sediment types representative of various aquatic environments (Kilgour & Associates Ltd. 2016). Testing was conducted with sediments from Lake Erie representing a pelagic sediment, marsh sediments from a hard water lake (Long Point), and sediment from a soft water lake on the Canadian Shield (Lake Restoule) (Kilgour & Associates Ltd. 2016). The study found that the EC_{10} and EC_{20} determined for *C. riparius* in Lake Erie sediment were 80.0 and 110 mg Zn/kg dwt respectively, lower than the ISQG derived by the CCME (1999). Several other endpoints (i.e., EC_{50}, LC_{10}, LC_{20}) for the same species were lower than the PEL value of 315 mg Zn/kg dw sediment. Endpoints for other organisms in Lake Erie sediments and other sediments were generally above the PEL. The EU zinc sediment PNEC of 49 mg Zn/kg dw was based on the lowest chronic no observed effect concentration (NOEC) of 488 mg/kg dw, for *H. azteca*, with an assessment factor of 10 applied to account for major routes of exposure, possible uptake through ingestion of sediment and inter-species sensitivity in the effect assessment.

7.3.3 Terrestrial toxicity

The toxicity of zinc to soil invertebrates may be affected by various factors. Ageing removes metals from the soil solution to the solid phases through various mechanisms (McLaughlin 2001; Smolders et al. 2007), rendering them less bioavailable, thus lowering the toxicity in aged soils compared to freshly spiked soils (Lock and Janssen

2003; Redeker et al. 2008). Soil pH, organic carbon content, and clay content are the toxicity modifying factors (TMF) that most influence zinc availability in soil. Soil pH was shown to be a good predictor of metal solubility but a poor predictor of metal toxicity across soils (Smolders et al. 2009). The cation exchange capacity (CEC), which is defined by the total capacity of the soil to retain or bind cations, best integrates the variations of these TMFs (Redeker et al. 2008). The higher the CEC, the lower the bioavailable zinc concentration will be in the pore water and vice-versa. These TMFs determine the amount and type of metal species available for uptake and the resulting possible toxic response and/or bioaccumulation for plants, invertebrates, and soil microorganisms (ICMM 2007). Smolders et al. (2009) showed that toxicity thresholds based on total soil metal concentrations rise almost proportionally to the effective CEC of soil.

An extensive review of the toxicity of zinc to soil organisms was recently conducted for the development of Canadian Soil Quality Guidelines for the protection of the environmental and human health. Zinc toxicity studies were identified for microbial processes, plants, invertebrates, livestock and wildlife (CCME 2018a). A threshold effects concentration of 250 mg Zn/kg soil dw, for agriculture and residential/park-land was derived on the basis of a 25th percentile using species sensitivity distribution ($ESSD_{25}$) (CCME 2018a).

In 2008, the European Commission estimated the 5th percentile for plants/soil invertebrates to be 52 mg/kg dw and an assessment factor of 2 was applied to this value to obtain a PNEC of 26 mg/kg dw. It also estimated the 5th percentile for soil microorganisms to be 27 mg/kg dw and applied an assessment factor of 1 to derive a PNEC of 27 mg/kg dw.

7.4 Ecological exposure assessment

7.4.1 Background concentrations and toxicity modifying factors

Zinc is ubiquitous in the environment, and in some areas of Canada not impacted by anthropogenic activities, zinc concentrations (i.e., those representative of background) may be naturally elevated. In other areas, anthropogenic activities cause zinc concentrations to be higher than background levels (CCME 2018a).

Background concentration ranges, or normal ranges, of total zinc (Zn_T) in surface waters for Canadian ecozones were recently estimated by Kilgour & Associates Ltd. (2016). Median concentrations of Zn_T for Canadian ecozones were calculated using the approach outlined in Kilgour & Associates Ltd. (2016) from reference samples from a variety of federal and provincial surface water quality monitoring programs and repositories (Table G-1 in Appendix G). Median concentrations of Zn_T were also calculated for Lake Erie, Lake Ontario and Lake Superior using data collected by ECCC during the period 2005 to 2015. Similarily, additional federal water quality data were collected to develop median concentrations of Zn_T for the Taigia Shield (ECCC 2016).In all cases, non-detects were substituted with half the reported detection limit. Median total zinc background concentrations ranged from 0.200 to 3.60 µg/L (Table G-1 in

Appendix G). For comparison, concentrations of zinc in surface waters from uncontaminated areas have been reported by Shuhaimi-Othman (2006) to range from 1.6 to 4.4 µg/L in Ontario lakes and by Nriagu et al. (1996) to range from 0.09 to 0.3 µg/L in Lakes Erie, Ontario, and Superior. Doyle et al. (2003) reported an average background level of 12 µg/L of zinc based on the 95th percentile for zinc in Canadian surface waters.

The long-term CWQG for dissolved zinc requires data for three TMFs: total hardness, pH, and DOC (Section 7.3). Representative TMF data were derived for Canadian ecozones and for Great Lakes (Table G-2 in Appendix G). The central tendencies of the TMFs developed for the ecozones were based on data identified as being in reference condition, as defined by the approach in Kilgour & Associates (2016). In all cases, non-detects were substituted with half of the reported detection limit. Where measured data were unavailable for the receiving environment, the central tendencies of the TMFs for the relevant ecozone were used as a substitute.

The central tendencies of the TMFs developed for the ecozones were also based on data identified as being in reference condition, as defined by the approach in Kilgour & Associates 2016. In all cases, non-detects were substituted with half of the reported detection limit.

For the sediment and soil compartments, the current assessment aligns with recent hazard characterizations based on zinc concentration only and does not quantify bioavailability adjustment for these compartments. McKeague and Wolynetz (1980) reported a mean of 74 mg Zn/kg dw in Canadian soils. By region, the mean concentrations of zinc in soil from the Canadian Shield is 54 mg/kg; from the Interior Plains, 64 mg/kg; from the Cordilleran Region, 73 mg/kg; from the St. Lawrence Lowlands, 80 mg/kg; and from the Appalachians, 81 mg/kg. Sheppard et al. (2007) reported an overall Canadian background zinc concentration in soil ranging from 6.3 to 360 mg/kg with a mean concentration of 76 mg/kg, while Impelliteria et al. (2003) reported soil zinc concentrations, ranging from 91.5 to 431.2 mg/kg. According to the scientific criteria document for the development of the Canadian Soil Quality Guidelines for zinc (CCME 2018a), zinc concentrations range from < 1 mg/kg to 1350 mg/kg. Soil concentrations can be elevated from atmospheric fallout around mining and smelting operations; concentrations up to 4771 mg/kg have been measured in surface soils in some communities near such operations (Manitoba Conservation 2007).

7.4.2 Approach for the exposure characterization

Multiple sectors of activity may be sources of zinc to the environment. Exposure scenarios were developed for the sectors of activity with the highest reported releases (Section 5) or the highest use quantities (Section 4), namely metal mining, base metal smelting and refining, iron and steel manufacturing, and wastewater treatment. It is noted that other sectors of activity may be sources of zinc to the environment (Section 5). However, preliminary analyses conducted using effluent data for some of these sectors revealed that they are of lower concern or that data was lacking.

For each scenario, predicted environmental concentrations (PECs), expressed as concentrations of elemental zinc, were estimated for the aquatic environment using measured concentrations of zinc in surface water when available (preferably dissolved zinc, Zn_D, otherwise zinc total, Zn_T). The adequacy of measured environmental concentrations was assessed considering factors such as year and season, analytical method and detection limits.

When environmental measured concentrations were unavailable, PECs were estimated by adding the appropriate median background concentration of total zinc in surface water (Table G-1 in Appendix G) to the estimated aquatic concentrations (EAC) of zinc in the receiving environment resulting from the activity (i.e., PEC = EAC + median background concentration). When relying on yearly average loadings of zinc in effluent, EACs based on Zn_T were derived by summing the average yearly concentrations using data submitted (Ontario 2016) and then applying a dilution factor of 10, reflective of conditions near the discharge point, to the calculated total effluent concentration. This is also based on the assumption that full dilution does not occur immediately upon release to large waterbodies.

The exposure characterization of zinc in the aquatic environment in this assessment requires data for three TMFs (total hardness, pH, and DOC) to derive site-specific PNECs (Section 7.3.1). Certain sectors provide measured data for the TMFs in the receiving environment. For sectors where no receiving environment data are available, representative data for TMFs were derived for applicable ecozones and Great Lakes (Table G-2 in Appendix G).

Box plots were generated for each facility of a given sector to display the distribution of zinc concentrations (Zn_D or Zn_T). They are interpreted as follows: the lower and upper hinges (edges) of the box represent the 25th and 75th percentiles, respectively, while the horizontal line within the box represents the 50th percentile. The distance between the 25th and 75th percentile is called the inter quartile range (IQR). The lower and upper whiskers represent the lowest or highest data that are within the Q1 – 1.5 x IQR thresholds or the Q3 + 1.5 x IQR thresholds, respectively. Data exceeding these thresholds appear as circles. Otherwise, the lower and upper whiskers represent the minimum and maximum of the dataset. The 95th percentile was added in addition to the box plots (blue line). The sample size (n) and detection frequency (e.g., 100%) are also displayed above each boxplot.

7.4.3 Metal mining

Zinc is mined in Canada (Section 4.2.1) and ore may be extracted from underground or above ground mines (Environment Canada 2009b). After extraction, the ore is crushed, ground in mills and concentrated by differential flotation to produce zinc concentrate (Environment Canada 2009b). The processing of ore during extraction and concentration generates dust, which may escape and be deposited nearby, and effluent, which may be stored in tailings ponds or treated and released to surface water. The generated dusts, potential leachates from tailings ponds, and effluent releases to surface water are all pathways through which zinc may be released into the surrounding

environment (Rashed 2010). From 2011 to 2015, annual releases of zinc and its compounds to water reported to the NPRI by the metal mining sector ranged from 10 to 222 t (Section 5.0).

Canadian metal mines that deposit effluent at any time into any water at a flow rate exceeding 50 m^3/day are subject to *the Metal and Diamond Mining Effluent Regulations* (MDMER 2018) under the *Fisheries Act*. During the period 2011 to 2015, 123 mining facilities were subject to the MDMER (EEM 2016). Schedule 4 of the MDMER sets concentration limits in effluent for certain parameters, including zinc. The maximum authorized monthly mean concentration of total zinc (Zn_T) in effluent under the 2018 amendment to Schedule 4 is 0.50 mg/L (unchanged from the limit before the 2018 amendments), but a lower limit of 0.40 mg/L was introduced for any new mines that become subject after June 2021. The daily maximum authorized limits under Schedule 4 of the MDMER are 0.75 mg/L Zn_T in a composite sample and 1.0 mg/L Zn_T in a grab sample. Facilities are also required to conduct environmental effects monitoring (EEM) and perform investigation of cause under which water quality monitoring, including analysis for total zinc, must be completed in the exposure area surrounding the point of entry of effluent into water from each final discharge point and from the related reference areas.

Concentrations of Zn_T measured in surface water samples collected from exposure areas and reference areas between 2011 and 2015 and submitted to ECCC under the MDMER and EEM program (EEM 2016) were analyzed. Non-detects were replaced with half of the corresponding method detection limit (MDL). Submissions containing blanks or zero values without reported MDLs were removed. The MDLs ranged from 0.01 to 1000 µg/L.

Site statistics are presented for seven of the facilities subject to the MDMER for the period 2011 to 2015, which were identified based on zinc enrichment in the exposure areas, and a sample size equal to or greater than 10 (Figure 7-1). Zn_T concentrations were reported in the effluent for all facilities, confirming the release of zinc into the aquatic environment from this sector. Zinc enrichment was observed in the exposure areas for all seven facilities and ranged from 1.8 to 180 times higher than the reference areas as determined by comparison of median concentrations of Zn_T.

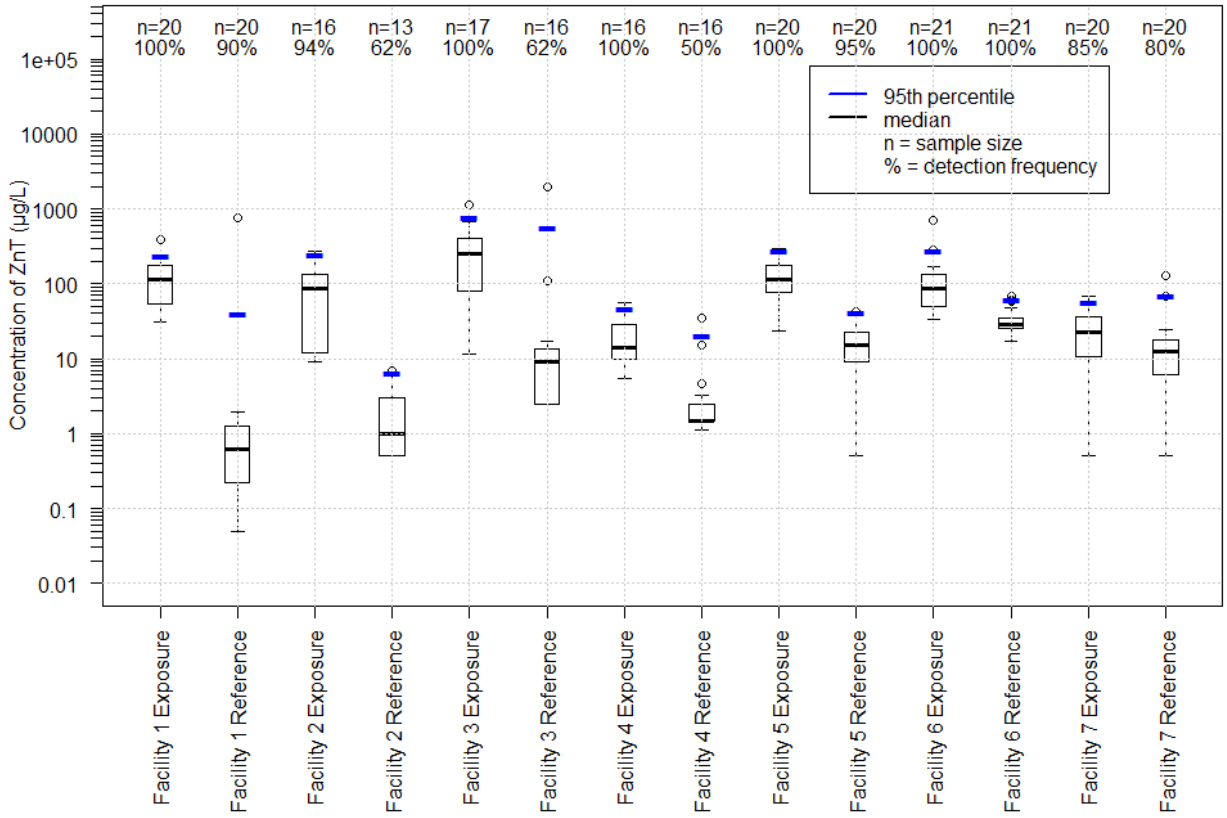

Figure 7-1. Box plots for Zn_T in surface waters from exposure and reference areas reported by seven facilities subject to the MDMER from 2011 to 2015 (EEM 2016)

In addition to the analysis of total zinc required for the EEM, pH and total hardness measurements in the exposure and reference areas are also required. While monitoring of DOC was not required, some facilities provided this data. The TMF data were analyzed or estimated to generate site-specific PNECs using the approach described in section 7.4.2. The resulting PNECs are presented in Table G-3.

The TMFs in the exposure areas differ from those in the reference areas, notably for total hardness. Hardness may be greater in the exposure areas due to the addition of lime during effluent treatment in order to precipitate dissolved metals and to modify pH (Lane and Associates Limited 1990). The median PNECs in exposure areas range from 15 to 315 µg/L and the median PNECs in reference areas range from 5.2 to 22 µg/L for all seven facilities. Table G-3 provides details on TMFs selected for these areas and the corresponding PNECs obtained.

7.4.4 Base metal smelters and refining

Canada is a producer of refined zinc and other zinc compounds (Section 4.2.1). There are 12 base metal smelters and refineries (BMS) in Canada (Cheminfo 2013). The BMS

sector processes concentrates from metal mines and mills as well as other feedstocks (i.e., recycled materials such as electronics; and batteries) to produce metals (ECCC 2006) including zinc. From 2011 to 2015, total annual releases of zinc and its compounds to water reported to the NPRI by BMS facilities ranged from 10 to 12 t (Section 5.0). Annual releases to land reported to the NPRI in the same period of 2011 to 2015 were negligible (i.e., 0 to 0.006 t) (NPRI 2016).

Releases from primary and secondary copper smelters and copper refineries and releases from primary and secondary zinc smelters and zinc refineries were assessed under the Priority Substances List (PSL) (Environment Canada, Health Canada 2001). Air emissions from these facilities were concluded to be toxic under CEPA (Environment Canada, Health Canada 2001), and "particulate matter containing metals that is released to the atmosphere from copper smelters or refineries, or from both", as well as "particulate matter containing metals that is released in emissions from zinc plants" were listed on Schedule 1 in 2001. All BMS facilities in Canada were subsequently subject to a Pollution Prevention Planning Notice published in the *Canada Gazette* in 2006.[4] Given these previous risk assessment and risk management activities, air emissions of zinc from these sources are not considered. However, this current assessment does consider releases of zinc to the aquatic environment as a result of effluent discharges from these sources as they were not specifically considered in the previous assessment.

Between 2011 and 2015, five BMS facilities had combined effluents with mines and were therefore subject to the MDMER 2002 under the *Fisheries Act* (Section 7.4.3). Concentrations of Zn_T measured in surface water in exposed areas downstream of the combined effluent discharge and in reference areas are therefore available under the MDMER and EEM programs. Surface water monitoring data for the five combined facilities for the period 2011 to 2015 are summarized in Figure 7-2. Two combined facilities (Facility 1 and Facility 4) show higher median and 95th percentile zinc concentrations in exposure areas compared to reference areas (Figure 7-2). For the other three combined facilities, the comparison of zinc concentrations in the exposure areas ranging from 2.5 to 122 µg/L versus the reference areas ranging from 3.40 to 250 µg/L do not reflect zinc enrichment due to effluent releases from BMS or mining. Zinc concentrations that are higher in the reference areas compared to the exposure areas may be due to natural variations in geology and current or historical anthropogenic inputs. Overall, these data indicate that elevated zinc concentration in the exposure area from Facility 1 is potentially from BMS or mining activities as these activities are combined at this site.

Exposure data is available for two other facilities that are not subject to the MDMER, Facility 6 and Facility 7. Zn_T and Zn_D water concentrations from Facility 6 were measured at two reference sites (1.9 and 9.7 km upstream of the facility) and three exposure sites (0.2, 1.1 and 15.8 km downstream of the facility) from 2011 to 2013. For

[4] https://www.canada.ca/en/environment-climate-change/services/pollution-prevention/planning-notices/performance-results/base-metals-smelters-refineries-overview.html

the data analysis, only the farthest reference site (9.7 km) and closest two exposure sites from the source (0.2 and 1.1 km) were considered. Median Zn_D water concentrations were calculated and ranged from 0.025 µg/L to 3.56 µg/L at the reference site and from 0.05 µg/L to 15.9 µg/L at the exposure sites.

Zn_T was also measured in the depositional sediment compartment at the same reference site and downstream exposure sites for Facility 6 in 2012 by Ecoscape Environmental Consultants Ltd. and Larratt Aquatic Consulting Ltd. (EEC Ltd & LAC Ltd 2014). Average concentrations of Zn were 59.7 and 1794.3 mg/kg for the reference site and exposure sites, respectively.

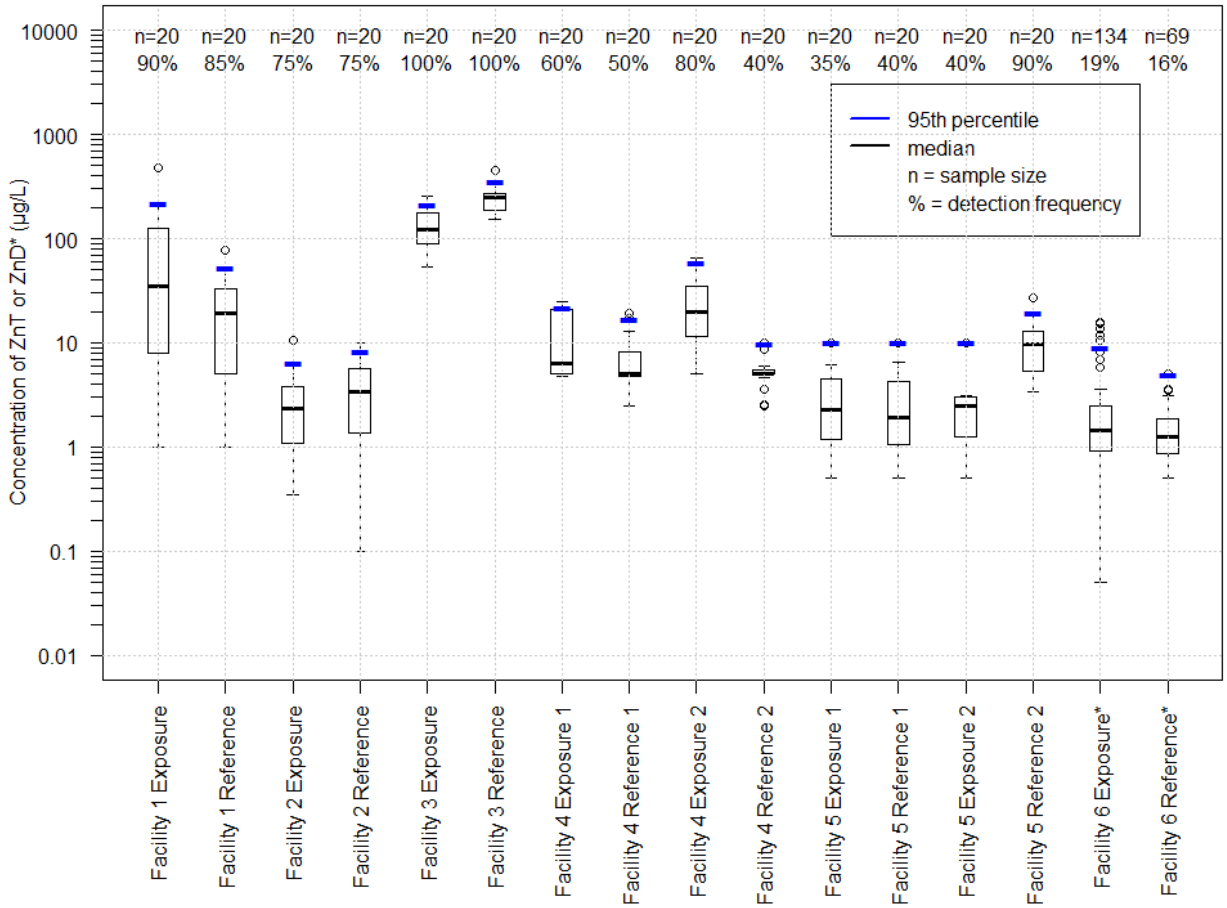

Figure 7-2. Box plots of Zn_T in surface waters from exposure and reference areas reported by base metal smelters subject to the MDMER from 2011 to 2015 and one smelter not subject to MDMER from 2012 to 2014 (EEM 2016; EEC Ltd & LAC Ltd 2014)

Under Ontario Regulation 560/94, *Effluent Monitoring and Effluent Limits – Metal Mining Sector* (Government of Ontario 1990a), certain BMS facilities discharging effluents to the environment are required to report monthly releases of zinc to the receiving

environment (as loadings of Zn_T) to the Ministry of the Environment, Conservation and Parks (MECP) (formerly the Ministry of the Environment and Climate Change). Zinc loadings are reported for process effluent (Ontario 2016) and data are available for Facility 7. PECs were determined to range from 1.4 to 2.4 µg Zn/L according to the method described in section 7.4.2, using the median background concentration of Zn_T for the related corresponding receiving waterbody.

Measured values of hardness and pH were available for the five facilities subject to the MDMER. However, DOC data were unavailable, and therefore the ecozone central tendencies of the TMF data were applied, using the approach described in section 7.4.2. The resulting median PNECs in exposure areas range from 37 to 190 µg/L, and the median PNECs in reference areas range from 11 to 40 µg/L. Details on TMFs selected for these areas and the corresponding PNECs are described in Table G-4.

7.4.5 Iron and steel manufacturing

There are 15 iron and steel manufacturing facilities in Canada, including nine facilities in the province of Ontario. The major use of zinc in iron and steel manufacturing is the coating of iron and steel products to render them resistant to corrosion and rust. This process, known as galvanizing, accounts for approximately 48% of the global use of zinc (NRCan 2007). In 2008, 0.1 t to greater than 10 t of zinc compounds were imported into Canada in 2008 for use by the iron and steel sector (Environment Canada 2009a). From 2011 to 2015, annual releases of zinc compounds to water reported to the NPRI by iron and steel sector ranged from 10 to 16 t (NPRI 2016).

Monitoring studies conducted on the Hamilton Harbour water in the vicinity of several iron and steel manufacturing facilities over the period 2000 to 2014 reported high concentrations of zinc in sediments. While zinc concentrations (means) have decreased in some areas over the time, they remain elevated at other sites. Zinc levels remain above the Canadian Sediment Guideline Probable Effect Level in most areas of the harbour indicating the potential for adverse effects on benthic biota (Milani et al. 2017). Measured zinc concentrations in St. Laurence River sediments upstream and downstream of effluent source of an iron and steel facility, show zinc concentration to range from 0.481 to 2.180 mg/kg which are well below the recommended sediment guideline of 123 mg/kg (CSQG 1999).

Under Ontario Regulation 214/95, *Effluent Monitoring and Effluent Limits - Iron and Steel Manufacturing Sector* (Government of Ontario 1990b), facilities from the iron and steel sector discharging effluents to the environment are required to report monthly releases of zinc (as loadings of Zn_T) to the receiving environment to the Ontario Ministry of Environment and Climate Change. Zinc loadings are reported quarterly by industry and data from 2012 to 2014 for process effluent, once-through cooling water effluent and combined effluent (Ontario 2016) were analyzed. Data from Ontario facilities releasing to the Great Lakes were used to represent the exposure scenario for the iron and steel sector as a whole.

Estimated aquatic concentrations (EAC) based on Zn_T were derived by summing the average annual concentrations for each effluent stream using data submitted quarterly by industry from 2012 to 2014 (Ontario 2016) and then applying a dilution factor of 10 to the total effluent concentration. The PECs were then derived (Table 7-1) by summing the EACs and the appropriate median background concentration of total zinc (Table G-1) according to the method described in section 7.4.2.

Table 7-1. Calculated PECs of Zn_T for the iron and steel sector based on effluent concentrations from 2012 to 2014 (Ontario 2016)

Facility	Year	Zn_T yearly loading (kg)[a]	Average Zn_T in diluted effluent (µg/L)[b]	Median background Zn_T (µg/L)	PEC (µg Zn/L)
1	2012	4414	5.1	0.200	5.3
1	2013	4338	4.9	0.200	5.1
1	2014	4640	4.8	0.200	5.0
2	2012	6044	12.0	0.370	12.4
2	2013	7857	18.0	0.370	18.4
2	2014	6536	13.0	0.370	13.4
3	2012	830	2.2	0.370	2.5
3	2013	400	1.4	0.370	1.7
3	2014	172	1.0	0.370	1.3
4	2012	708	7.2	0.445	7.6
4	2013	660	8.0	0.445	9.0
4	2014	670	7.2	0.445	7.7

[a] Total annual loadings calculated on the basis of monthly loadings reported to the Ontario MECP for three types of effluents (process effluent, once-through cooling water effluent, and combined effluent)
[b] Average effluent concentration calculated using three types of effluents (process effluent, once-through cooling water effluent, and combined effluent) with a dilution factor of 10 applied.

Representative TMFs for each site were selected using the approach described in section 7.4.2 to calculate site-specific PNECs for the iron and steel manufacturing sector (Table G-5). The resulting PNECs for this sector range from 9.3 to 20 µg/L. Table G-5 provides details on the TMFs and the corresponding PNECs derived.

7.4.6 Wastewater

Effluent discharges to surface waters from wastewater treatment systems (WWTS) may contain zinc, despite the wastewater having undergone treatment. Zinc in WWTS influent, and therefore effluent, originates from consumer, commercial or industrial uses,

not from effluent treatment. From 2011 to 2015, annual releases of zinc and its compounds to water reported to the NPRI by WWTS ranged from 11 to 130 t (Section 5) (NPRI 2016).

Effluent monitoring data were collected under the Chemicals Management Plan (CMP) Environmental Monitoring and Surveillance Program (EMSP) from 25 WWTS located across Canada from February 2009 to March 2012 (Environment Canada 2009-2012). A total of 191 raw influent, 90 primary effluent, and 191 final effluent 24 h composite samples were collected and analyzed for Zn_T. Zinc was detected in all samples, with concentrations ranging from 19.2 to 337 µg Zn/L in raw influent, 22.4 to 154 µg Zn_T/L in primary effluent, and 0.682 to 133 µg Zn_T/L in final effluent. Median concentration values were 81.4 µg Zn_T/L for raw influent, 59.1 µg Zn_T/L for primary effluent and 25.2 µg Zn_T/L for final effluent. The median percentage of removal of zinc from influent to final effluent was 67.0%.

PECs for the wastewater sector were derived for 21 WWTS facilities that release effluent to freshwater (Table 7-10). PECs were calculated by applying a dilution factor of 10 to final effluent concentrations and adding the median background zinc concentrations (Table 7-1) corresponding to the facility.

Table 7-2. Calculated PECs of Zn_T for the wastewater sector based on effluent concentrations from 21 WWTSs across Canada from 2009 to 2012 (Environment Canada 2009-2012)

Plant	Sample size	Diluted effluent range (µg Zn_T/L)	Median background concentration (µg Zn_T/L)	PEC range (µg Zn_T/L)
1	5	0.735–2.95	2.3	3.0–5.2
2	12	0.23–6.18	2.0	2.2–8.2
3	6	0.110–1.71	0.22	0.34–1.9
4	6	0.343–1.49	2.0	2.4–3.5
5	24	0.511–2.46	3.5	4.0–6.0
6	6	0.195–2.37	2.0	2.2–4.4
7	6	0.852–9.73	2.3	3.1–12
8	6	0.0682–3.65	1.0	1.1–4.7
9	12	1.42–2.00	2.0	3.4–4.0
10	24	2.04–4.94	2.0	4.0–7.0
11	11	2.12–2.72	0.77	2.9–3.5
12	12	1.93–4.13	0.22	2.2–4.4
13	12	1.07–8.09	0.20	1.3–8.3
14	6	1.88–9.71	0.370	2.25–10.1
15	12	3.00–5.56	2.0	5.0–7.6
16	6	1.4–3.00	0.370	1.77–3.37
17	12	1.99–5.81	0.370	2.36–6.18

Plant	Sample size	Diluted effluent range (µg Zn_T/L)	Median background concentration (µg Zn_T/L)	PEC range (µg Zn_T/L)
18	6	0.929–2.53	0.370	1.30–2.90
19	12	5.44–6.93	3.5	8.9–10
20	24	2.74–4.94	3.5	6.2–8.4
21	12	4.04–6.05	1.0	5.0–7.0

The resulting site-specific PNECs for the wastewater sector range from 6.0 to 65 µg/L and were determined using the approach described in section 7.4.2. Table G-6 provides details on TMFs and the corresponding PNECs calculated.

7.5 Characterization of ecological risk

The approach taken in this ecological screening assessment was to examine assessment information and develop proposed conclusions using a weight–of-evidence approach and precaution. Evidence was gathered to determine the potential for zinc to cause harm in the Canadian environment. Lines of evidence considered include those evaluated in this assessment that support the characterization of ecological risk in the Canadian environment. Secondary or indirect lines of evidence are considered when available, including regulatory decisions and classification of hazard or fate characteristics made by other regulatory agencies. This ecological screening assessment of zinc and its compounds focuses on the zinc moiety.

7.5.1 Risk quotient analyses

Risk quotient analyses were performed by comparing monitoring data and realistic worst-case estimates of exposure (PECs; see the Ecological Exposure Assessment section) with ecological toxicity information (PNECs; see the Ecological Effects Assessment section) to determine whether there is potential for ecological harm in Canada. Risk quotients (RQs) were calculated by dividing the PEC by the PNEC for relevant environmental compartments and associated exposure scenarios. RQs were calculated for the aquatic environment (i.e., surface water) in the exposure scenarios described in Section 7.4 for four sectors of activity, namely metal mining, base metal smelting and refining, iron and steel manufacturing, and wastewater treatment. PECs were estimated using measured or estimated concentrations of total zinc in surface water (Zn_T). Site-specific PNECs were calculated using the long-term CWQG for aquatic organisms (CCME 2018b) from measured or estimated concentrations of TMFs.

Results for the risk characterization conducted for the four sectoral activities considered in this assessment indicate that median RQs were greater than 1 for some facilities within the metal mining sector, and near or slightly above 1 for some of the combined facilities (base metal smelting and refining sector and metal mining). Median RQs lower than 1 were observed for both the iron and steel manufacturing and wastewater sectors.

Table 7-3. Risk quotient (RQ) calculations in surface water for exposures scenarios for four sectors of activity

Sector	Facilities	Years	Range of median and average PECs[d] (µg Zn_T/L)	Range of median PNECs[d] (µg Zn/L)	Range of median and average RQs[d]
Metal mining	116	2011–2015	0.210–215	5.7–329	0.0036–1.7
Metal mining[a]	7	2011–2015	13.8–253	15.2–180	0.38–5.6
Base metal smelting and refining[b]	6	2011–2015	2.30–122	36.0–186	0.012–1.1
Base metal smelting and refining[c]	1	2012–2014	0.025–3.64	7.53–15.1	0.00–0.0004
Iron and steel	4	2012–2014	1.4–18	9.3–20	0.067–0.89
Wastewater	21	2009–2012	1.1–9.7	6.0–65	0.076–0.69

[a] The seven sites are those selected for the site-specific analysis of MMER EEM data and are a subset of the facilities, which reported to the MDMER during the period 2011 to 2015. These data are not included in the summary for the 116 sites of the metal mining sector.
[b] BMS facilities subject to the MDMER due to having their effluents combined with mines.
[c] BMS facilities not subject to MDMER.
[d] The range of median and average RQs expresses the range of the median and average RQs calculated on a facility basis. Averages are reported for the PECs and RQs of the iron and steel sector.

The range of median RQs presented in Figure 7-3 and Figure 7-4 for these two sectors were calculated using the Zn_T medians for all of the facility-specific exposure monitoring data (PECs) and the facility-specific PNEC, based on the site-specific TMFs. Similarly, reference RQs were obtained by comparing data from the reference monitoring sites to PNECs based on the site-specific TMFs. As can be seen in Figures 7-3 and 7-4, RQs in exposure areas can be substantially higher than in reference areas but not at all sites. The water chemistry of the exposure areas and the reference areas differ such that the PNECs of the exposure areas are often higher (e.g., exposure area median PNECs versus reference area median PNECs in Tables G-3 and G-4).

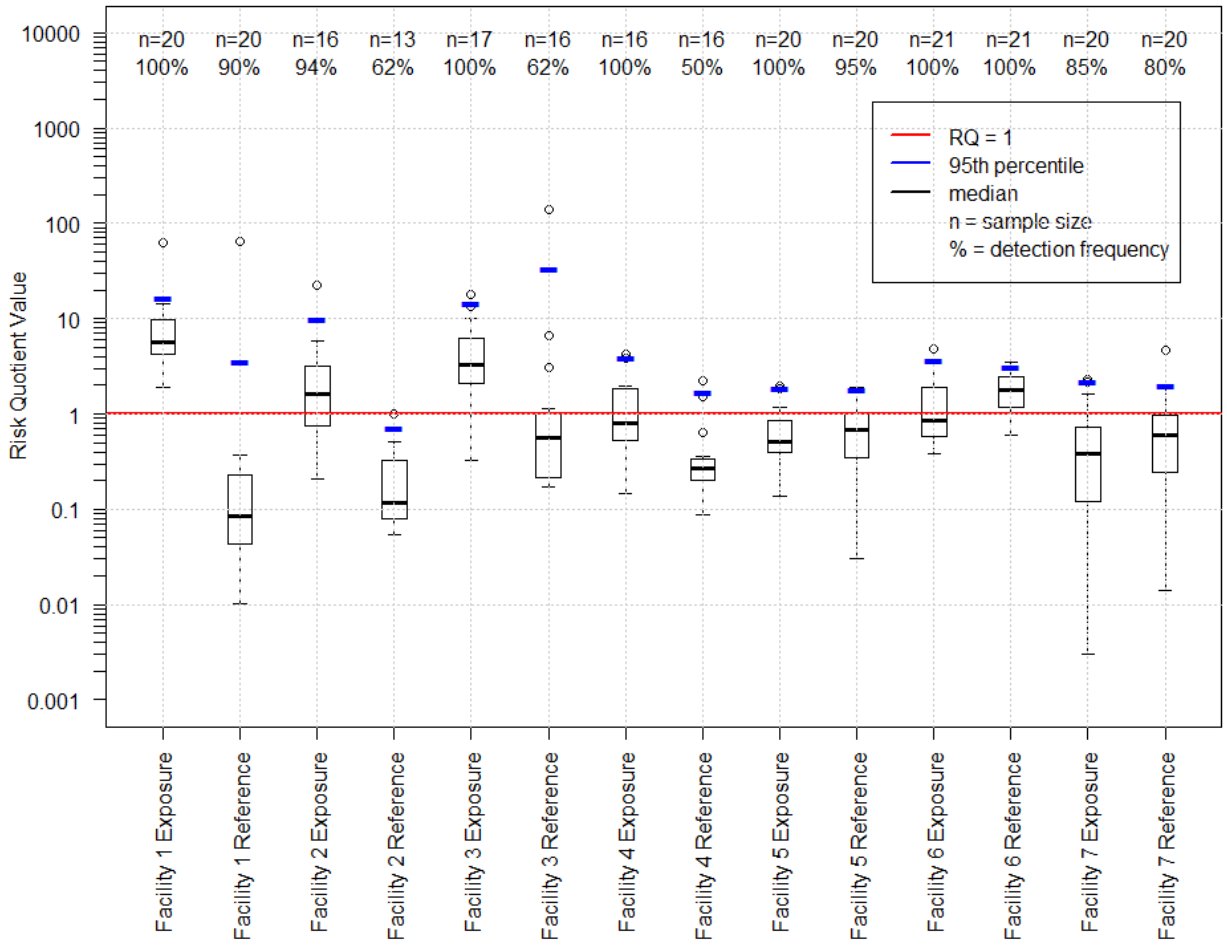

Figure 7-3. Metal mining sector box plots of risk quotients for seven facilities subject to the MDMER from 2011 to 2015 (EEM 2016)

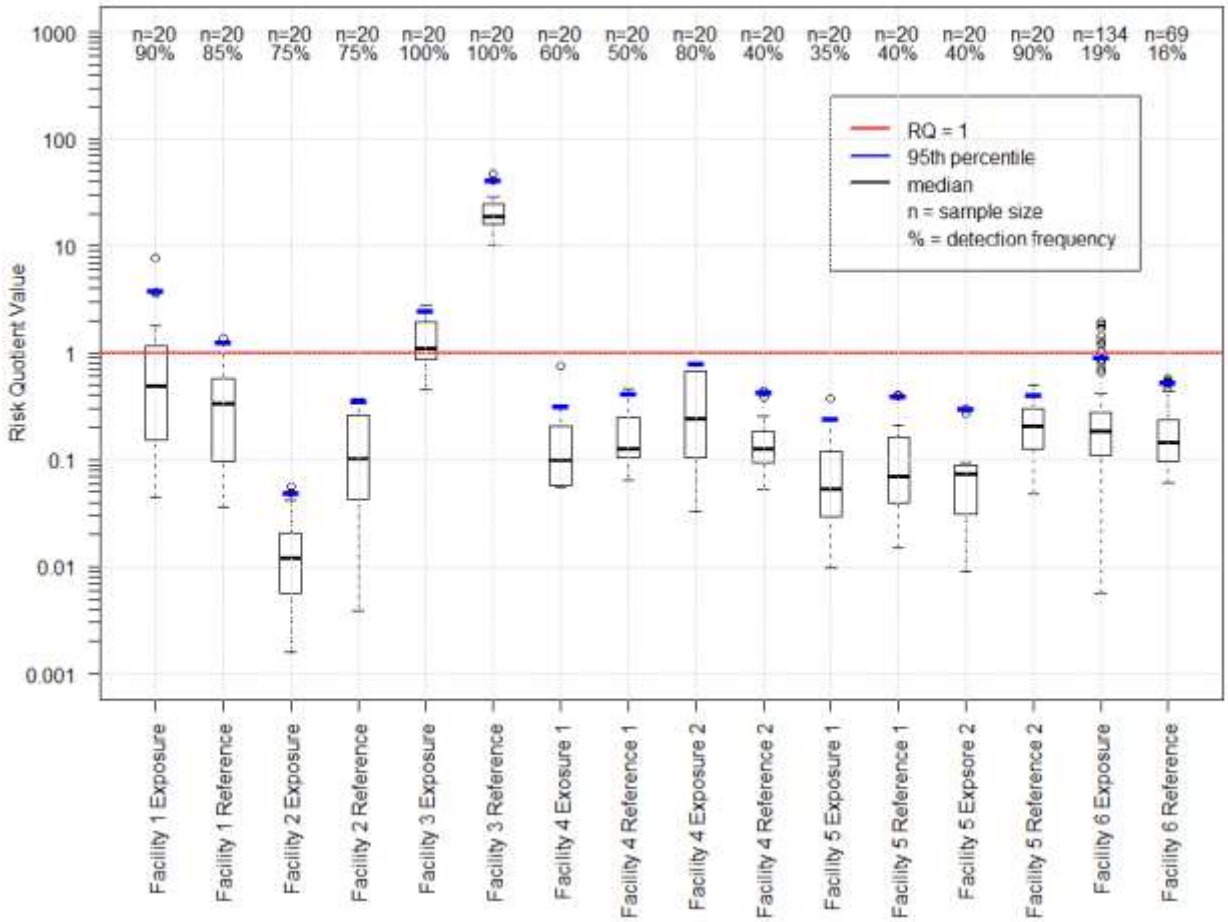

Figure 7-4. Base metal smelting sector box plots of risk quotients for five facilities subject to the MDMER from 2011 to 2015 and one smelter not subject to MDMER from 2012 to 2014 (EEM 2016; EEC Ltd & LAC Ltd 2014)

7.5.2 Consideration of the lines of evidence

To characterize the ecological risk of zinc and its compounds, technical information for various lines of evidence was considered (as discussed in the relevant sections of this report) and qualitatively weighted. The key lines of evidence supporting the assessment conclusion are presented in Table 7-3, with an overall discussion of the weight of evidence provided in section 7.5.3. The level of confidence refers to the combined influence of data quality and variability, data gaps, causality, plausibility and any extrapolation required within the line of evidence. The relevance refers to the impact the line of evidence has when determining the potential to cause harm in the Canadian environment. Qualifiers used in the analysis ranged from low to high, with the assigned weight having five possible outcomes.

Table 7-4. Weighted lines of key evidence considered to determine the potential for zinc and its compounds to cause harm in the Canadian environment

Line of evidence	Level of confidence	Relevance in assessment	Weight assigned
Persistence in the environment	High	High	High
Bioaccumulation in aquatic; terrestrial organisms	High	Low	Moderate
Mode of action and/or other non-apical data	Moderate	Low	Low to Moderate
PNEC for aquatic organisms in surface water	High	High	High
PNEC for aquatic organisms in sediment	Moderate	Low	Low to moderate
Toxicity Modifying Factors (hardness, pH and DOC	High	High	High
Monitoring data for concentrations in wastewater effluents	Moderate	High	Moderate to high
Monitoring data for concentrations in surface water	High	High	High
PEC(s) in surface water – metal mining	High	High	High
PEC(s) in surface water – base metal smelting and refining	Moderate	High	Moderate to high
PEC(s) in surface water – Iron and steel manufacturing	Moderate	High	Moderate to high
PEC(s) in surface water – Wastewater treatment sector	Moderate	High	Moderate to high
RQ(s) for surface water	High	High	High

7.5.3 Weight of evidence for determining potential to cause harm to the Canadian environment

Once released in the environment, zinc and its compounds may dissolve, dissociate or degrade to release the zinc moiety, which is infinitely persistent and can therefore accumulate in the environment over time, resulting in long-term exposure in environmental media. Zinc is an essential element that can bioaccumulate in certain organisms. However, there is no evidence of biomagnification in ecosystems. In the aquatic environment, zinc may be found in both dissolved and particulate forms, partitioning between the water column and sediments. The speciation of zinc in surface water depends on composition and quality of the receiving water. The free ion Zn^{2+} is typically considered the base species for expressing the bioavailability and toxicity of zinc and is predominant under conditions of low pH, low alkalinity, and high dissolved oxygen. However, when deriving PNECs, consideration was given to three main zinc TMFs in surface water – hardness, pH, and dissolved organic carbon – which influence the speciation and bioavailability of zinc and consequently, the chronic toxicity to aquatic organisms.

Zinc is released to the aquatic environment from many industries, including metal mining. Surface water monitoring data gathered under the MDMER indicate that detectable measurements of Zn_T were more frequent in exposure areas than in the corresponding reference areas across Canada (Table G-3). The monitoring data for the seven metal mines included in the site-specific analysis indicate zinc enrichment in the exposure areas for some facilities when comparing the median concentrations of the exposure areas to that of the reference areas. The site analysis shows there are some metal mining facilities with PECs exceeding PNECs (derived using site-specific TMFs), indicating that chronic effects on aquatic organisms may be occurring.

There were five BMS facilities subject to the MDMER from 2011 to 2015 because of the combination of their effluents with those of metal mines, and two facilities not subject to MDMER. For three of the combined BMS facilities, no PECs exceeded the corresponding PNECs, while two BMS facilities (Facilities 1 and 3) showed detected PECs exceeding PNECs. However, reference values for Facility 3 suggest that this may be due to elevated geochemical zinc concentrations. The elevated exposure levels for Facility 1 indicate that BMS or mining activities at this site contribute to potential chronic effects on aquatic organisms. In addition, sediment concentrations at Facility 6 (1754 mg/kg), which is not subject to MDMER, are well above the interim potential effect level for sediments (315 mg/kg).

This information indicates that zinc and soluble zinc compounds have the potential to cause ecological harm in Canada.

7.5.4 Sensitivity of conclusion to key uncertainties

Exposure scenarios for surface water were developed for four sectors of activity (metal mining, base metal smelting and refining, iron and steel manufacturing and wastewater treatment), but many other uses or sectors of activity may release zinc to the environment and to surface water. However, the four sectors reported direct releases of zinc and its compounds to surface water to the NPRI and were the primary sectors of interest based on the magnitude of the releases reported. At the time of the development of this document, enough data were not available to fully assess some of the other sectors contributing to zinc in the environment, e.g., pulp and paper sector.

PECs for iron and steel manufacturing, wastewater treatment, and in some cases base metal smelting and refining were modelled based on effluent concentrations. As a result, representative background concentrations for the site of discharge were added to the estimated aquatic concentration for a specific site. While site specific background values were not systematically available, representative background concentrations corresponding to the sites' ecozones were derived using the approach proposed by Kilgour & Associates (2016) and provided realistic background estimates for the particular sites.

PNECs for surface water were calculated using the zinc long-term CWQG equation recently derived by the CCME (2018b) and incorporated hardness, pH and DOC data in water for specific sites or monitoring stations. TMFs data were not always available or of

sufficient quality (e.g., small sample size) for certain sites or monitoring stations and values for specific TMFs had to be estimated. When required, estimates corresponding to the sites' ecozones were derived using the approach proposed by Kilgour & Associates (2016) to provide realistic estimates. For the Great Lakes, estimates were based on geometric means of each lake for specific TMFs.

Site-specific PNECs integrating TMFs considerations are more accurate predictors of the bioavailability and chronic toxicity of zinc to aquatic organisms in surface water. However, TMFs may attenuate the toxicity of zinc and risk to organisms may not necessarily be observed in the water column under certain conditions.

8. Potential to cause harm to human health

8.1 Health effects assessment

Essentiality

Zinc is an essential element for human health (ATSDR 2005). Zinc is vital for the function of more than 300 metalloenzymes, which are involved in the maintenance of catalytic functions, structural stability, and regulatory functions (Bel-Serrat et al. 2014; ATSDR 2005). Zinc is also involved in DNA and ribonucleic acid (RNA) synthesis and cell proliferation (ATSDR 2005).

Zinc deficiency is associated with a wide range of clinical symptoms, including dermatitis, anorexia, growth restriction, poor wound healing, hypogonadism with impaired reproductive capacity, impaired immune function, and depressed mental function. Increased incidence of congenital malformations in infants is also believed to be related to zinc deficiency in mothers (ATSDR 2005; IOM 2001). As a result, the Institute of Medicine (IOM) derived estimated average requirements (EARs) to ensure nutritional adequacy of the general population in North America (see Table H-1 of Appendix H).

Toxicokinetics and adequacy of biomarker

The fraction of zinc absorption through the gastrointestinal (GI) system ranges from 8% to 81% (ATSDR 2005). The average absorption in humans with adequate nutrition is considered to be 33% (Roohani et al. 2013). Individuals with zinc-deficient diets absorb greater proportions of administered zinc than individuals with zinc-sufficient diets (ATSDR 2005). The GI absorption of zinc is greatly influenced by the amount of zinc in the GI tract and the presence of ligands. Phytate is the main zinc-binding ligand and is commonly found in plant-based diets, such as bran products (wheat bran, rice bran, whole wheat, oat bran, etc.) and legumes. Phytate forms insoluble zinc complexes causing inhibitory effects on zinc absorption (Sandstead and Freeland-Graves 2014; Gibson 2012; Lowe et al. 2009). A study in mice indicated that zinc absorption decreases with age, with a significantly lower fractional absorption in young adult and adult mice compared to weanlings and adolescents (US EPA 2005). There are no quantitative data that suggest zinc can be absorbed through intact skin, but absorption

has been reported through damaged or burned skin (ATSDR 2005; EC 2004). On the basis of an *in vitro* system, EC (2004) reported dermal absorption of zinc from a solution of zinc sulphate and a suspension of zinc oxide of 1.6% and 14.9%, respectively. EC (2004) also reported 40% inhalation absorption of soluble zinc compounds and 20% inhalation absorption of less soluble or insoluble zinc compounds.

Absorbed zinc is widely distributed throughout the body. Approximately 60% of zinc in the body is found in skeletal muscles and 30% in bones, which are considered slow-releasing zinc pools. However, unlike other elements, such as iron, there are no storage forms of zinc that can be freely released during nutritional deficiency (Lowe et al. 2009). Zinc is also found in the liver, gastrointestinal tract, kidney, skin, lung, brain, heart, pancreas and blood (ATSDR 2005). Approximately 70% of the zinc in circulation is loosely bound to plasma/serum albumin (Roohani et al. 2013). Plasma/serum zinc is the most metabolically active zinc in the body (Hess et al. 2007).

The primary route of zinc excretion is through feces, which accounts for the elimination of about 60% to 80% of daily dietary intake (Dlugaszek et al. 2011). Fecal elimination includes both unabsorbed dietary zinc and zinc released from endogenous sources. Zinc absorbed via inhalation can also be eliminated through the fecal route (EC 2004). Age-dependent fecal elimination pattern was observed in animal studies, where the highest fecal elimination is reported in adult mice compared to weanlings, adolescents or young adults (US EPA 2005). Approximately 3% of dietary of zinc is eliminated via urine (Dlugaszek et al. 2011; King and Keen 1999). Some authors have reported up to 25% urinary elimination of zinc (US EPA 2005). For chronic exposure scenarios, a value of 4% urinary elimination has been estimated on the basis of controlled dosing studies in humans (Johnson et al. 1982, 1993; Jackson et al. 1984; Turnlund et al. 1986; Wada et al. 1985; Wastney et al. 1986; Lee et al. 1993; Cunningham et al. 1994; Iyengar et al. 1998; Donangelo et al. 2002; Kim et al. 2004, 2007). After analyzing the trace metal content of human volunteers (46 females aged 8 to 71 years and 28 males 4 to 83 years), Dlugaszek et al. (2011) reported that men have two times higher zinc elimination in urine than women; children have higher zinc elimination in urine than adults. According to kinetic models, zinc elimination follows biphasic elimination; an initial rapid phase with a half-life in humans of 10.2 ± 1.5 days, and the slower pool with a half-life of 376 ± 73.2 days (Watson et al. 1999). Lung retention half-lives of 14 and 6.3 hours were reported in inhalation studies in animals (EC 2004).

In population level biomonitoring studies, zinc has been measured in different biological fluids and tissues, such as urine, whole blood, plasma, serum and breast milk (Health Canada [modified 2013]; AFN 2013; Government of Alberta 2010; Alberta Health and Wellness 2008; INSPQ 2004). Both plasma/serum and urine are considered suitable biomarkers for the quantification of zinc intake in a population (Lowe et al. 2009). A study group convened by the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the International Atomic Energy Agency (IAEA), and the International Zinc Nutrition Consultative Group (IZiNCG) to review methods of assessing population zinc status concluded that serum or plasma zinc concentration is the best available biomarker that reflects dietary zinc intake during both zinc deficiency and supplementation (Benoist et al. 2007). Available data indicate that there are no

considerable differences in zinc concentration in plasma and serum (Moran et al. 2012; Lowe et al. 2009; Hess et al. 2007). The approximate ratio for whole blood to plasma/serum was derived as 7:1 by Health Canada on the basis of data from Iyengar and Woittiez (1988), Minoia et al. (1990), Błażewicz et al. (2013), and INSPQ (2004-unpublished). The majority of whole blood zinc consists of zinc in erythrocytes. Erythrocyte zinc concentrations reflect long-term zinc exposure, as the biological half-life of erythrocyte zinc is about 120 days (WHO 2001). Zinc concentration in blood is regulated through homeostatic mechanisms (ATSDR 2005). Homeostasis is maintained by the secretion of zinc into the gastrointestinal tract (fecal elimination), absorption of zinc from the gastrointestinal tract, excretion of zinc in urine, exchange of zinc with erythrocytes and release of zinc from tissues (EC 2004). However, meta-analyses on the basis of supplementation studies have reported positive associations between zinc intakes and plasma/serum zinc concentrations, suggesting that the plasma/serum zinc concentration can be used as a quantitative biomarker of zinc exposure in a population (Lowe et al. 2012; Moran et al. 2012; Lowe et al. 2009; Hess et al. 2007). Conversely, information regarding the relationship between intake and zinc in erythrocytes or whole blood is very limited (Lowe et al. 2009).

Zinc levels in urine have also been identified as a suitable biomarker of exposure during supplementation (Lowe et al. 2009; Wastney et al. 1986). Lowe et al. (2009) reported a statistically significant increase in urinary elimination of zinc during supplementation. Using an isotope-tracer technique, King et al. (2001) reported that both plasma and urine zinc concentration decrease significantly during extreme zinc deficiency (65% and 96% decrease for plasma and urine, respectively) and therefore, these biomarkers (particularly urinary zinc concentration) might not be suitable for quantifying exposure during nutritionally insufficient zinc intakes. However, zinc deficiency is not an area of focus in this screening assessment.

On the basis of a review of available data, it has been established that urine zinc concentration may be a more reliable biomarker than blood zinc concentration for investigating zinc exposure given the homeostatic control of zinc in blood. Generally, blood zinc concentrations are maintained at a constant level by homeostasis mechanisms under conditions of excess zinc intake. In addition, there are limited studies that investigated the effectiveness of whole blood as a biomarker for quantifying exposure. Some systematic and meta-analyses indicated that erythrocyte zinc concentration, which is the main component of whole blood zinc, does not correlate well with zinc intake levels (Lowe et al. 2009, 2013). As a result, urinary zinc concentration will be considered as the most suitable biomarker for quantifying exposure in the risk characterization of zinc and its compounds.

Health effects

Health Canada has reviewed zinc in order to establish limits on the amount of zinc permitted in multi-vitamin/mineral supplements (Health Canada [modified 2018a]) and in supplemented foods (Health Canada [modified 2016b]) and for the derivation of soil quality guidelines (CCME 2018a) and drinking water guidelines as an aesthetic objective (Health Canada [modified 2017b]). The health effects of zinc have also been

assessed by other international organizations (EFSA 2006; US EPA 2005; ATSDR 2005; EC 2004; WHO 2003; IOM 2001; JECFA 1982). These evaluations were used to inform the health effects characterization in this screening assessment. A literature search was conducted from the year prior to the most recent assessment, i.e., the 2006 EFSA review (so from 2005 onwards). No health effects studies that could impact the risk characterization (i.e., result in different critical endpoints or lower points of departure (PODs) than those stated in existing reviews and assessments) were identified.

The focus of the current risk assessment is the health effects associated with excess zinc exposure in the general population rather than the adverse health effects of zinc deficiency. Several international organizations have previously established exposure guidance values to protect against zinc toxicity. The IOM has derived tolerable upper intake levels (ULs) for different age groups of the North American population. The IOM did not derive a separate UL for pregnant and lactating women because there were inadequate data to justify a different UL. Hence, the same UL for adolescents and adults was used for pregnant and lactating women (IOM 2001). In addition, the US Environmental Protection Agency (US EPA 2005) has established a reference dose (RfD) and the Agency for Toxic Substances and Disease Registry (ATSDR 2005) has established a minimal risk level (MRL). In 1982, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) proposed a provisional maximum tolerable daily intake (PMTDI). The European Food Safety Authority (EFSA) has derived a UL to ensure the safety of fortified foods and food supplements containing zinc (EFSA 2006). The European Union has also published a risk assessment report for zinc (EC 2004), and the EU Scientific Committee on Consumer Safety recently published an opinion document specific to zinc pyrithione (SCCS 2018). After consulting available human studies, the World Health Organization (WHO 2003) concluded that the derivation of a health-based drinking water guideline for zinc is not required. These exposure guidance values and the critical PODs from the EU risk assessment report (EC 2004) are summarized in Table H-1 of Appendix H.

The majority of exposure guidance values for excess zinc intake are derived on the basis of reduced copper status in adults, with an uncertainty factor to account for inter-individual variability (EFSA 2006; US EPA 2005; ATSDR 2005; IOM 2001; JECFA 1982). As presented in Table H-1 of Appendix H, human supplementation studies conducted by Fischer et al. (1984), Yadrick et al. (1989), Milne et al. (2001) and Davis et al. (2000) were considered the key studies for the selection of endpoints in the derivation of exposure guidance values. In all these studies, the individuals were given a basal diet supplemented with 50 mg Zn/day for an exposure duration in the range of 6 to approximately 13 weeks. The zinc content of the basal diet ranged from 3 to 15.9 mg Zn/day. Although these studies did not show a significant decrease in plasma copper levels, the reduced copper status was measured by monitoring erythrocyte copper-zinc superoxide dismutase (ESOD) activity, which is a marker of copper status. The reduced copper levels were not considered adverse, but they could be an indicator of more severe effects occurring at higher dose levels (US EPA 2005). In addition, the reduced copper status is rarely reported in humans (IOM 2001). On the basis of these observations, all the exposure guidance values described above, with the exception of the IOM UL, have considered the supplemented dose of 50 mg Zn/day as a no

observed adverse effect level (NOAEL). The US EPA (2005), ATSDR (2005) and EFSA (2006) did not consider subclinical changes in copper status (i.e., decreased ESOD activity) in human supplementation studies as adverse effects. Hence, the supplemental dose of 50 mg/day and the dietary intake of 10 mg/day (0.91 mg/kg bw/day) were considered a NOAEL in the derivation of exposure guidance values. In contrast, the IOM UL considers the decreased ESOD activity reported at the supplemented dose of 50 mg Zn/day (with an average dietary intake of 10 mg/day) as a LOAEL (IOM 2001).

The EU risk assessment report (EC 2004) also considered the supplemented dose of 50 mg Zn/day used in human volunteer studies (Milne et al. 2001; Davis et al. 2000; Yadrick et al. 1989; Fischer et al. 1984) to be a NOAEL and used this value in risk characterization. The assessment provided the following rationale for this consideration: the changes in ESOD activity in Milne et al. 2001 and Davis et al. 2000 were mild and within the range of natural variation. Further analysis revealed that when volunteers were supplemented with zinc up to 50 mg Zn/day, only the plasma/serum zinc concentrations were elevated, while the plasma/serum copper levels remained steady (EC 2004). The individuals who showed reduced plasma/serum copper levels in the above volunteer studies were the cohorts in the low copper diet groups.

The EU risk assessment report (EC 2004) identified a LOAEL of 150 mg Zn/day from a human volunteer study by Samman and Roberts (1987). In this double-blind cross-over trial, 47 healthy volunteers (26 females and 21 men) were given zinc sulphate capsules containing 220 mg zinc sulphate, 3 times a day with each meal for 6 weeks (resulting in a total daily dose of 150 mg Zn, or 2.0 and 2.4 mg Zn/kg bw/day assuming body weights of 73.9 and 61.3 kg for males and females, respectively). Women appeared to be more sensitive than men to adverse health effects associated with excess zinc intake. Eighty-four percent of the women and 18% of the men showed clinical signs, such as headaches, nausea, vomiting, loss of appetite and abdominal cramps, which were the basis for the LOAEL. According to the study authors (Samman and Roberts), gastric discomfort was associated with lower body weights and with taking the capsules with small meals or on an empty stomach. Although these clinical signs were considered adverse, it is likely that the effects were reversible. No significant changes in plasma copper levels were reported in either sex, but a 20% decrease in ESOD activity was noted in women (Samman and Roberts 1987, 1988).

EU risk assessment report applied an uncertainty factor of 1 to the NOAEL of 50 mg/day in its risk assessment because the study was conducted in the most sensitive subpopulation for zinc (i.e., women), and changes in ESOD activity observed in Samman and Roberts (1987) were within natural variation. The uncertainty factor of 1 is further supported by supplementation studies in children where no zinc-related health effects were observed when children were supplemented with zinc in the range of 3 to 15 mg/day (dietary intake in the range of approximately 10 to 15 mg/day) for 4 to 6 months (Wuehler et al. 2008; Bertinato et al. 2013). The PODs (NOAEL and LOAEL) identified in the EU risk assessment report do not account for the dietary intakes (approximately 10 mg/day) and therefore, the reported effects at the LOAEL are likely happening at a slightly higher intake level.

There were no one or two generation reproductive studies available for zinc (EC 2004). In repeated dose studies in experimental animals, developmental and reproductive effects were only reported at very high oral dose levels (ATSDR 2005; EC 2004).

The available data in both humans and animals following oral or inhalation exposure are inadequate to evaluate potential associations between zinc exposure and cancer (ATSDR 2005; US EPA 2005; EC 2004). Genotoxicity studies conducted in a variety of test systems have not provided evidence for mutagenicity of zinc. However, weak clastogenic effects were seen in *in vivo* and *in vitro* assays (ATSDR 2005). On the basis of the US EPA Guidelines for Carcinogen Risk Assessment, the US EPA (2005) has determined that there is inadequate information to assess carcinogenic potential of zinc.

While the majority of inhalation effects of exposure to zinc compounds were seen at the site of exposure (i.e., respiratory tract), the nature of effects vary somewhat on the basis of the type of zinc compound (ATSDR 2005; EC 2004). The most common effect of inhalation exposure to zinc metal and many other zinc compounds, such as zinc oxide, was “metal fume fever”, which was observed under occupational exposure to the airborne levels in the range of 77 to 600 mg Zn/m^3. In these studies, it was difficult to account for exposure to other metals and therefore, the ATSDR (2005) has not derived inhalation MRLs for zinc. The U.S. EPA (2005) did not establish an inhalation RfD because of insufficient data in humans and experimental animals. Studies have indicated that zinc (predominantly as zinc oxide and zinc sulfide), one of the key metals found in particulate matter in indoor air, is capable of generating reactive oxygen species (ROS) that could trigger oxidative stress (NAS 2016; Fortoul et al. 2015; Beauchemin et al. 2014). However, there is limited specific knowledge about the association of a disease and the inhalation exposure of metals in particulate matter (Fortoul et al. 2015).

According to the ATSDR (2005), no studies were identified for respiratory, cardiovascular, gastrointestinal, musculoskeletal, hepatic, renal, or other systemic effects in humans or animals after dermal exposure to zinc.

The critical PODs from the EU risk assessment report (EC 2004), including the human oral NOAEL of 50 mg Zn/day (0.83 mg Zn/kg bw/day) and the LOAEL of 150 mg/d (2.0 and 2.4 mg Zn/kg bw/day for men and women, respectively) established on the basis of headaches, nausea, vomiting, loss of appetite and abdominal cramps, will be carried forward as the critical health effects for risk characterization of zinc and its compounds. The use of PODs, as opposed to the IOM UL, the most commonly used exposure guidance values for the general population in North America, was further supported by the results of several subsequent studies in infants and children that suggested the re-examination of the IOM UL values for these age groups because the ULs were likely set too low (Wuehler et al. 2008; Bertinato et al. 2013). Several supplementation or dietary survey studies reported that dietary intake alone exceeds the IOM UL in infants and children (Zlotkin 2006; Wuehler et al. 2008; Butte et al. 2010; Rangan and Samman 2012; Bertinato et al. 2013; Ahluwalia et al. 2016). None of the studies that supplemented children with zinc (up to 15 mg/day in addition to dietary intake of >10

mg/day) reported any zinc-related health effects (Wuehler et al. 2008; Bertinato et al. 2013).

Derivation of biomonitoring equivalent (BE)

There are no existing BE values or other human biomonitoring guidance values for zinc. As such, BE values were derived for zinc for the purposes of this assessment and the details of this derivation can be found in Poddalgoda et al. (2019). The details of biomonitoring guidance values, their application in risk assessment and the associated uncertainties can be found in Hays et al. (2008); Health Canada [modified 2016a] and Zidek et al. (2017).

A BE is defined as the concentration or range of concentrations of a chemical or its metabolites in a biological medium (blood, urine, or other medium) that is consistent with an existing health-based exposure guidance value such as a reference dose (RfD) or a tolerable daily intake (TDI) (Hays et al. 2008). In the current assessment, BE values were derived for the critical PODs (i.e., NOAEL and LOAEL of 50 and 150 mg/day, respectively) from the EU risk assessment report (EC 2004) with an uncertainty factor of 1. In the EU risk assessment, the internal values for the NOAEL were estimated using worst-case assumptions for the percentages absorbed via different exposure routes (i.e., 20, 40 and 0.2% for oral, inhalation and dermal routes, respectively). However, the approaches used in the BE derivation (regression correlation and mass balance approach for blood and urine, respectively) indirectly account for those kinetic parameters and therefore it is not necessary to consider those absorption fractions in the BE derivations. The BE values were derived for blood and urinary zinc assuming a steady state exposure. Steady state exposure can be expected regardless of the length of elimination half-life because people are exposed to zinc multiple times during the day though ingestion of food.

The plasma/serum BE derived by Health Canada was based on a regression correlation between oral zinc intakes and plasma/serum zinc concentrations (Figure 8-1) (Poddalgoda et al. 2019). A literature search was carried out in order to identify studies that measured or quantified both oral zinc intake and plasma/serum zinc concentrations. Approximately 60 data points from zinc supplementation and depletion studies conducted in healthy adults formed the basis for the underlying data in the regression analysis as presented in Table H-2 of Appendix H. The linear regression resulted in the following mathematical relationship:

Plasma/serum concentration (µg Zn/L) = 200.83x + 839.49, R^2=0.58, $p < 0.001$

Where oral intakes (x) are in mg Zn/kg bw/day.

The plasma/serum BE values for the NOAEL and the LOAEL, with an uncertainty factor of 1 from the EU risk assessment report, were 1.0 and 1.3 mg/L, respectively. Considering the kinetics of zinc in whole blood and plasma, the whole blood BE values for the same PODs and UFs were estimated as 7 and 9 mg/L, respectively, based on the whole blood/plasma conversion factor of 7 (described in section 8.1.1).

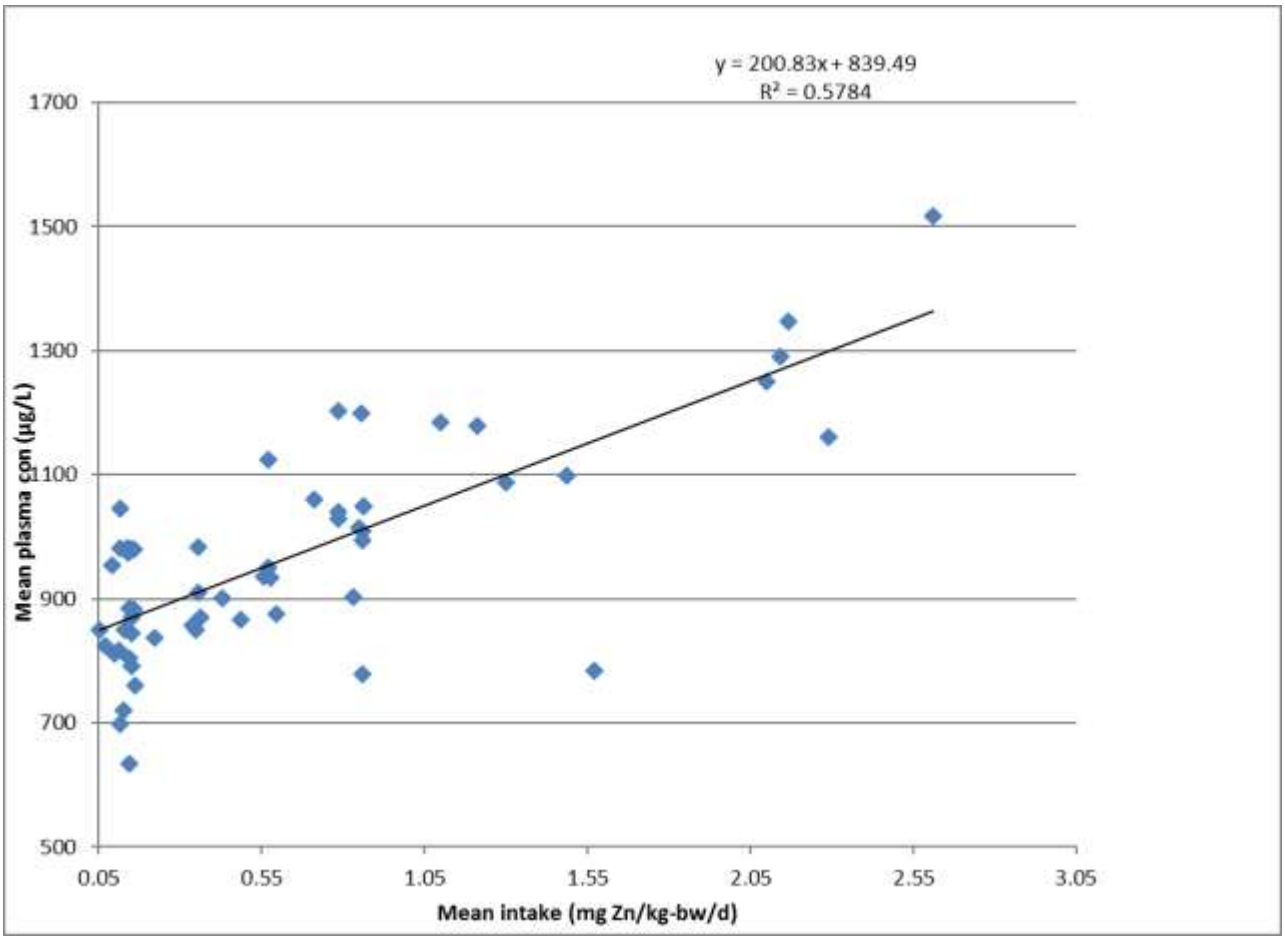

Figure 8-1. Plasma zinc concentration as a function of daily intakes based on a large number of dietary intakes and supplementation studies in adults (see Table H-2 of Appendix H)

The mass balance equation explained in Hays et al. (2010) was used to derive urinary BE.

Urinary BE = (unit dose x F_{UE})/(V_{24} or Cr_{24})

where F_{UE} is the urinary excretion fraction, and V_{24} and Cr_{24} are the 24-hour urinary volume and creatinine excretion, respectively. The average V_{24} and Cr_{24} for adult men and women were approximately 1.7 L and 1.4 g creatinine, respectively. The average urine excretion fraction for both adult men and women was considered to be 4% based on multiple controlled dosing studies in humans (Johnson et al. 1982, 1993; Jackson et al. 1984; Turnlund et al. 1986; Wada et al. 1985; Wastney et al. 1986; Lee et al. 1993; Cunningham et al. 1994; Iyengar et al. 1998; Donangelo et al. 2002; Kim et al. 2004, 2007). The urinary BE values for the NOAEL and the LOAEL from the EU risk assessment report were 1693 and 4488 µg/g creatinine, respectively.

The BE values associated with exposure guidance values for nutritional requirements (i.e., IOM EAR) were also derived. The BE values for the IOM EAR for men and women were 6.1 and 6.0 mg/L in whole blood, and 265 and 204 µg/g creatinine in urine (Poddalgoda et al. 2019). It is noteworthy that the median whole blood concentration of zinc in Canadians is near the IOM EAR. The urinary BE values showed a wider margin between nutritional and toxicological effects compared to blood BE values. The narrow margin between blood BE values for nutrition and toxicity is likely the result of homeostatic control of blood zinc levels. Since the urinary BE is more responsive to changes in zinc intake than the blood BE, the urinary BE values for the NOAEL and LOAEL from EU risk assessment report will be used for the risk characterization.

8.2 Exposure assessment

Environmental media, food and drinking water

Zinc is a naturally occurring element present in all environmental media in Canada. Relative to other metals, zinc is found in much higher concentrations in environmental media, drinking water, and human blood and urine. Food is considered to be the primary source of zinc exposure for the general population (ATSDR 2005; CCME 2018a)

a). On the basis of zinc measurements from the Canadian Total Diet Study (TDS) from 1993 to 2007, average dietary intakes for Canadians (all ages, males and females combined) were steady, ranging from 190 to 227 µg/kg bw/day (Health Canada [modified 2011a). Infants between 2 to 3 months had the highest average dietary intakes (based on infant formula, cow's milk), ranging from 678 to 899 µg/kg bw/day. Dietary intakes of zinc decline with age (on a per body weight basis). Intake estimates based on the TDS do not include breast milk concentrations, which are a source of exposure for nursing infants. Average and 95th percentile intakes of 246.7 µg/kg bw/day and 291.2 µg/kg bw/day, respectively, were derived for nursing infants aged 0 to 6 months on the basis of measured concentrations of zinc in breast milk from 2001 Canadian mothers between 2008 and 2011, as part of the core MIREC study (2017 email from the Bureau of Chemical Safety, Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, unreferenced; Arbuckle et al. 2013). Dietary exposure estimates calculated as part of the Canadian TDS identify meats, cereals and dairy products as the main contributors to dietary zinc exposure (personal communication, emails from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, January 2018, unreferenced). Meat products contain relatively high concentrations of zinc, whereas fruits and vegetables have relatively low concentrations. People who consume large amounts of foods high in zinc content, such as oysters and mussels, may be exposed to elevated levels of zinc (ATSDR 2005).

Zinc sulphate is on the *List of Permitted Yeast Foods (Lists of Permitted Food Additives)* for use in beer and bacterial cultures (Health Canada [modified 2012]). Various zinc compounds may be used as components in the manufacture of food packaging materials and in incidental additives used in food processing establishments (personal

communication, emails from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, May 25, 2017, unreferenced). In Canada, zinc is permitted to be added as a mineral nutrient to breakfast cereals, infant formulas and formulated liquid diets, foods represented for use in very low energy diets, meal replacements and nutritional supplements, simulated meat products and products simulating whole egg as a mineral additive (Canada 1978). However, it is not permitted to be added to supplemented foods targeted to the general population as the 95th percentile zinc intake from these foods would be above the tolerable upper intake level (UL) in children 4 to 8 years of age. Zinc is permitted in supplemented foods that are intended for adults only, at levels such that the daily intake of zinc from the food would not exceed 5 mg per day. These supplemented foods must be labelled specifically that they are not intended for children (Martineau et al. 2014; Health Canada [modified 2016b]).

Usual average intakes for First Nation peoples living on reserve in British Columbia, Alberta, Manitoba and Ontario were derived as part of the First Nations Food, Nutrition and Environment Study (FNFNES) and ranged from 183 to 267 µg/kg bw/day (Chan et al. 2011, 2012, 2014, 2016). These intakes are similar to estimates derived for the general Canadian population. Traditional foods are considered to be an important source of dietary zinc. The greatest contributors to dietary intakes were moose in BC, and beef and moose in Manitoba, Ontario and Alberta (Chan et al. 2011, 2012, 2014, 2016). Whale was the predominant contributor to zinc dietary intakes for Inuit living in Nunavut (Baffin, Kivalliq, Kitikmeot) and Nunatsiavut (Rosol et al. 2016). Dietary intake estimates were derived for Yukon First Nations, Dene/Métis and Inuit adults living in the Yukon and NWT. Intake estimates were significantly higher on days where traditional foods were consumed than days where no traditional foods were consumed. For adult Yukon First Nations, Dene/Métis and Inuit, dietary intakes were 390, 336 and 303 µg/kg bw/day on days where traditional foods were consumed compared with 185, 217 and 134 µg/kg bw/day on days were no traditional foods were consumed (assuming a body weight of 70.9 kg) (Kuhnlein et al. 2007).

Zinc is present in drinking water, and concentrations of zinc at the tap may be higher than in distribution systems because of potential leaching from galvanized pipes, hot water tanks and brass fittings (Health Canada [modified 2017b]). There is no-health based drinking water guideline for zinc in Canada, but there is an aesthetic objective of 5 mg/L based on taste. Water containing zinc levels above the aesthetic objective tends to be opalescent and develops a greasy film when boiled. It is recommended to flush plumbing before consumption (Health Canada [modified 2017b]).

Zinc is commonly found bound to particles in air and house dust. In a study conducted in Windsor, Ontario, zinc concentrations measured in outdoor air ($PM_{2.5}$) were higher than in indoor air (Rasmussen 2016). However, zinc concentrations in air are relatively low and fairly constant, except near sources such as smelters (ATSDR 2005). In the Canadian House Dust study, bioaccessible concentrations of zinc in house dust in urban homes were 22 times greater than that of the natural background, suggesting that anthropogenic sources dominate the indoor environment (Rasmussen et al. 2013; Beauchemin et al. 2014). Further analysis revealed that the bioaccessibility of zinc in

house dust increased significantly (by 21% to 65%) when dust samples were exposed to humid conditions for 4 months. Thus, transformations in damp environments where house dust accumulates, such as window troughs, can increase the bioaccessibility of particle-bound zinc (Rasmussen et al. 2014).

Zinc concentrations in soil throughout Canada vary on the basis of geology and anthropogenic inputs. According to the Scientific Criteria document for the development of the Canadian Soil Quality Guidelines (CCME 2018a), zinc concentrations in soil range from < 1 mg/kg to 1350 mg/kg (CCME 2018a). However, in areas where there are point sources of exposure such as mining and smelting activities, soil concentrations can be elevated from atmospheric fallout. Median and 90th percentile zinc surface soil concentrations of 1390 and 4771 mg/kg, respectively, were measured across 93 sampling sites in Flin Flon, Manitoba, in 2006. Flin Flon has been home to a base metal mining and a smelting facility since the 1930s. In neighbouring Creighton, Saskatchewan, soil concentrations of zinc were much lower, with median and 90th percentile zinc concentrations of 340 and 859 mg/kg, respectively (Manitoba Conservation 2007). The highest zinc concentrations were on undeveloped parcels of land, while lower concentrations in parks/playgrounds and schools..

As exemplified above, total zinc has been measured in indoor and outdoor air, household dust, drinking water distribution systems, food, and breast milk as part of several research initiatives undertaken by Health Canada and Environment and Climate Change Canada, as well as monitoring conducted by the provinces and several Canadian studies. Zinc concentrations measured in environmental media are presented in Table 8-1 below. Further information regarding the Health Canada Total Diet Study and associated dietary intake estimates are available online (Health Canada [modified 2011a]).

Table 8-1. Concentrations of zinc in environmental media in Canada

Media	Median	95th percentile	n	Reference
Drinking water, National survey in distribution systems (dissolved)	2.5 µg/L	34 µg/L	97	Tugulea 2016
Drinking water, provincial data from ON, SK, NL	Mean 11 µg/L	Max 2861 µg/L	14714	CCME 2018a
Drinking water, on reserve in ON, MN, AB, BC	na	Range <1 – 6890[a] µg/L	na	FNFNES Chan et al. 2011, 2012, 2014, 2016
NAPS Outdoor air $PM_{2.5}$	8 ng/m^3	28 ng/m^3	910	NAPS 2011
Outdoor air $PM_{2.5}$	29 ng/m^3	75 ng/m^3	447	Rasmussen 2016
Indoor air $PM_{2.5}$	12 ng/m^3	50 ng/m^3	437	Rasmussen 2016

Personal air $PM_{2.5}$	16 ng/m^3	53 ng/m^3	445	Rasmussen 2016
House dust	725 mg/kg	1627 mg/kg	1025	Rasmussen et al. 2014
Bioaccessible house dust	534 mg/kg	1285 mg/kg	1025	Rasmussen et al. 2014
Outdoor soil Canadian range	na	Canadian range < 1 – 1350 mg/kg	157	CCME 2018a
Outdoor soil Ontario typical range	57 mg/kg	124 mg/kg	483	Ontario 2015
Outdoor soil Canadian elevated levels	1 390 mg/kg	90th percentile 4771 mg/kg	93	Manitoba Conservation 2007

Abbreviations: na = not available

[a] Flushed samples were below aesthetic objective

Products

In addition to environmental media, food and drinking water, zinc has widespread industrial, commercial and consumer uses which contribute to daily exposure. Zinc is present in thousands of products available to consumers in Canada, including drugs and natural health products (DPD [modified 2018]; LNHPD [modified 2018]; NHPID [modified 2018]). In 2015, 45.6% of Canadians used at least one nutritional supplement, and multi-vitamins were the most common nutritional supplement taken (Statistics Canada 2017). Zinc is also present in cosmetics, with restrictions for zinc borate and zinc peroxide (personal communication, emails from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated May 26, 2017; unreferenced; Health Canada [modified 2018b]), in pesticides (Health Canada [modified 2016c]; Health Canada 2010), in toys and children's products (Guney and Zagury 2012; Washington State Department of Ecology 2014; Danish Environmental Protection Agency 2016; CPCat 2014), and in a variety of other products available to consumers including paints and coatings, sealants, cleaning products, automotive products (e.g., transmission fluid, steering fluid, motor oil) and plant fertilizers (CPCat 2014; Household Products Database 1993-; Danish Environmental Protection Agency 2016). Given the low dermal absorption of zinc, dermal exposure is not expected to be a significant contributor to general population exposure. Some products available to consumers containing zinc will contribute to oral and inhalation exposure.

Biomonitoring data

Total zinc measured in blood (e.g., whole blood, plasma, serum) and urine in individuals within a population can provide a measure of integrated exposure of the population from all routes (oral, dermal and inhalation) and all sources (including environmental media, diet, and frequent or daily use products to which they were exposed). Sufficient high-quality biomonitoring data exist for zinc to adequately characterize exposure to the

Canadian population, including sub-populations of interest, such as children, pregnant women and Indigenous populations.

Total zinc concentrations in whole blood and/or urine were measured in over 12,000 Canadians as part of several studies including the Canadian Health Measures Survey (CHMS), the First Nations Biomonitoring Initiative (FNBI), and the Maternal-Infant Research on Environmental Chemicals (MIREC-CD Plus) Study. The Canadian Health Measures Survey (CHMS) is a national survey carried out by Statistics Canada in partnership with Health Canada and the Public Health Agency of Canada, which collects information from Canadians about their general health (Health Canada [modified 2011b]; Health Canada [modified 2013]). This survey was designed to be nationally representative and includes a biomonitoring component. The CHMS is not a targeted survey and thus does not target individuals with high metal exposure or those living near point sources of exposure. This dataset would include individuals taking multi-vitamin/mineral supplements containing zinc. Cycle 1 and 2 datasets include both fasting and non-fasting individuals.

In addition to national level biomonitoring data, zinc concentrations were measured in Canadians living in specific regions of Canada and belonging to specific sub-populations of interest, including pregnant women, toddlers and Indigenous peoples. A national pregnancy cohort study, MIREC, recruited 2000 pregnant women from Vancouver, Edmonton, Winnipeg, Sudbury, Ottawa, Toronto, Hamilton, Kingston, Montreal and Halifax (Arbuckle et al. 2013). Although zinc concentrations were not measured in the blood and urine of the participating mothers, 847 breast milk samples collected from 2008 to 2010 were analyzed for zinc. Median zinc breast milk concentrations were 1841 µg/L with a maximum of 5535 µg/L (Health Canada 2017). In addition, whole blood zinc concentrations were measured in a subset of approximately 500 children from the mothers participating in MIREC as part of a follow-up child development study (MIREC-CD Plus). Regional zinc data was also available from the Quebec Region and Alberta (INSPQ 2004; Alberta Health and Wellness 2008; Government of Alberta 2010).

Zinc in whole blood was detected in all Canadians, which was anticipated as it is an essential element for human health (Health Canada [modified 2013]). Median and 95th percentile population-weighted concentrations of zinc in whole blood of Canadians, aged 6 years and older, collected from 2007 to 2011 (n = 10884), were 6.2 and 7.8 mg/L, respectively (Walker 2017). Median blood zinc concentrations in children 1 to 3 years old from MIREC were similar to those of the 3- to 5-year olds and slightly lower than those measured I older children in the CHMS, with a median concentration of 4.6 mg/L (Liang 2016; Health Canada [modified 2013]). Whole blood zinc concentrations increase with age, and the highest zinc concentrations in whole blood were found in adults aged 60 to 79 years of age. Median and 95th percentile population-weighted concentrations of urinary zinc, aged 6 years and older, from 2007-2011 (n = 11187), were 320 and 810 µg/g creatinine, respectively (Walker 2017). Urinary zinc concentrations have a U- shaped pattern, with the highest concentrations found in 3 to 5 year olds (median: 630 µg/g creatinine; 95th percentile: 1300 µg/g creatinine as measured in CHMS Cycle 2), then decreasing until the age of 20 to 39 years, then

increasing with age (Health Canada [modified 2013]). This increase is likely attributed to loss of zinc from bone and muscle with age. Zinc concentrations in whole blood and urine are significantly higher in males than in females (Karthikeyan et al. 2017).

In an analysis of the CHMS 2007 to 2011 whole blood data, zinc concentrations in children (6 to 19 years of age), were associated with age, sex and time of sampling (morning versus afternoon), and whole blood concentrations in adults (20 to 79 years) were correlated with age, sex and fasting status. Blood zinc concentrations in both children and adults were not associated with body mass index, income, smoking status, drinking water source, water treatment type, or frequency of consumption of nuts, shellfish and legumes. Whole blood zinc concentrations were also not associated with fasting status in children or with time of sampling and education in adults (Karthikeyan et al. 2017).

The First Nations Biomonitoring Initiative (FNBI), conducted in 2011, is a cross-sectional study that measured zinc in whole blood and urine of adults from 15 rural or isolated First Nations communities south of the 60º parallel (AFN 2013). The study had 503 adult participants ranging from 20 to 99 years of age; pregnant women and individuals undergoing chemotherapy were excluded from this study. Blood zinc concentrations measured in the First Nations people living on reserve in Canada were significantly lower than those measured in the CHMS, while urinary zinc concentrations were significantly higher (AFN 2013).

Overall, blood zinc concentrations decrease during pregnancy (Wilson et al. 2016). Pregnant women in the CHMS had significantly lower whole blood zinc concentrations than non-pregnant females of childbearing age (Walker 2016). Plasma zinc concentrations measured in pregnant Dene/Metis, Inuit and Caucasian women from Arctic Canada (Northwest Territories and Nunavut) between 1994 and 1999 were similar to Caucasian women living in northern Canada and lower than serum zinc concentrations in Canadians living in southern Canada (Walker et al. 2006; INSPQ 2004). However, average serum zinc concentrations were higher in pregnant women in Alberta when compared with serum data from the Quebec Region and the United States (CDC 2017; Alberta Health and Wellness 2008; INSPQ 2004). Regardless, changes during pregnancy are anticipated because of increased maternal blood volume and fetal demands for zinc (Wilson et al. 2016).

Zinc concentrations in breast milk are highest in colostrum and decline with the length of lactation (Wasowicz et al. 2001, as cited in CCME 2018a). Friel et al. (1999) measured zinc concentrations in breast milk of mothers in Newfoundland and Labrador. Zinc concentrations were higher in the first week (4580 µg/L) than at 12 weeks after birth (1140 µg/L). These concentrations align with breast milk concentrations measured in the MIREC study (Health Canada 2017).

Although the above mentioned studies were not longitudinal in nature and had only one sample per individual, the number of samples across the Canadian population provide high quality data for the characterization of exposure to Canadians. Biomonitoring data of total zinc in urine from the CHMS and the FNBI will be used to characterize exposure

to the Canadian population as urine is considered to be the most suitable biomarker. Further details on age, sex, and subpopulations are presented in Appendix I.

8.3 Characterization of risk to human health

Given the availability of adequate and representative Canadian biomonitoring data and the development of a biomonitoring guidance value for zinc, the potential for harm to human health is based on a science approach developed by Health Canada for the use of biomonitoring data in risk assessments, Biomonitoring Approach 2 (Health Canada [modified 2016a]).

Urinary zinc concentration is considered to be a more reliable biomarker of exposure than blood zinc concentration for use in this screening assessment as it is more responsive to changes in dietary intake. Hence, the median and the 95th percentile urine zinc concentration data from the CHMS survey are used to represent the total zinc exposure in the general population of Canada.

The PODs for risk characterization include a NOAEL of 50 mg Zn/day (0.83 mg Zn/kg bw/day) and a LOAEL of 150 mg Zn/day (2 or 2.4 mg Zn/kg bw/day, men and women, respectively), established on the basis of clinical signs, such as headaches, nausea, vomiting, loss of appetite and abdominal cramps reported in human volunteers following supplementation with zinc (EC 2004). The associated urinary BE values for the NOAEL and the LOAEL are 1693 and 4488 µg/g creatinine, respectively.

Exposures to total zinc in the Canadian population, characterized by urine concentration data (both median and 95th percentiles) from the CHMS survey, are lower than the urinary BE values for both the NOAEL and the LOAEL (Figure 8-2).

The EU risk assessment report considered an uncertainty factor of 1 to be sufficient for consumers given that the NOAEL was based on the most sensitive population in zinc supplementation studies (i.e., women) and that clinical signs begin to appear at an oral dose 3 times higher than this NOAEL. Neither the NOAEL or the LOAEL take into account dietary intake (approximately 10 mg/day), so the actual effect levels would likely be occurring at higher doses. In addition, the Canadian biomonitoring data capture variability across the Canadian population and include exposure data on sub-populations of interest (e.g., pregnant women).

Figures 8-2 below provide all relevant exposure and critical health effect levels for zinc for the determination of risk.

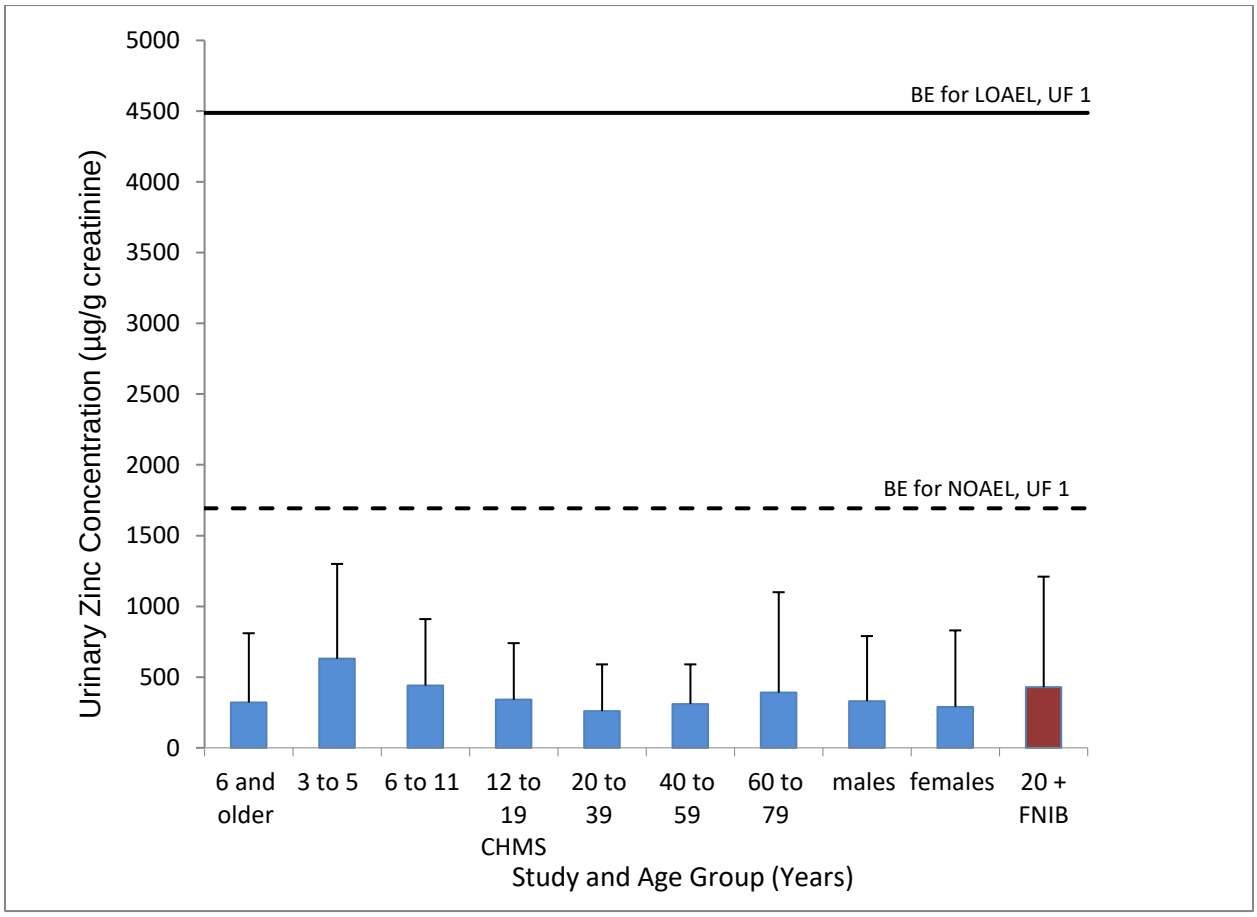

Figure 8-2. Comparison of median (bar) and 95th percentile (whiskers) concentrations of urinary zinc (µg/g creatinine) with BE values of 1693 µg/g creatinine and 4498 µg/g creatinine, based on a NOAEL of 50 mg/day and a LOAEL of 150 mg/day as identified in the EU risk assessment report (EC 2004), indicated by hatched and solid lines, respectively. Biomonitoring data are for both males and females combined. Concentration data are presented in Appendix I.

Overall, exposure to zinc for the Canadian population, including sub-populations of interest, such as children, pregnant women and Indigenous populations, is low enough to account for uncertainties in the health effects and exposure database. Therefore, zinc and its compounds are considered a low concern to the health of the general population of Canada at current levels of exposure.

8.4 Uncertainties in evaluation of risk to human health

A detailed analysis of uncertainties associated with biomonitoring data (especially spot urine data) and the application of BE values in interpreting biomonitoring data in risk assessments can be found in Health Canada [modified 2016a], Hays et al. (2008), Aylward et al. (2012, 2014), LaKind and Naiman (2015) and Zidek et al. (2017). The uncertainties associated with this particular assessment are summarized below.

Uncertainties related to the adequacy of biomarkers of exposure exist. Although zinc is primarily excreted via fecal route followed by urinary elimination, there is sufficient evidence from human supplementation studies to indicate that urine is a reliable biomarker to quantify zinc intake. In addition, urine zinc concentrations can be influenced by factors unrelated to dietary zinc intakes, such as infections and stress, or other dietary factors including a phytate-rich diet, reduced food intake, or time of sampling from food intakes and changes in creatinine levels.

There is variability in zinc urine excretion fractions (F_{UE}). The urinary BE was derived using an average F_{UE} value of 0.04, but higher F_{UE} values have been presented in the other assessments (e.g., 0.25 in US EPA 2005). The F_{UE} used in the current analysis is considered to be conservative.

The BE values for urine were derived on the basis of adult data. Therefore, the applicability in interpreting biomonitoring data in children is unclear. Animal kinetic data indicated that oral absorption of zinc decreases and fecal elimination increases with age (ATSDR 2005). A human volunteer study showed that children have higher urinary zinc excretion than adults (Dlugaszek et al. 2011). Hence, it is unlikely that children accumulate more zinc than adults. In addition, zinc supplementation studies with children age 1 to 8 years did not show any sensitivity to zinc supplementation above the regular dietary intakes (Wuehler et al. 2008; Bertinato et al. 2013).

9. Conclusion

Considering all available lines of evidence presented in this draft screening assessment, there is risk of harm to the environment from zinc and soluble zinc compounds. It is proposed to conclude that zinc and soluble zinc compounds meet the criteria under paragraph 64(*a*) of CEPA as they are entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, it is proposed to conclude that zinc and soluble zinc compounds do not meet the criteria under paragraph 64(*b*) of CEPA as they are 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.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that zinc and its compounds do not meet the criteria under paragraph 64(*c*) of CEPA as they are 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.

It is therefore proposed to conclude that zinc and soluble zinc compounds meet one or more of the criteria set out in section 64 of CEPA.

It is also proposed that zinc and soluble zinc compounds meet the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

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Appendices

Appendix A. Substance identity information

Table A-1. Substances identified as priorities for assessment under subsection 73(1) of CEPA and the Revised In Commerce List

CAS RN	DSL or R-ICL Name	Inventory /Priority
127-82-2	Benzenesulfonic acid, 4-hydroxy-, zinc salt (2:1)	DSL
136-23-2	Zinc, bis(dibutylcarbamodithioato-S,S')-, (T-4)-	DSL
136-53-8	Hexanoic acid, 2-ethyl-, zinc salt	DSL
155-04-4	2(3H)-Benzothiazolethione, zinc salt	DSL
546-46-3	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, zinc salt (2:3)	R-ICL
556-38-7	Pentanoic acid, zinc salt (2:1)	R-ICL
557-05-1	Octadecanoic acid, zinc salt	DSL
557-07-3	9-Octadecenoic acid (Z)-, zinc salt	DSL
557-08-4	10-Undecenoic acid, zinc salt	DSL
557-34-6	Acetic acid, zinc salt	DSL
1314-13-2	Zinc oxide (ZnO)	DSL
1314-22-3	Zinc peroxide (Zn(O2))	DSL
1314-84-7	Zinc phosphide (Zn3P2)	R-ICL
1314-98-3	Zinc sulfide (ZnS)	DSL
1345-05-7	C.I. Pigment White 5	DSL
1405-89-6	Bacitracin Zinc	R-ICL
2452-01-9	Dodecanoic acid, zinc salt	DSL
3486-35-9	Carbonic acid, zinc salt (1:1)	DSL
4259-15-8	Zinc, bis[O,O-bis(2-ethylhexyl) phosphorodithioato-S,S']-, (T-4)-	DSL
4468-02-4	Zinc, bis(D-gluconato-O1,O2)-	DSL
5970-45-6	Acetic acid, zinc salt, dihydrate	DSL
7446-19-7	Sulfuric acid, zinc salt (1:1), monohydrate	DSL
7446-20-0	Sulfuric acid, zinc salt (1:1), heptahydrate	DSL
7446-26-6	Diphosphoric acid, zinc salt (1:2)	DSL
7646-85-7	Zinc chloride (ZnCl2)	DSL
7733-02-0	Sulfuric acid, zinc salt (1:1)	DSL
7779-88-6	Nitric acid, zinc salt	DSL
7779-90-0	Phosphoric acid, zinc salt (2:3)	DSL
8011-96-9	Calamine (pharmaceutical preparation)	DSL
8048-07-5	C.I. Pigment Yellow 35	DSL
10139-47-6	Zinc iodide (ZnI2)	R-ICL
11103-86-9	Chromate(1-), hydroxyoctaoxodizincatedi-, potassium	DSL
12001-85-3	Naphthenic acids, zinc salts	DSL

CAS RN	DSL or R-ICL Name	Inventory /Priority
12122-17-7	Hydrozincite (Zn5(CO3)2(OH)6)	DSL
12442-27-2	Cadmium zinc sulfide ((Cd,Zn)S)	DSL
13189-00-9	2-Propenoic acid, 2-methyl-, zinc salt	DSL
13463-41-7	Zinc, bis(1-hydroxy-2(1H)-pyridinethionato-O,S)-, (T-4)-	DSL
13530-65-9	Chromic acid (H2CrO4), zinc salt (1:1)	DSL
13598-37-3	Phosphoric acid, zinc salt (2:1)	DSL
14324-55-1	Zinc, bis(diethylcarbamodithioato-S,S')-, (T-4)-	DSL
14476-25-6	Smithsonite (Zn(CO3))	DSL
14726-36-4	Zinc, bis[bis(phenylmethyl)carbamodithioato-S,S']-, (T-4)-	DSL
15337-18-5	Zinc, bis(dipentylcarbamodithioato-S,S')-, (T-4)-	DSL
15454-75-8	Zinc, bis(5-oxo-L-prolinato-.kappa.N1,.kappa.O2)-, (T-4)-	R-ICL
16260-27-8	Tetradecanoic acid, zinc salt	DSL
16283-36-6	Zinc, bis(2-hydroxybenzoato-O1,O2)-, (T-4)-	DSL
16871-71-9	Silicate(2-), hexafluoro-, zinc (1:1)	DSL
17949-65-4	Zinc, bis(2-pyridinecarboxylato-.kappa.N1,.kappa.O2-, (T-4)-	R-ICL
19210-06-1	Phosphorodithioic acid, zinc salt	DSL
20427-58-1	Zinc hydroxide (Zn(OH)2)	DSL
24308-84-7	Benzenesulfinic acid, zinc salt	DSL
24887-06-7	Zinc, bis(hydroxymethanesulfinato-OS,O1)-, (T-4)-	DSL
27253-29-8	Neodecanoic acid, zinc salt	DSL
28016-00-4	Naphthalenesulfonic acid, dinonyl-, zinc salt	DSL
28629-66-5	Zinc, bis(O,O-diisooctyl phosphorodithioato-S,S')-	DSL
36393-20-1	Zincate(2-), bis[L-aspartato(2-)-.kappa.N,.kappa.O1]-, dihydrogen, (T-4)-	R-ICL
37300-23-5	C.I. Pigment Yellow 36	DSL
38714-47-5	Zinc(2++), tetraammine-, (T-4)-, carbonate (1:1)	DSL
40861-29-8	Carbonic acid, ammonium zinc salt (2:2:1)	DSL
49663-84-5	Zinc chromate hydroxide (Zn5(CrO4)(OH)8)	DSL
50922-29-7	Chromium zinc oxide	DSL
51810-70-9	Zinc phosphide	R-ICL
61617-00-3	2H-Benzimidazole-2-thione, 1,3-dihydro-4(or 5)-methyl-, zinc salt (2:1)	DSL
68457-79-4	Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts	DSL
68611-70-1	Zinc sulfide (ZnS), copper chloride-doped	DSL
68649-42-3	Phosphorodithioic acid, O,O-di-C1-14-alkyl esters, zinc salts	DSL

CAS RN	DSL or R-ICL Name	Inventory /Priority
68784-31-6	Phosphorodithioic acid, mixed O,O-bis(sec-Bu and 1,3-dimethylbutyl) esters, zinc salts	DSL
68918-69-4	Petrolatum (petroleum), oxidized, zinc salt	DSL
68988-45-4	Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl and iso-Bu and pentyl) esters, zinc salts	DSL
73398-89-7	Xanthylium, 3,6-bis(diethylamino)-9-[2-(methoxycarbonyl)phenyl]-, (T-4)-tetrachlorozincate(2-) (2:1)	DSL
84605-29-8	Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts	DSL
85940-28-9	Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl and iso-Bu and iso-Pr) esters, zinc salts	DSL
102868-96-2	Zinc, bis[N-(acetyl-.kappa.O)-L-methioninato-.kappa.O]-, (T-4)-	R-ICL
113706-15-3	Phosphorodithioic acid, mixed O,O-bis(sec-Bu and isooctyl) esters, zinc salts	DSL
1434719-44-4	Protein hydrolyzates, *Saccharomyces cerevisiae* zinc complexes	R-ICL

Appendix B. Physical-chemical properties

Table B-1. Physical-chemical properties for zinc substances identified as priorities for assessment under subsection 73(1) of CEPA

DSL Name	Formula	CAS RN	Molecular weight (g·mol-1)	Solubility (mg/L H_2O)
Benzenesulfonic acid, 4-hydroxy-, zinc salt	C12H10O8S2Zn	127-82-2	411.72	625000 in "cold water"[c]
Zinc, bis(dibutylcarbamodithioato-S,S')-, (T-4)-	C18H36N2S4Zn	136-23-2	474.14	0.1 at 25 °C[a]
Hexonic acid, 2-ethyl, zinc salt	C6H30O4Zn	136-53-8	351.8	5586 at 20 °C, pH 6.2-6.5[a]
2(3H)-Benzothiazolethione, zinc salt	C14H8N2S4Zn	155-04-4	397.88	20.6 at 20 °C, pH 6.3[a]
Octadecanoic acid, zinc salt	C36H70O4Zn	557-05-1	632.33	Insoluble[a]
9-octadecanoic acid (Z)-, zinc salt	C36H66O4Zn	557-07-3	628.3	-
10-Undecenoic acid, zinc salt	C22H38O4Zn	557-08-4	431.92	-
Acetic acid, zinc salt	C8H7BrO2	557-34-6	215.04	3.0 x105 at 0 °C[b]
Zinc oxide	ZnO	1314-13-2	81.408	Insoluble [a]
Zinc peroxide	ZnO2	1314-22-3	97.39	Insoluble[c]
Zinc sulphide	ZnS	1314-98-3	97.46	4.57 x10-7 at pH 5.7[a]
C.I. Pigment White 5	BaO5S2Zn2	1345-05-7	412.23	-
Dodecanoic acid, zinc salt	C24H46O4Zn	2452-01-9	464.01	5.2 at 20 °C, pH 7.8[a]
Carbonic acid, zinc salt (1:1)	CO3Zn	3486-35-9	125.4	100 at 15 °C[b]
Zinc, bus[O,O-bis(2-ethylhexyl) phosphorodithioato-S,S']-,(T-4)-	$C_{32}H_{68}O_4P_2S_4Zn$	4259-15-8	772.47	9.1 at 22 °C[a]
Zinc, bis(D-gluconato-O1,O1)-	C12H22O14Zn	4468-02-4	455.68	-
Zinc acetate dihydrate	C4H10O6Zn	5970-45-6	219.51	-

Sulphuric acid, zinc salt (1:1), monohydrate	H2O5SZn	7446-19-7	179.47	-
Sulphuric acid, zinc salt (1:1), heptahydrate	H14O11SZn	7446-20-0	287.56	-
Diphosphoric acid, zinc salt (1:2)	O7P2Zn2	7446-26-6	304.72	-
Zinc chloride	ZnCl2	7646-85-7	136.315	408 at 25 °C[a]
Sulphuric acid, zinc salt (1:1)	O4SZn	7733-02-0	161.45	2.10 x105 at 20 °C, pH 3.7-4.07[a]
Nitric acid, zinc salt	N2O6Zn	7779-88-6	189.4	9.98 x105 at 22°C, pH 6.96[a]
Phosphoric acid, zinc salt (2:3)	O8P2Zn3	7779-90-0	386.11	2.7 at 20 °C[a]
Calamine	Fe2O4Zn	8011-96-9	241.07	-
C.I. Pigment Yellow 35	CdS2Zn	8048-07-5	-	0.00148 at 22 °C[a]
Naphthenic acids, zinc salts	2(C11H7O2)·Zn	12001-85-3	319.71	-
Hydrozincite	C2H2O6Zn	12122-17-7	187.42	-
Cadmium zinc sulphide	CdS2Zn	12442-27-2	241.93	-
2-Propenoic acid, 2-methyl-, zinc salt	C8H10O4Zn	13189-00-9	235.55	652 at 20 °C[a]
Zinc, bis(1-hydroxy-2(1H)-pyridinethionatio-O,S)-, (T-4)-	C10H8N2O2S2Zn	13463-41-7	317.7	4.93 at 20 °C, pH 7.3-7.6[a]
Phosphoric acid, zinc salt (2:1)	H4O8P2Zn	13598-37-3	259.36	1.0 x106 at 22 °C, pH 6.96[a]
Zinc, bis(diethylcarbamodithioato-S,S')-, (T-4)-	C10H20N2S4Zn	14324-55-1	361.93	1.06 at 20 °C, pH 5.9-6.4[a]
Smithsonite	CH2O3·Zn	14476-25-6	127.41	-
Zinc, bis[bis(phenylmethyl)carbamodithioato-S,S']-, (T-4)-	C30H28N2S4Zn	14726-36-4	610.21	1.06 at 20 °C, pH 5.9-6.4[a]
Zinc, bis(dipentylcarbamodithiato-S,S')-, (T-4)-	C22H44N2S4Zn	15337-18-5	530.25	-

Tetradecanoic acid, zinc salt	C28H54O4Zn	16260-27-8	520.12	-
Zinc, bis(2-hydroxybenzoato-O1,o2)-, (T-4)-	C14H10O6Zn	16283-36-6	339.62	-
Silicate(2-), hexafluoro-, zinc (1:1)	F6SiZn	16871-71-9	207.47	500 at 20 °C[f]
Phosphorodithioic acid, zinc salt	O4P2S4Zn3	19210-06-1	450.38	-
Zinc hydroxide	H2O2Zn	20427-58-1	99.4	648 at 20 °C, pH 6.81-6.94[a]
Benzenesulfinic acid, zinc salt	C12H14O6S2Zn	24308-84-7	383.76	-
Zinc, bis(hydroxymethanesulfinato-o#S,o1)-, (T-4)-	C2H6O6S2Zn	24887-06-7	255.59	-
Neodecanoic acid, zinc salt	C20H38O4Zn	27253-29-8	407.9	740.6 at 20 °C, pH 5.9-6.1[a]
Naphthalenesulfonic acid, dinonyl-, zinc salt	C56H86O6S2Zn	28016-00-4	984.8	2.29 x 10-4 at 20°C[a]
Zinc, bis(O,O-diisooctyl phosphorodithioato-S,S')	C16H35O2PS2 · ½ Zn	28629-66-5	772.5	32.9 at 20 °C, pH 5-6[a]
Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased	CH12N4O3Zn	38714-47-5	193.5	-
Carbonic acid, ammonium zinc salt (2:2:1)	C2H8N2O6Zn	40861-29-8	221.5	-
2H-Benzimidazole-2-thione, 1,3-dihydro-4(or 5)-methyl-, zinc salts	C16H14N4S2Zn	61617-00-3	391.83	32 at 20 °C, pH 5.9-7[a]
Phosphorodithioic acid, mixed o,o-bis(iso-Bu and pentyl) esters, zinc salts	C16H36O4P2S4Zn	68457-79-4	548.05	1.66 x 103 at pH 5, 22 °C[a]
Zinc sulphide, copper chloride-doped	SZn	68611-70-1	-	0.0251 at pH 8.9, 20 °C[a]
Phosphorodithioic acid, o,o-di-C1-14-alkyl esters, zinc salts	C28H60O4P2S4Zn	68649-42-3	716.39	Insoluble[a]
Petrolatum (petroleum), oxidized, zinc salt	-	68918-69-4	-	-

Phosphorodithioic acid, mixed o,o-bis(sec-Bu and 1,3-dimethylbutyl) esters, zinc salts	C20H44O4P2S4Zn	68784-31-6	604.18	617 at pH 7, 25 °C[a]
Phosphorodithioic acid, mixed o,o-bis(2-ethylhexyl and iso-Bu and pentyl) esters, zinc salts	-	68988-45-4	-	6.74 x 10-7 at 25°C [a]
Xanthylium, 3,6-bis(diethylamino)-9-[2-(methoxycarbonyl)phenyl]-, (T-4)-tetrachlorozincate(2-) (2:1)	C58H66Cl4N4O6Zn	73398-89-7	1122.37	22100 at 20 °C pH 2.6[a]
Phosphorodithioic acid, mixed o,o-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts	C18H40O4P2S4Zn	84605-29-8	576.12	2.76 x103 at pH 5, 22 °C[a]
Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts	-	85940-28-9	-	1.62 x 10-5 at 20 °C[a]
Phosphorodithioic acid, mixed O,O-bis(sec-Bu and isooctyl) esters, zinc salts	C24H52O4P2S4Zn	113706-15-3	660.28	1.09 at 20 °C[e]
Chromate(1-), hydroxyoctaoxodizincatedi-, potassium	HCr2KO9Zn2	11103-86-9	418.91	500-1500 at pH 6-9[a]
Chromic acid (H2CrO4), zinc salt (1:1)	CrO4Zn	13530-65-9	181.4	-
C.I. Pigment Yellow 36	CrKO4Zn	37300-23-5	220.5	-
Zinc chromate hydroxide (Zn5(CrO4)(OH)8)	CrH8O12Zn5	49663-84-5	579.00	500 at pH 6-9[a]
Chromium zinc oxide	Cr2O5Zn2	50922-29-7	314.77	-

[a] ECHA (2017)
[b] US EPA (2017)
[c] TOXNET (2017)
[d] Canadian DSL (2017)
[e] Judson et al. (2008)
[f] GSBL (2017)
"-" = not available

Appendix C. Summary of information on Canadian manufacturing and import of zinc compounds

Table C-1. Summary of information on Canadian manufacture and import of zinc and its compounds submitted pursuant to a CEPA section 71 survey

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
127-82-2	Benzenesulfonic acid, 4-hydroxy-, zinc salt (2:1)	NR	1–10	2008	Environment Canada 2009a
136-23-2	Zinc, bis(dibutylcarbamodithioato-S,S')-, (T-4)-	1–10	100–1000	2008	Environment Canada 2009a
136-53-8	Hexanoic acid, 2-ethyl-, zinc salt	0.1–1	10–100	2008	Environment Canada 2009a
155-04-4	2(3Ò)-Benzothiazolethione, zinc salt	NR	10–100	2008	Environment Canada 2009a
546-46-3	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, zinc salt (2:3)	NR	1–10	2015	ECCC 2017
556-38-7	Pentanoic acid, zinc salt (2:1)	NR	NR	2015	ECCC 2017
557-05-1	Octadecanoic acid, zinc salt	100–1000	1000–10000	2008	Environment Canada 2009a
557-07-3	9-Octadecenoic acid (Z)-, zinc salt	NR	10–100	2008	Environment Canada 2009a
557-08-4	10-Undecenoic acid, zinc salt	NR	NR	2008	Environment Canada 2009a
557-34-6	Acetic acid, zinc salt	<0.1	10–100	2008	Environment Canada 2009a
1314-13-2	Zinc oxide (ZnO)	1000–10 000	1000–10 000	2008	Environment Canada 2009a

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
1314-22-3	Zinc peroxide (Zn(O2))	NR	0.1–1	2008	Environment Canada 2009a
1314-84-7	Zinc phosphide (Zn3P2)	NR	NR	2015	ECCC 2017
1314-98-3	Zinc sulfide (ZnS)	1000–10 000	1000–10 000	2008	Environment Canada 2009a
1345-05-7	C.I. Pigment White 5	NR	10–100	2008	Environment Canada 2009a
1405-89-6	Bacitracin Zinc	NR	NR	2015	ECCC 2017
2452-01-9	Dodecanoic acid, zinc salt	10–100	NR	2008	Environment Canada 2009a
3486-35-9	Carbonic acid, zinc salt (1:1)	<0.1	100–1000	2008	Environment Canada 2009a
4259-15-8	Zinc, bis[O,O-bis(2-ethylhexyl) phosphorodithioato-S,S']-, (T-4)-	<0.1	1000–10 000	2008	Environment Canada 2009a
4468-02-4	Zinc, bis(D-gluconato-O1,O2)-	NR	1–10	2008	Environment Canada 2009a
5970-45-6	Acetic acid, zinc salt, dihydrate	NR	1–10	2008	Environment Canada 2009a
7446-19-7	Sulfuric acid, zinc salt (1:1), monohydrate	100–1000	1000–10 000	2008	Environment Canada 2009a
7446-20-0	Sulfuric acid, zinc salt (1:1), heptahydrate	100–1000	<0.1	2008	Environment Canada 2009a
7446-26-6	Diphosphoric acid, zinc salt (1:2)	NR	1–10	2008	Environment Canada 2009a
7646-85-7	Zinc chloride (ZnCl2)	100–1000	1000–10 000	2008	Environment Canada 2009a

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
7733-02-0	Sulfuric acid, zinc salt (1:1)	1000–10 000	100–1000	2008	Environment Canada 2009a
7779-88-6	Nitric acid, zinc salt	1–10	100–1000	2008	Environment Canada 2009a
7779-90-0	Phosphoric acid, zinc salt (2:3)	10–100	1000–10 000	2008	Environment Canada 2009a
8011-96-9	Calamine (pharmaceutical preparation)	NR	0.1–1	2011	Environment Canada 2012
8048-07-5	C.I. Pigment Yellow 35	<0.1	1–10	2008	Environment Canada 2009a
10139-47-6	Zinc iodide (ZnI2)	NR	NR	2015	ECCC 2017
11103-86-9	Chromate(1-), hydroxyoctaoxodizincatedi-, potassium	NR	0.1–1	2011	Environment Canada 2012
12001-85-3	Naphthenic acids, zinc salts	10–100	10–100	2008	Environment Canada 2009a
12122-17-7	Hydrozincite (Zn5(CO3)2(OH)6)	NR	10–100	2008	Environment Canada 2009a
12442-27-2	Cadmium zinc sulfide ((Cd,Zn)S)	NR	NR	2011	Environment Canada 2012
13189-00-9	2-Propenoic acid, 2-methyl-, zinc salt	NR	10–100	2008	Environment Canada 2009a
13463-41-7	Zinc, bis(1-hydroxy-2(1H)-pyridinethionato-O,S)-, (T-4)-	NR	100–1000	2008	Environment Canada 2009a
13530-65-9	Chromic acid (H2CrO4), zinc salt (1:1)	NR	1–10	2011	Environment Canada 2012

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
13598-37-3	Phosphoric acid, zinc salt (2:1)	NR	1000–10 000	2008	Environment Canada 2009a
14324-55-1	Zinc, bis(diethylcarbamodithioato-S,S')-, (T-4)-	< 0.1	10–100	2008	Environment Canada 2009a
14476-25-6	Smithsonite (Zn(CO3))	NR	NR	2011	Environment Canada 2012
14726-36-4	Zinc, bis[bis(phenylmethyl)carbamodithioato-S,S']-, (T-4)-	NR	10–100	2008	Environment Canada 2009a
15337-18-5	Zinc, bis(dipentylcarbamodithioato-S,S')-, (T-4)-	NR	0.1–1	2008	Environment Canada 2009a
15454-75-8	Zinc, bis(5-oxo-L-prolinato-.kappa.N1,.kappa.O2)-, (T-4)-	NR	0.1–1	2015	ECCC 2017
16260-27-8	Tetradecanoic acid, zinc salt	NR	NR	2008	Environment Canada 2009a
16283-36-6	Zinc, bis(2-hydroxybenzoato-O1,O2)-, (T-4)-	NR	NR	2011	Environment Canada 2012
16871-71-9	Silicate(2-), hexafluoro-, zinc (1:1)	NR	1–10	2011	Environment Canada 2012
17949-65-4	Zinc, bis(2-pyridinecarboxylato-.kappa.N1,.kappa.O2-, (T-4)-	NR	NR	2015	ECCC 2017
19210-06-1	Phosphorodithioic acid, zinc salt	NR	NR	2011	Environment Canada 2012

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
20427-58-1	Zinc hydroxide (Zn(OH)2)	1000–10 000	1–10	2008	Environment Canada 2009a
24308-84-7	Benzenesulfinic acid, zinc salt	NR	0.1–1	2008	Environment Canada 2009a
24887-06-7	Zinc, bis(hydroxymethanesulfinato-OS,O1)-, (T-4)-	NR	0.1–1	2008	Environment Canada 2009a
27253-29-8	Neodecanoic acid, zinc salt	<0.1	10–100	2008	Environment Canada 2009a
28016-00-4	Naphthalenesulfonic acid, dinonyl-, zinc salt	<0.1	10–100	2008	Environment Canada 2009a
28629-66-5	Zinc, bis(O,O-diisooctyl phosphorodithioato-S,S')-	NR	0.1–1	2008	Environment Canada 2009a
36393-20-1	Zincate(2-), bis[L-aspartato(2-)-.kappa.N,.kappa.O1]-, dihydrogen, (T-4)-	NS	NS	NS	NS
37300-23-5	C.I. Pigment Yellow 36	NR	<0.1	2008	Environment Canada 2009a
38714-47-5	Zinc(2++), tetraammine-, (T-4)-, carbonate (1:1)	1–10	100–1000	2008	Environment Canada 2009a
40861-29-8	Carbonic acid, ammonium zinc salt (2:2:1)	0.1–1	10–100	2008	Environment Canada 2009a
49663-84-5	Zinc chromate hydroxide (Zn5(CrO4)(OH)8)	NR	NR	2011	Environment Canada 2012
50922-29-7	Chromium zinc oxide	–	0.1–1	2011	Environment Canada 2012

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
51810-70-9	Zinc phosphide	NR	NR	2015	ECCC 2017
61617-00-3	2H-Benzimidazole-2-thione, 1,3-dihydro-4(or 5)-methyl-, zinc salt (2:1)	NR	10–100	2008	Environment Canada 2009a
68457-79-4	Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts	NR	10–100	2008	Environment Canada 2009a
68611-70-1	Zinc sulfide (ZnS), copper chloride-doped	NR	1–10	2008	Environment Canada 2009a
68649-42-3	Phosphorodithioic acid, O,O-di-C1-14-alkyl esters, zinc salts	1 000–10 000	1 000–10 000	2008	Environment Canada 2009a
68784-31-6	Phosphorodithioic acid, mixed O,O-bis(sec-Bu and 1,3-dimethylbutyl) esters, zinc salts	<0.1	100–1 000	2008	Environment Canada 2009a
68918-69-4	Petrolatum (petroleum), oxidized, zinc salt	NS	NS	NS	NS
68988-45-4	Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl and iso-Bu and pentyl) esters, zinc salts	NR	10–100	2008	Environment Canada 2009a
73398-89-7	Xanthylium, 3,6-bis(diethylamino)-9-[2-(methoxycarbonyl) phenyl]-, (T-4)-tetrachlorozincate(2-) (2:1)	NR	0.1–1	2008	Environment Canada 2009a

CAS RN	Chemical name	Total manu-factured highest quantity (t)	Total imported highest quantity (t)	Reporting year	Survey reference
84605-29-8	Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts	NR	100–1 000	2008	Environment Canada 2009a
85940-28-9	Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl and iso-Bu and iso-Pr) esters, zinc salts	NR	100–1 000	2008	Environment Canada 2009a
102868-96-2	Zinc, bis[N-(acetyl-.kappa.O)-L-methioninato-.kappa.O]-, (T-4)-	NR	NR	2015	ECCC 2017
113706-15-3	Phosphorodithioic acid, mixed O,O-bis(sec-Bu and isooctyl) esters, zinc salts	NR	100–1 000	2008	Environment Canada 2009a
1434719-44-4	Protein hydrolyzates, saccharomyces cerevisiae zinc complexes	NS	NS	NS	NS

Abbreviations: NR: not reported above set threshold; NS: not surveyed

Appendix D. Releases reported to the NPRI for 2011 to 2015 for "Zinc and its compounds"

The reporting threshold for "zinc and its compounds" is 10 tonnes Manufactured, Processed or Otherwise used (MPO) at a concentration of 1% or greater. The top 43 sectors covered by the NPRI (NAICS 4) are listed in Table C-2 and appear in decreasing order in terms of total on-site releases (to air, water and/or land).

Units are tonnes of zinc on an elemental basis. For the purpose of this assessment, the term "manufactured" includes the incidental production of zinc or zinc compounds at any concentration as a result of the manufacturing, processing or other uses of other substances, mixtures or products. In other words, the unintentional production of a substance as a by-product is considered incidental. This definition is equivalent to the one used by Environment Canada's NPRI (NPRI 2013).

Table D-1. Yearly release ranges reported to the NPRI for 2011 - 2015 for "Zinc and its compounds" (in tonnes)

Sectors (NAICS 4)	Air (t)	Land (t)	Water (t)	Total[a] (per year) (t)
Alumina and Aluminum Production and Processing (3313)	0.2–6	20.8–26	0–0	0.2–28
Animal Food Manufacturing (3111)	0.1–11	0–0	0–0	0.1–11
Architectural and Structural Metals Manufacturing (3323)	0.8–2	0–0	0–0	0.8–2
Basic Chemical Manufacturing (3251)	0.1–11	0–0	0.2–2	0.3–11
Cement and Concrete Product Manufacturing	0–0.1	0–0	0–0	0–0.1
Coal Mining (2121)	0–0.1	2–20	0.7–12	0.7–23
Coating, Engraving, Heat Treating and Allied Activities (3328)	14–17	0–0	0–0	14–17
Defence Services (9111)	0.2–0.6	51–92	0–0	51.2–92
Electric Power Generation, Transmission and Distribution (2211)	1.6–10	0–0	0–0.8	2–10.8
Forging and Stamping (3321)	1.8–4	0–0	0–0	1.8–4
Foundries (3315)	21.5–69	0–0	2.9–6	27. 6–72.8
Iron and Steel Mills and Ferro-Alloy Manufacturing (3311)	67.9–83.3	0–0	10.2–16.1	81.3–95.9
Metal Ore Mining (2122)	31.8–108.3	4.5–16.5	10–222[c]	50.3–1421.93

Sectors (NAICS 4)	Air (t)	Land (t)	Water (t)	Total[a] (per year) (t)
Motor Vehicle Body and Trailer Manufacturing (3362)	18.5–37	0–0	0–0	18.5–37
Motor Vehicle Manufacturing (3361)	0.34–0.8	0–0	0.2–0.7	0. 7–1.3
Motor Vehicle Parts Manufacturing (3363)	0–2	0–0	0–0	0–2
Non-Ferrous Metal (except Aluminum) Production and Processing (3314)	116.1–140.5	0–0	10.7–12.4	127.6–151.2
Oil and Gas Extraction (2111)	2–5.7	0–0	0–0	2–5.7
Other Chemical Product Manufacturing (3259)	0.2–0.2	0–0	0–0	0–0.2
Other Miscellaneous Manufacturing (3399)	0–0.1	0–0	0–0	0–0.1
Pesticide, Fertilizer and Other Agricultural Chemical Manufacturing	0.1–0.3	0–0	0–0	0.1–0.3
Petroleum and Coal Product Manufacturing[e]	1. 5–5.5	0–0	0–25.7	1.5–27.4
Pulp, Paper and Paperboard Mills (3221)	5–38.5	11.6–47.1	32.3–53.6	61.6–128.4
Recyclable Material Wholesaler-Distributors (4181)	0.1–0.2	0–0	0–0	0.1–0.2
Resin, Synthetic Rubber, and Artificial and Synthetic Fibres and Filaments Manufacturing (3252)	0.3–0.5	0–0	0–0	0.3–0.5
Rubber Product Manufacturing (3262)	5.4–6.1	0–0	0–0.2	5.4–6.3
Steel Product Manufacturing from Purchased Steel (3312)	9.8–10.8	0–0	0–0.5	9.8–11.1
Support Activities for Water Transportation (4883)	0–0	0–0	0.7–0.7	0–0.7
Waste Treatment and Disposal (5622)	0–4.7	0–0	0–0	0–4.7
Water, Sewage and Other Systems (2213)	1.2–1.5	0–0	110.6–132.7	112–134

[a] Total minimum quantity of zinc releases from 2011 to 2015 presented here may be lower than yearly minimum releases since there were years where there was no reported releases in some of the environmental compartments.
[c] This value (222 t) excludes the spill of 1342.47 tonnes of zinc to water due to the Mount Polley tailings dam failure in 2014. Higher releases of zinc to water reported for 2014 (1564 t) resulted from the Mount Polley tailings dam failure. Data include 1342.47 t, released from the spill from Imperial Metals Corporation (Mount-Polley Mine) in 2014. The total quantity without the spill is 222 t.
[e] Zinc releases to water from Petroleum and Coal Product Manufacturing increased from 0.15 tonnes to 13 tonnes between 2013 and 2014, and from 13 tonnes to 25 tonnes between 2014-2015. Suncor Edmonton Refinery (ID 3903) reported that these changes are due respectively to a change in production and a corrosion in the cooling tower.

1. There is a degree of complexity surrounding NPRI data reporting such as meeting reporting thresholds and possession of key data and therefore uncertainties exist in the reported quantities. Numbers are rounded to 0.1 t. Quantities for on-site and off-site disposal as well as for off-site recycling not shown.
2. NPRI requires that zinc in tailings and by-products be included in the calculation of the reporting threshold regardless of the concentration of zinc in these materials (including less than 1%). All releases, disposals and transfers of zinc (except for quantities in waste rock at less than 1%) must then be reported on to the NPRI if the threshold for reporting was met. The requirement to include all zinc in tailings in the calculation of the MPO threshold may contribute to more extensive reporting from the metal mining sector compared to other sectors.

Appendix E. Summary of partition coefficients for zinc

Table E-1. Summary of partition coefficients for zinc

Partition coefficient	Experiment or Predicted	Range of Values	Average	Reference
log K_{sw} (partition coefficient soil-water, dimensionless)	Experimental	2.477-4.006	3.384	Thibault et al. 1990
log K_{sdw} (partition coefficient sediment-water, dimensionless)	Experimental	3.405-5.112	4.067	Borgmann et al. 2004; Cain et al. 1992; Davis et al. 1996; van Hattum et al. 1991; Shutes et al. 1993; Timmermans et al. 1989; Diamond et al. 1990; Besser et al. 2001; Harvey et al. 2007.
log K_{ssw} (partition coefficient suspended particles-water, dimensionless)	Experimental	4.441-6.262	5.261	Lofts et al. 2000; Warren and Zimmerman 1994; Rondeau et al. 2005; Gobeil et al. 2005; Chiffoleau et al. 1994; Diamond et al. 1990

Appendix F. Chronic toxicity data set used to develop the SSD-based long-term Canadian Water Quality Guideline (CWQG) for zinc (CCME 2018c)

Table F-1. Chronic toxicity data set used to develop the SSD-based long-term Canadian Water Quality Guideline (CWQG) for zinc (CCME 2018c)

SSD rank order	Species name	Endpoint	Life stage	Data quality	Measured effect concentration[a] ($\mu g \cdot L^{-1}$)	Reference	Adjusted effect concentration[b] ($\mu g \cdot L^{-1}$)
1	*Chironomus riparius* (Chironomid)	11-week LOEC (Development)	1st instar	2	100	Timmermans et al. 1992	9.89
2	*Ceriodaphnia dubia* (Water flea)	7-d MATC (Reproduction)	Neonate	1	18.1	Cooper et al. 2009	11.3
3	*Pseudokirchneriella subcapitata* (Green algae)	72-h EC_{10} (Growth rate)	Exponential phase	-	Geometric mean	-	13.8
4	*Daphnia magna* (Cladoceran)	21-d EC_{10} (Reproduction)	Newborn juvenile	-	Geometric mean	-	15.0
5	*Potamopyrgus jenkinsi* (Snail)	12-week MATC (Growth)	Juvenile	2	91	Dorgelo et al. 1995	19.1
6	*Jordanella floridae* (Flagfish)	100-d MATC (Growth)	Larva	2	36	Spehar 1976	27.9
7	*Cottus bairdi* (Mottled sculpin)	30-d EC_{10} (Mortality)	Less than 2 months	1	155.7	Brinkman and Woodling 2005	31.5

SSD rank order	Species name	Endpoint	Life stage	Data quality	Measured effect concentration[a] ($\mu g \cdot L^{-1}$)	Reference	Adjusted effect concentration[b] ($\mu g \cdot L^{-1}$)
8	*Brachionus havanaensis* (Rotifer)	18-d EC_{10} (Population growth inhibition)	Adults and juveniles	2	78.2	Juarez-Franco et al. 2007	36.5
9	*Phoxinus phoxinus* (Eurasian minnow)	150-d LC_{10} (Mortality)	Yearling	2	102	Bengtsson 1974	51.0
10	*Dreissena polymorpha* (Zebra mussel)	10-week LC_{10} (Mortality)	Adult	2	517	Kraak et al. 1994	51.1
11	*Pimephales promelas* (Fathead minnow)	7-d IC_{10} (Growth)	Larva	2	83.9	Norberg and Mount 1985	68.2
12	*Brachionus calyciflorus* (Rotifer)	48-h EC_{10} (Intrinsic rate of population increase)	Less than 2 hours	-	Geometric mean	-	73.0
13	*Oncorhynchus mykiss* (Rainbow trout)	30-d LC_{10} (Mortality)	Juvenile	-	Geometric mean	-	101
14	*Lampsilis siliquoidea* (Fatmucket)	28-d IC_{10} (Length)	Juvenile	1	55 (95% CI 24-181)	Wang et al. 2010	104
15	*Bufo boreas* (Boreal toad)	4-week MATC (Development)	Egg	1	264	Davies and Brinkman 1999	108

SSD rank order	Species name	Endpoint	Life stage	Data quality	Measured effect concentration[a] ($\mu g \cdot L^{-1}$)	Reference	Adjusted effect concentration[b] ($\mu g \cdot L^{-1}$)
16	*Lymnaea stagnalis* (Snail)	28-d EC_{10} (Growth)	21 days	-	Geometric mean	-	113
17	*Salmo trutta* (Brown trout)	58-d MATC (Weight)	Early life stage	1	196	Davies et al. 2002	130
18	*Prosopium williamsoni* (Mountain whitefish)	90-d IC_{10} (Biomass)	Eyed egg to fry	1	380	Brinkman and Vieira 2008	133
19	*Salvelinus fontinalis* (Brook trout)	24-week IC_{10} (Egg fragility)	Egg	2	200	Holcombe *et al.* 1979	161
20	*Oncorhynchus clarkii pleuriticus* (Cutthroat trout)	30-d MATC (Biomass)	Swim-up fry	-	Geometric mean	-	169
21	*Chlorella* sp. (Green algae)	48-h IC_{50} (Growth rate)	Exponential growth	-	Geometric mean	-	225
22	*Physa gyrina* (Snail)	30-d NOEC/L (Mortality)	Adult	2	570	Nebeker et al. 1986	344
23	*Lemna minor* (Duckweed)	7-d EC_{10} (Growth)	Not reported	2	1379.05	Ince et al. 1999	400
24	*Lyngbya* sp. (Cyanobacteria)	18-d EC_{10} (Growth rate)	Population	2	2438	Cairns et al. 1978	415

SSD rank order	Species name	Endpoint	Life stage	Data quality	Measured effect concentration[a] ($\mu g \cdot L^{-1}$)	Reference	Adjusted effect concentration[b] ($\mu g \cdot L^{-1}$)
25	*Cyclotella meneghiniana* (Diatom)	5-d EC_{10} (Growth rate)	Population	2	2803	Cairns et al. 1978	477
26	*Ceratophyllum demersum* (Hornwort)	15-d LOEC (Chlorophyll content and biomass)	Not reported	2	3000	Umebese and Motajo 2008	1116
27	*Chlamydomonas* sp. (Green algae)	10-d EC_{10} (Growth rate)	Population	2	8381	Cairns et al. 1978	1428
28	*Scenedesmus quadricauda* (Green algae)	5-d EC_{10} (Growth rate)	Population	2	9559	Cairns et al. 1978	1628
29	*Rhithrogena hageni* (Mayfly)	10-d EC_{10} (Mortality)	Nymph	1	2069.2	Brinkman and Johnston 2008	1696

[a] Geometric mean value taken from studies with same species, endpoint and duration, and similar life stage and test water quality parameters. Geometric means were also calculated from studies with varying hardness, pH, and/or DOC because the long-term *Oncorhynchus mykiss* MLR normalization equation standardized endpoint values for these variables. For details on which individual studies were used to calculate geometric means, as well as additional details on all studies, see Appendix of CCME 2018b.

[b] Adjusted effect concentrations were calculated using the *Oncorhynchus mykiss* MLR normalization equation: Standardized $EC_{10} = \exp[\ln(EC_{10meas}) - 0.398(\ln[DOC_{meas}] - \ln[DOC_{target}]) + 0.815(pH_{meas} - pH_{target})] - 0.947(\ln[hardness_{meas}] - \ln[hardness_{target}])$. Total concentrations were converted to dissolved concentrations using a total: dissolved conversion factor of 0.986 (US EPA 1996).

Appendix G. Zinc concentrations and toxicity modifying factors for Canadian ecozones and Great Lakes

Table G-1. Total zinc (Zn_T) concentrations for Canadian ecozones and Great Lakes

Region	Sample size	Range of Zn_T (µg/L)	Median[b] of Zn_T (µg/L)
Atlantic Maritime[a]	12	0.150–2.00	0.225
Boreal Cordillera	301	0.100–2.30	1.05
Boreal Plains	645	0.100–29.9	2.03
Boreal Shield	1949	0.0004–48.4	2.29
Mixedwood Plains	4501	0.00273–48.5	2.01
Montane Cordillera	1943	0.025–85.7	1.00
Pacific Maritime	1265	0.025–0.312	0.770
Prairies	335	0.500–0.442	3.50
Taiga Cordillera	21	0.200–0.530	3.60
Taiga Shield[c]	162	0.190–36.1	0.400
Lake Erie[d]	106	<0.050–16.6	0.445
Lake Ontario[d]	165	0.090–12.2	0.370
Lake Superior[d]	83	0.140–4.30	0.200

[a] Total zinc median concentrations are unavailable for the Atlantic Maritime ecozone and therefore dissolved zinc median concentrations are reported.
[b] BQMA 2015; FQMS 2014; FQMS 2016; NLTWQM 2016; PWQMN 2015; RAMP 2016; personal communication, data prepared by the Water Stewardship Division, Province of Manitoba, for the Ecological Assessment Division, Environment and Climate Change Canada, dated February 24 2016; unreferenced; personal communication, data prepared by the Environmental and Municipal Management Services, Saskatchewan Water Security Agency, for the Ecological Assessment Division, Environment and Climate Change Canada, dated February 25 2016; unreferenced).
[c] ECCC 2016
[d] personal communication, data provided by the Water Quality Monitoring and Surveillance Division, Environment and Climate Change Canada (ECCC) for the Ecological Assessment Division, ECCC, dated June 20 2017; unreferenced

Table G-1. Canadian ecozones and Great Lakes toxicity modifying factors[a] used for PNEC calculations

Region	Total hardness sample size	Geometric mean total hardness (mg/L)	pH sample size	Average pH	DOC sample size	Geometric DOC (mg/L)
Atlantic Maritime	5	32	110	7.2	35	4.4
Boreal Cordillera	305	79	283	8.0	294	1.5
Boreal Plains	643	120	656	8.1	486	19
Boreal Shield	1655	40	1981	7.8	1009	7.4
Mixedwood Plains	4941	150	5154	8.3	1394	5.3
Montane Cordillera	1936	61	1858	7.9	1853	1.2

Region	Total hardness sample size	Geometric mean total hardness (mg/L)	pH sample size	Average pH	DOC sample size	Geometric DOC (mg/L)
Pacific Maritime	1490	19	1475	7.3	1184	1.4
Prairies	369	260	420	8.1	20	10
Taiga Cordillera	22	110	22	8.0	20	10
Taiga Shield	98	7.4	175	6.9	161	3.6
Lake Erie	362	118	1666	8.03	560	2.5
Lake Ontario	305	125	1990	7.98	260	2.3
Lake Superior	46	45.3	1150	7.60	79	1.6

[a] The calculation of geometric means for total hardness and DOC were preferred since these parameters follow a log-normal distribution in the environment whereas the calculation of averages was preferred for pH since it follows a normal distribution. Central tendencies of the TMFs were also developed for certain Great Lakes using data collected during the period 2005 to 2015 (personal communication, data provided by the Water Quality Monitoring and Surveillance Division, Environment and Climate Change Canada (ECCC) for the Ecological Assessment Division, ECCC, dated June 20 2017; unreferenced). Hardness geometric means were calculated using dissolved measurements of calcium and magnesium (US EPA 2015) as direct measurements were unavailable (personal communication, data provided by the Water Quality Monitoring and Surveillance Division, Environment and Climate Change Canada (ECCC) for the Ecological Assessment Division, ECCC, dated July 27 2017; unreferenced).

Table G-2. Toxicity modifying factors and calculated PNECs for surface waters from exposure areas and reference areas for seven mining facilities subject to the MDMER from 2011 to 2015 (EEM 2016)

Site	Area type	Range of total hardness (mg $CaCO_3$/L)	Range of pH	Range of DOC[a] (mg/L)	Range of PNECs[b] (µg/L)	Median PNEC (µg/L)	Type of TMF data
1	Exposure	31.6–189	6.95–7.89	1.4	5.3–33	15	S, E
1	Reference	6.62–19.2	6.01–8.08	1.4	3.2–12	5.2	S, E
2	Exposure	0.370–455	6.90–7.50	2.4–4.2	9.1–130	315	S
2	Reference	12.8–24.1	6.50–7.60	2.3–3.1	6.1–15	7.0	S
3	Exposure	9.20–610	4.25–7.20	2.6–12	18–170	37	S
3	Reference	13.0–24.0	6.66–9.22	3.5–9.8	5.7–18	12	S
4	Exposure	50.9–130	6.74–8.02	0.25–12	8.1–38	17	S
4	Reference	29.4–76.0	7.21–7.94	0.25–9.0	6.0–17	10	S
5	Exposure	150–1.8 x 10^3	6.22–7.70	7.4	120–330	180	S, E

Site	Area type	Range of total hardness (mg $CaCO_3$/L)	Range of pH	Range of DOC[a] (mg/L)	Range of PNECs[b] (µg/L)	Median PNEC (µg/L)	Type of TMF data
5	Reference	8.00–36.0	5.02–7.17	7.4	16–31	22	S, E
6	Exposure	62.6–936	6.66–9.24	7.4	15–230	87	S, E
6	Reference	29.7–103	6.89–10.8	7.4	8.2–40	19	S, E
7	Exposure	27.0–322	5.70–7.90	7.4	8.2–240	56	S, E
7	Reference	12.0–92.0	6.02–7.60	7.4	9.4–36	22	S, E

Type of TMF data: S = site specific data; E = ecozone geometric mean for hardness and/or DOC and/or average pH

[a] For facilities in the Northern Arctic and Southern Arctic ecozones, the ecozone geometric means for DOC for the Taiga Shield were applied since monitoring data were unavailable for these ecozones.

[b] The aquatic long-term WQG MLR boundaries are 6.5 to 8.13 for pH, 23.4 to 399 mg/L for hardness, and 0.3 to 22.9 mg/L for DOC. Values outside of this range are replaced with the lower or upper limit as appropriate.

Table G-3. Toxicity modifying factors and calculated PNECs for surface waters from exposure areas and reference areas for base metal smelters and refineries

Site	Area type	Range of Total Hardness (mg $CaCO_3$/L)	Range of pH	DOC (mg/L)	Range of PNECs[1] (µg/L)	Median PNECs	Type of TMF data
1	Exposure	90.0–517	7.00–9.40	7.4	23–180	69	S, E
1	Reference	30.0–484	6.60–9.50	7.4	22–120	40	S, E
2	Exposure	275–501	6.40–7.60	7.4	110–330	190	S, E
2	Reference	19.2–375	6.41–7.40	7.4	13–220	23	S, E
3	Exposure	375–1850	6.65–8.71	7.4	82–290	94	S, E
3	Reference	33.4–69.9	7.20–8.95	7.4	8.3–22	11	S, E
4	Exposure	0.500–1670	6.80–8.96	7.4	6.7–150	87.1	S, E

Site	Area type	Range of Total Hardness (mg $CaCO_3$/L)	Range of pH	DOC (mg/L)	Range of PNECs[1] (µg/L)	Median PNECs	Type of TMF data
4	Reference	32.1–178	6.85–7.97	7.4	12–64	39.2	S, E
5	Exposure	96.2–232	7.18–8.74	7.4	23–56	37	S, E
5	Reference	67.2–223	7.18–8.45	7.4	21–72	33	S, E
6	Exposure	56.3–74.1	7.93–8.11	1.2	7.53–9.26	N/A	TTOR
6	Reference	53.9–74.9	7.09–8.6	1.2	8.24–15.1	N/A	TTOR

N/A = Not applicable
Type of TMF data: S = site specific data; E = ecozone geometric mean for hardness and/or DOC and/or average pH; GL = Great Lakes central tendencies geometric mean for hardness and/or DOC and/or average pH, TTO=Teck Trail Operations Report.
[1]The aquatic long-term WQG MLR boundaries for 6.5 to 8.13 for pH, 23.4 to 399 mg/L for hardness, and 0.3 to 22.9 mg/L for DOC. Values outside of this range are replaced with the lower or upper limit as appropriate. For base metal smelters and refineries, TMF data for Lake Erie was used to derive a site-specific PNEC for Facility 7. For Facility 6, specific TMF data (pH and hardness) were provided for each sample but the geometric means of DOC (1.2 mg/L, Table G-2) for the Montane Cordillera eco-region were used as they were not available in the study.

Table G-5. Toxicity modifying factors and site-specific PNECs for the iron and steel sector

Site[a]	Total hardness[b] (mg/L)	pH	Dissolved organic carbon (mg/L)	PNEC (µg Zn/L)	Type of TMF data
1	45	7.60	1.6	9.3	GL
2	120	7.98	2.3	20	GL
3	120	7.98	2.3	20	GL
4	120	8.03	2.5	19	GL

Type of TMF data: GL = Great Lakes geometric mean for hardness and/or DOC and/or average pH
[a] Lake Superior was chosen to provide representative TMFs for Facility 1.
[b] Calculated using dissolved calcium and dissolved magnesium measurements.

Table G-6. Toxicity modifying factors and calculated PNECs for the wastewater sector

Site	Total hardness (mg/L)[a]	pH	Dissolved organic carbon (mg/L)	PNEC (µg Zn/L)[b]	Type of TMF data
1	40	7.8	7.4	13	E
2	150	8.3	5.3	30	E
3	32	7.2	4.4	13	E
4	150	8.3	5.3	30	E
5	260	8.2	10	65	E

Site	Total hardness (mg/L)[a]	pH	Dissolved organic carbon (mg/L)	PNEC (µg Zn/L)[b]	Type of TMF data
6	150	8.3	5.3	30	E
7	40	7.8	7.4	13	E
8	79	8	1.5	11	E
9	150	8.3	5.3	30	E
10	150	8.3	5.3	30	E
11	19	7.3	1.4	6.0	E
12	32	7.2	4.4	13	E
13	45	7.6	1.6	9.2	GL
14	120	7.98	2.3	20	GL
15	150	8.3	5.3	30	E
16	120	7.98	2.3	20	GL
17	120	7.98	2.3	20	GL
18	120	7.98	2.3	20	GL
19	260	8.2	10	65	E
20	260	8.2	10	65	E
21	61	7.9	1.2	8.6	E

Type of TMF data: E = ecozone geometric for hardness and/or DOC and/or average pH; GL = Great Lakes geometric for hardness and/or DOC and/or average pH

[a] For the ecozone geometric, measured total hardness values expressed as mg $CaCO_3$/L are reported whereas for the Great Lakes, calculated values using dissolved calcium and dissolved magnesium measurements are reported.

[b] The aquatic long-term WQG MLR boundaries are, 23.4 to 399 mg/L for hardness, 6.5 to 8.13 for pH and 0.3 to 22.9 mg/L for DOC. Values outside of this range are replaced with the lower or upper limit as appropriate.

Appendix H. Health effects assessment information

Table H-1. Available exposure guidance values for zinc for protection against toxicity (cited from Poddalgoda et al. – manuscript submitted)

Criteria organization, (year)	Critical endpoint and references	Dose level	UF	Exposure guidance value
UL[a], IOM (2001)	Reduced copper status as measured by decrease in erythrocyte copper-zinc superoxide dismutase (ESOD) activity in healthy adult female volunteers supplemented with zinc (50 mg Zn/day from supplement + 10 mg Zn/day from diet) for 10 weeks (principal study: Yadrick et al. 1989 and supported by Fischer et al. 1984; Samman and Roberts 1988).	LOAEL= 0.86 mg Zn/kg/day	1.5	0.57 mg Zn/kg bw/day (40 mg Zn/day)
RfD, US EPA (2005)	Reduced copper status as measured by decrease ESOD activity in healthy adult male and female volunteers supplemented with 50 mg Zn/day+dietary intakes of 10 mg/day for approximately 13 weeks[i] (co-principal studies: Milne et al. 2001; Davis et al. 2000; Yadrick et al. 1989; Fischer et al. 1984;)	Average NOAEL= 0.91 mg Zn/kg/day[b]	3	0.3 mg Zn/kg bw/day (20 mg Zn/day)
Intermediate and chronic MRL, ATSDR (2005)	Subclinical changes in copper status (decreased ESOD activity) and iron status (decreased ferritin levels) in women supplemented with zinc 50 mg Zn/day plus dietary intakes of 10 mg/day for 10 weeks[9] (principal study: Yadrick et al. (1989) and supported by Milne et al. 2001; Davis et al. 2000; Black et al. 1988; Fischer et al. 1984; Freeland-Graves et al. 1982; Prasad et al. 1978).	NOAEL=0.83 mg Zn/kg/day[c]	3	0.3 mg Zn/kg bw/day (20 mg Zn/day)
UL, EFSA (2006)	Based on the absence of any adverse effects on a wide range of relevant indicators of copper status in healthy adults (Bonham et al. 2002a, 2002b; Milne et al. 2001; Davis et al. 2000).	NOAEL= 0.83 mg Zn/kg bw/day[c]	2	0.42 mg Zn/kg bw/day (25 mg Zn/day)
PMTDI, JECFA (1982)	Based on the results of toxicological studies in experimental animals, including the effects of zinc in copper and iron status and clinical studies in humans.	Clinical studies showed daily tolerable dose of 200 mg ZnSO4/day (81 mg Zn/ /day[d])	n/a	1.0 mg Zn/kg bw/day[e] (specific details of derivation are not available).

EC, NOAEL and LOAEL (2004)	NOAEL of 50 mg Zn/day (principal studies: Milne et al. 2001, Davis et al. 2000 and supported by Yadrick et al. 1989; Fischer et al. 1984) and LOAEL of 150 mg Zn/day based on headaches and gastric discomfort reported after 6 weeks of supplementation. Dietary intake is not included in these endpoints (Samman and Roberts 1987).	NOAEL= 0.83 mg Zn/kg bw/day[c], LOAEL (men, women) = 2.0, 2.4 mg Zn/kg bw/day[f], respectively	1[g]	n/a[h]
SCCS (2018) NOAEL and LOAEL	NOAEL of 0.5 mg Zn/kg bw/day and LAOEL of 2.5 mg/kg bw/day based on reduced muscle mass and axonal degeneration of adult females in a two-generation reproductive toxicity assay. The test material used was zinc pyrithione, a material only found in anti-dandruff shampoos. The results of this oral study are not deemed relevant to the expected route of exposure.			

Abbreviations: IOM: Institute of Medicine; ATSDR: Agency for Toxic Substances and Disease Registry; US EPA: US Environmental Protection Agency; EFSA: European Food Safety Authority; JECFA: Joint FAO/WHO Expert Committee on Food Additives; EAR: estimated average requirements; RDA: recommended daily allowance; UL: tolerable upper intake level; RfD: reference dose; MRL: maximum residue limit, PMTDI: provisional maximum tolerable daily intake, EC: European Union risk assessment report; UF: uncertainty factor.

[a] Guidance values in IOM (2001) report were presented as mg/day of zinc; not presented as per body weight basis. Body weight for both adult men and women was assumed to be 70 kg when converting per body weight basis.

[b] The dose conversion factor was based on reference adult body weights for the appropriate gender as presented in US EPA (2005).

[c] Body weight was assumed to be 60 kg for women as per ATSDR (2005).

[d] molecular weights of Zn and $ZnSO_4$ were considered as 65.39 and 161.452, respectively as per ChemIDPlus.

[e] Body weight was assumed to be 70 kg as per JECFA (1982).

[f] Body weight was assumed to be 73.9 and 61.3 kg for men and women, respectively, as per Samman and Roberts (1987).

[g] UF was considered 1 as the studies were conducted in women who are considered to be the most sensitive sub-population for zinc toxicity

[h] An exposure guidance value was not derived by the EC risk assessment report.

[l] Exposure duration was for the principal study/studies.

Table H-2. Summary of plasma/serum zinc concentrations and intakes levels used for the generation of regression correlation for the derivation of blood BEs for the critical PODs (cited from Poddalgoda et al. - manuscript submitted)

Cohort type (gender and age in years), # of participants	Exposure type/duration (diet/ supplement) and study design	Mean intake (mg Zn/kg bw/d)[e]	Mean plasma Zn con. ±SD (µg Zn/L)[e]	Reference
MF (73-106), 23	Dietary	0.10[a]	811 ± 44[c,g]	Boukaiba et al. 1993
MF (65-95), 53	Dietary, RCT	0.13[a]	850 ± 13[c,g]	Swanson et al. 1988
M (65-75), 12	Dietary	0.15[a]	791 ± 52[c,g]	Kant et al. 1989
M (65-89), 35	Dietary	0.09[a]	955 ± 164[c,g]	Payette and Gray-Donald 1991
F (65-89), 47	Dietary	0.07[a]	824 ± 170[c,g]	Payette and Gray-Donald 1991
MF (70-85), 24	Dietary	0.13[a]	719[c,g]	Bunker and Clayton 1989
M (68-73), 32	Dietary	0.14[a]	981[c,g]	Wright et al. 1995
M (74-90), 28	Dietary	0.14[a]	981[c,g]	Wright et al. 1995

F (68-73), 42	Dietary	0.12[a]	981[c,g]	Wright et al. 1995
F (74-90), 43	Dietary	0.12[a]	1046[c,g]	Wright et al. 1995
M (71-91), 8	Dietary	0.14[a]	634[c,g]	Artacho et al. 1997
F (74-89), 36	Dietary	0.12	698[c,g]	Artacho et al. 1997
M (21.1), 23	Dietary, B/A	0.16[a]	760[d]	Pachotikarn et al. 1985
M (19-29), 9	Placebo (dietary), RCT	0.16	883 ± 23[c]	Black et al. 1988
M (25-35), 12	Dietary	0.16	980	Kant et al. 1989
M (45-55), 12	Dietary	0.15	870	Kant et al. 1989
MF (60-89), 36	Placebo (dietary)	0.11	818	Bogden et al. 1988
MF (55-70), 188	Placebo (dietary)	0.15	844	Hininger-Favier et al. 2007
MF (55-87), 25	Placebo (dietary)	0.14	885	Prasad et al. 2007
MF (35-60), 200	Placebo (dietary)	0.14	804	Preziosi et al. 1998
M (24.3), 10	dietary (before supplementation), RCT	0.22	837[c]	Gatto and Saman 1996
MF (20-60), 83	Dietary (before supplementation)	0.14	975[f]	Duchateau et al. 1981
M (65-75), 12	Dietary	0.15	980	Kant et al. 1989
M (adult), 26	Supplement, 6 weeks, RCT	0.86[a,b]	1200	Fischer et al. 1984
MF (37.5), 15	Supplement-for 6 weeks	0.79[a,b]	1030	Abdulla and Suck 1998
MF (37), 15	Supplement-6 weeks	0.57[a,b]	950	Abdulla and Suck 1998
MF (38), 15	Supplement-6 weeks	0.36[a,b]	910	Abdulla and Suck 1998
M (28.2), 21	Supplement, 6+6 weeks, RCT	2.17[b]	1347±301	Samman and Roberts 1987
F (26.8), 20	Supplement, 6+6 weeks, RCT	2.61[b]	1517 ± 412[c]	Samman and Roberts 1987
M (21.1), 23	Supplementation, 6 weeks, B/A	0.86[a,b]	1050 ± 3[d]	Pachotikarn et al. 1986
Adult (25), 7	Supplementation-12 weeks, B/A	2.10[a,b]	1250 ± 150[c]	Abdulla and Svensson 1979
F (71-93), 5	Supplementation for 28 days, B/A	0.86[a,b]	779 ± 128[c]	Field et al. 1987
F (71-93), 5	Supplementation for 28 days, B/A	1.57[a,b]	783 ± 159[c]	Field et al. 1987
F (71-93), 5	Supplementation for 28 days, B/A	2.29[a,b]	1162 ± 337[c]	Field et al. 1987
M (19-29), 13	Supplementation 12 weeks	0.86[a,b]	1010[c,g]	Medeiros et al. 1987
M (19-29), 9	Supplementation 12 weeks	1.21[a,b]	1180[c,g]	Medeiros et al. 1987
MF (55-70), 28	Supplementation 12 weeks, RCT	0.35[a]	850 ± 31[c,g]	Hodkinson et al. 2007
MF(55-70), 34	Supplementation 12 weeks, RCT	0.56[a]	935 ± 50[c,g]	Hodkinson et al. 2007

M (18 -29), 23	Supplementation 6 weeks, B/A	0.86[a]	1050 ± 3[c,g]	Pachotikarn et al. 1985
MF (> 64), 53	Supplementation 28 days, RCT	0.59[a]	876 ± 20[c,g]	Swanson et al. 1988
M (58 -68), 16	Supplementation for 6 months	0.36[a,b]	983 ± 147[c]	Feillet-Coudray et al. 2005
M (58 -68), 16	Supplementation for 6 months	0.57[a,b]	1124 ± 228[c]	Feillet-Coudray et al. 2005
F (23 -44), 12	Supplementation 22 days	0.05	850	Freeland-Graves et al. 1981
F (50-63), 5	Zn Repletion (27 days)	0.49[a]	866 ± 222	Milne et al. 1987
M/F (Mean 72.3), 56	Supplementation 24 months, RCT	1.30[a,b]	1087[g]	Stur et al. 1996
M(19-35), 25	Supplementation 18 days	0.83[b]	903 ± 39[c]	Sullivan and Cousins 1997
F (25-40), 18	Supplementation-10 weeks (50 mg/day)	0.71[a]	1059[c,g]	Yadrick et al. 1989
M (24.3), 10	Supplements for 2 weeks	0.86	994[c]	Gatto and Saman 1995
MF (24-), 18	Supplements-2 months	0.79[a,b]	1203[c]	Peretz et al. 1993
MF (36-64), 18	Supplements-2 months, RCT	0.79[a,b]	1288[c]	Peretz et al. 1993
MF (20-60), 83	Supplements-4 weeks	2.14	1290[g]	Duchateau et al. 1981
M (19-29), 13	Supplements-12 weeks-RCT	0.85[b]	1014 ± 29[c,g]	Black et al. 1988
M (19-29), 9	Supplements-12 weeks-RCT	1.10[b]	1184 ± 88[c,g]	Black et al. 1988
MF (60-89), 36	Supplement (3 months)	0.34	857	Bogden et al. 1988
MF (60-89), 31	Supplement (3 months)	1.49	1099	Bogden et al. 1988
MF (55-70), 188	Supplement (6 months)	0.36	870	Hininger-Favier et al. 2007
MF (55-70), 66	Supplement (6 months)	0.58	935	Hininger-Favier et al. 2007
MF (55-87), 24	Supplement (12 months)	0.79	1040	Prasad et al. 2007
MF (35-60), 109	Supplement (6 months)-RCT	0.43	902	Preziosi et al. 1998

M: exclusive male group; F: exclusive female group; MF: mixed male, female group; B/A: before and after study; RCT: randomized controlled trial

[a] assumed to weigh 70 kg as per Meek et al. 1994

[b] In the absence of dietary intake, a mean dietary intake of 10 mg/day as per IOM (2001) was added.

[c] data presented in µmol/L - used molecular weight of zinc as 65.4 g/mol to convert µg/L

[d] data presented in ppm; assumed ppm=mg/L. mg was converted to µg to get µg/L

[e] data presented on the basis of zinc (Zn)

[f] data presented in µg/100 ml. was converted to L multiplying by 10

[g] serum zinc concentration

Appendix I. Zinc biomonitoring data

Table I-1. Concentrations of total zinc in whole blood (mg/L) in Canadians

Study population	Sampling year(s)	Age (years)	Sex	n	Median (95% CI)	95th percentile (95% CI)
CHMS general population[a]	2007–2011	6+	M+F	10 884	6.2 (6.1–6.3)	7.8 (7.8–7.9)
MIREC-CD Plus[b] Children	2013–2014	1 to ≤3	M+F	214	4.6	5.7
CHMS general population[c]	2009–2011	3–5	M+F	495	4.6 (4.5–4.7)	5.6 (5.4–5.9)
CHMS general population[a]	2007–2011	6–11	M+F	1 861	5.1 (5.0–5.2)	6.3 (6.2–6.5)
CHMS general population[a]	2007–2011	12–19	M+F	1 942	5.8 (5.7–5.8)	7.2 (7.1–7.3)
CHMS general population[a]	2007–2011	20–39	M+F	2 478	6.2 (6.1–6.3)	7.8 (7.7–8.0)
CHMS general population[a]	2007–2011	40–59	M+F	2 442	6.3 (6.3–6.4)	7.8 (7.8–7.9)
CHMS general population[a]	2007–2011	60–79	M+F	2 161	6.4 (6.4–6.5)	7.9 (7.8–8.0)
CHMS general population[a]	2007–2011	6+	M	5 260	6.5 (6.4–6.5)	8.0 (7.8–8.2)
CHMS general population[a]	2007–2011	6+	F	5 624	5.9 (5.9–6.0)	7.2 (7.1–7.4)
CHMS Pregnant women[d]	2007–2011	18–49	F	67	5.7 (5.3–6.1)	6.5 (5.7–7.4)
FNBI First Nations Peoples[e]	2011	20+	M+F	473	5.8 (5.7–5.9)	6.9 (6.6–7.2)
Quebec Region[f]	2001	18–65	M+F	472	6.2 (6.1–6.3)	7.3

Abbreviations: n = sample size, CI = confidence interval, M = males, F = females

[a] Walker 2017

[b] Liang 2016
[c] Health Canada [modified 2013]
[d] Walker 2016
[e] AFN 2013
[f] INSPQ 2004

Table I-2. Concentrations of total zinc in serum or plasma (mg/L) in the Canadian and U.S. population

Study population	Sampling year(s)	Age years	Sex	n	Matrix	Median (95% CI)	95th percentile (95% CI)
Canada Health Survey[a]	1978	15 to <65	M+F	17 491	Serum	0.867[b]	na
Quebec Region[c]	2001	18–65	M+F	472	Serum	0.90 (0.89–0.91)	1.07[d]
Alberta[e]	2005	<25–31+	F	151 pools (n = 28484)	Serum	1.39[f]	na
Alberta[e]	2004–06	< 5 to 13	M+F	6 pools (n = 1373 samples)	Serum	0.8[f]	na
Arctic Canada Caucasian[g]	1994–99	15–45	F	132	Plasma	0.567[h]	Not reported
Arctic Canada Dene/Metis[g]	1994–99	15–45	F	91	Plasma	0.552[h]	Not reported
Arctic Canada Inuit[g]	1994–99	15–45	F	144	Plasma	0.544[h]	Not reported
Arctic Canada Other[g,i]	1994–99	15–45	F	13	Plasma	0.579[h]	Not reported
NHANES[j]	2013–14	6 and older	M+F	2 519	Serum	0.807 (0.78–0.83)	1.1 (1.0–1.1)

Abbreviations: n = sample size, CI = confidence interval, M = males, F = females, na = not available
[a] Health and Welfare Canada, Statistics Canada 1981
[b] arithmetic mean
[c] INSPQ 2004
[d] 90th percentile
[e] Alberta Health and Wellness 2008; Government of Alberta 2010
[f] average of average values from pools
[g] Walker et al. 2006, pregnant women
[h] geometric mean, values not significantly different from each other (*p* value = 0.60)
[i] Chinese, East Indian, Filipino, and multiple ethnicity

[j] CDC 2017

Table I-3. Concentrations of total zinc in urine (µg/g creatinine) in Canadians

Study population	Sampling year(s)	Age years	Sex	n	Median (95% CI)	95th percentile (95% CI)
Canadian general population[a]	2007–2011	6–79	M+F	11 187	320 (300–330)	810 (780–840)
Canadian general population[b]	2009–2011	3–5	M+F	572	630 (600–670)	1 300 (1 100–1 500)
Canadian general population[a]	2007–2011	6–11	M+F	2 078	440 (420–470)	910 (830–990)
Canadian general population[a]	2007–2011	12–19	M+F	2 021	340 (320–360)	740 (670–820)
Canadian general population[a]	2007–2011	20–39	M+F	2 484	260 (250–270)	590 (560–630)
Canadian general population[a]	2007–2011	40–59	M+F	2 441	310 (290–330)	770 (720–810)
Canadian general population[a]	2007–2011	60–79	M+F	2 163	390 (380–410)	1 100 (1 000–1 200)
Canadian general population[a]	2007–2011	6+	M	5 388	330 (320–340)	790 (750–820)
Canadian general population[a]	2007–2011	6+	F	5 799	290 (280–300)	830 (790–860)
FNBI First Nations Peoples[c]	2011	20+	M+F	494	429 (367–490)	1 210 (1 031–1 390)

Abbreviations: n = sample size, CI = confidence interval, M = males, F = females
[a] Walker 2017
[b] Health Canada [modified 2013]
[c] AFN 2013