



**Government of Canada**    **Gouvernement du Canada**

**Risk Management Approach  
for  
Selenium and its Compounds  
under the  
Selenium-containing Substance Grouping**

**Environment and Climate Change Canada**

**Health Canada**

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**Canada** 

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## Summary of Proposed Risk Management

This document outlines the proposed risk management actions for selenium and its compounds. In particular, Environment and Climate Change Canada is proposing measures to reduce anthropogenic releases of selenium to water from the following sectors to address ecological concerns:

- **Coal mining:** by developing a regulatory approach for limiting selenium discharges from this sector;
- **Metal mining:** by enhancing information gathering under the Metal Mining Effluent Regulations (MMER) to determine if additional risk management is required;
- **Base metals smelting and refining:** by addressing facilities that report to the MMER through the action proposed for metal mining, and by working with industry to gather additional information through a voluntary initiative with remaining facilities. If the voluntary initiative is not feasible, Environment and Climate Change Canada will examine other data collection methods, such as a mandatory section 71 notice under CEPA;
- **Power generation:** by implementing the performance standards of the Reduction of Carbon Dioxide Emissions from Coal-Fired Generation of Electricity Regulations that came into force in July 2015, resulting in the phase-out of the sector's selenium emissions from traditional coal-fired power plants;
- **Agriculture:** Agriculture and Agri-Food Canada will continue to collaborate with other government departments and industry on appropriate science initiatives, as required; and
- **Publicly-owned wastewater treatment systems:** by examining the effect of the Wastewater Systems Effluent Regulations on selenium to determine if additional risk management is required upstream.

Health Canada is proposing actions in the following area to address human health concerns:

- **Natural health products:** by finalizing the revised maximum daily dose allowed for selenium under the Natural and Non-prescription Health Products Directorate (NNHPD)'s Selenium and Multi-Vitamin/Mineral Supplements monographs.

If available, information on the following items should be provided to the contact identified in section 8 of this document, within 60 days following the publication of this document to inform environmental risk management decision-making:

- **Base metals smelters and refineries (that do not report to the MMER):** effluent volumes at discharge points, concentrations of total selenium in the effluent, in the environment upstream and downstream of the discharge point(s), and in tissues of fish living in the receiving water body.

- **Coal-fired power plants:** effluent volumes at discharge points, concentrations of total selenium in the effluent, in the environment upstream and downstream of the discharge point(s), and in tissues of fish living in the receiving water body; and information on electricity specific sector contribution to those releases and information on fly-ash disposal, wastewater treatment and monitoring practices.

The risk management actions outlined in this Risk Management Approach may evolve from additional information obtained from the public comment period, or through consideration of assessments and risk management actions published for other Chemicals Management Plan substances, as required, to ensure effective, coordinated, and consistent risk management decision-making.

**Note:** The above summary is an abridged list of actions proposed to manage selenium and its compounds and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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# 1. Context

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

As part of the second phase of the Chemicals Management Plan (CMP), the ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances, in 9 substance groupings (Government of Canada, 2011). The 29 substances, listed in Annex A, are included in the Selenium-containing Substance Grouping of the Substance Groupings Initiative of the CMP (Government of Canada, 2013a).

The final screening assessment for selenium and its compounds under the Selenium-containing Substance Grouping focuses on the selenium moiety and therefore includes substances containing selenium in all oxidation states (selenite, selenate, elemental, and selenide), organic selenium, and all forms of selenium found in the environment. The assessment therefore encompasses all 29 selenium-containing substances identified in the Selenium-containing Substance Grouping.

## 2. Issue

### 2.1 Final Screening Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of selenium and its compounds in Canada under section 68 and 74 of CEPA, and under the Selenium-containing Substance Grouping of the CMP Substance Groupings Initiative. A notice summarizing the scientific considerations of the final screening assessment for these substances was published in the Canada Gazette, Part I, on December 16, 2017 (Environment and Climate Change Canada and Health Canada, 2017).

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

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

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

On the basis of the information available, the final screening assessment concludes that selenium and its compounds meet the criteria under section 64(a) and (c) of CEPA because they may be entering 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, and constitute or may constitute a danger in Canada to human life or health. The ecological risks of concern, identified in the final screening assessment, are primarily based on the release of selenium to water from some facilities engaged in coal mining, metal mining, base metals smelting and refining, power generation, as well as from the agriculture sector, and publicly owned wastewater treatment. Although selenium is essential for human health, there are potential human health risks to certain sub-populations that have or are likely to have elevated selenium exposure levels. Some Inuit who eat traditional foods have been identified as a subpopulation with elevated exposure. Subsistence fishers consuming fish with elevated selenium concentrations (e.g. around certain industrial operations) and individuals consuming a subset of multi-vitamin/mineral supplements providing high levels of selenium are two additional subpopulations in Canada with the potential for elevated selenium exposure. As such, this document will focus on these activities and exposure sources of potential concern (section 5).

Note that the proposed risk management actions described in this document are preliminary and may be subject to change. For further information on the [final screening assessment of selenium and its compounds](#).

## **2.2 Recommendation under CEPA**

On the basis of the findings of the final screening assessment conducted under CEPA, the ministers recommend that selenium and its compounds be added to the List of Toxic Substances in Schedule 1 of the Act<sup>3</sup> as per section 77(2) of CEPA. According to section 91 of CEPA, a proposed regulation or instrument establishing “preventative control actions” must be published in the Canada Gazette, Part I within 24 months of the recommendation to add the substance to Schedule I. Once proposed, the ministers have a further 18 months to finalize the regulation or instrument (Environment Canada, 2004). If needed, additional regulations or instruments can be developed within that period or afterwards.

Once selenium and its compounds are added to the List of Toxic Substances, any selenium-containing substance that contributes or could contribute, presently or in the future, to concentrations of selenium into the environment above levels of concern could be subject to risk management actions. Where the uses of selenium-containing substances do not pose a risk to the environment throughout their life-cycle, Environment and Climate Change Canada does not intend to develop risk management instruments. Environment and Climate Change Canada will continue to inform

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

stakeholders of any proposed risk management and ensure they are consulted following due process.

The ministers have taken into consideration comments made and information provided by stakeholders during the 60-day public comment period on the draft screening assessment and the Risk Management scope in the preparation of the final screening assessment and the risk management approach.

## 2.3 Public Comment Period on the Risk Management Scope

The Risk Management scope for selenium and its compounds, which summarized the proposed risk management actions under consideration at that time, was published on July 18, 2015. Industry and other interested stakeholders were invited to submit comments on the Risk Management scope during a 60-day comment period. Comments received on the Risk Management scope were taken into consideration in the development of this document. A [summary of responses to public comments received](#).

## 3. Proposed Risk Management

Section 3 presents the environmental and health objectives and risk management objectives, as well as the proposed actions to achieve them for each sector of concern, which are coal and metal mining, base-metal smelting and refining, power generation, agriculture, publicly-owned waste water treatment and natural health products. Proposed actions for other sectors releasing selenium are also presented. For more information on the context and rationale for these actions, please consult sections 4 and 5 titled “Background” and “Exposure Sources and Identified Risks”, respectively.

Following the publication of this Risk Management Approach, additional information obtained from the public comment period and from other sources will be considered. The risk management actions outlined in this document may evolve through consideration of assessments and risk management actions published for other Chemicals Management Plan substances to ensure effective, coordinated, and consistent risk management decision-making<sup>4</sup>.

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<sup>4</sup> The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada’s Cabinet Directive on Regulatory Management (TBS 2012a) and Red Tape Reduction Action Plan (TBS 2012b). Of note, the Government of Canada has introduced the “One-for-One” Rule and the Small Business Lens (TBS 2012b). The “One-for-One” Rule and the Small Business Lens apply only to regulations. Depending on the risk management instrument(s) selected for these substances, the “One-for-One” Rule and/or the Small Business Lens may apply.

The One-for-One Rule is designed to control the overall administrative burden on Canadian business. The Rule will reduce administrative burden in two ways: first, by removing an existing regulation if a new regulation introduces administrative burden and second, when a new regulation or amendment increases administrative burden, that an equal amount of administrative burden is reduced from an existing regulation.

The purpose of introducing a Small Business Lens is to ensure that the specific needs of small businesses are considered and that the least burdensome but most effective approach to addressing these needs is identified.

### **3.1 Environmental and Human Health Objectives**

Environmental and human health objectives are quantitative or qualitative statements of what should be achieved to address environmental and human health concerns.

For these substances, the objectives are focused on addressing the exposure sources of concern outlined in section 5 of this document. As such, the environmental objective for selenium and its compounds is to reduce anthropogenic releases of selenium to water so as not to exceed levels observed to cause adverse effects to aquatic organisms. The human health objective is for Canadians to have sufficient intake of selenium, while not exceeding tolerable upper intake levels (e.g. 400µg/day or the corresponding whole blood level of 480µg/L for adults).

The environmental and human health objectives may be revised in subsequent risk management documents (e.g. consultation document on proposed instrument).

### **3.2 Risk Management Objectives and Proposed Actions**

Risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulation(s), instrument(s) and/or tool(s) for a given substance or group of substances.

The risk management objectives for selenium and its compounds are 1) to achieve the lowest level of releases of selenium to water that is technically and economically feasible, taking into consideration socio-economic factors, and 2) to achieve a reduction in human selenium exposures from oral natural health products intended for long-term/chronic use, such as/especially multi-vitamin/mineral supplements providing more than 200 µg/day of selenium.

The risk management objectives may be revised in subsequent risk management documents.

To achieve the risk management objectives and to work towards achieving the environmental and human health objectives, the proposed risk management actions being considered for selenium and its compounds will focus on reducing releases of selenium to water from the sectors of concern identified in the final screening assessment, and investigating measures to reduce selenium exposures from oral natural health products, as described in the subsections below. Selenium discharges to water can be managed and monitored. However, due to the continual cycling of selenium once incorporated into the aquatic food webs, selenium recovery in sediment and fish tissue concentrations will likely require more time (Janz et al., 2014).

The proposed actions for the sectors of concern, which are: coal and metal mining, base metal smelting, power generation, agriculture, publicly owned wastewater

treatment and natural health products are described below, along with other sectors releasing selenium. Context and rationale for these actions are discussed in section 5.

### **3.2.1 Coal mining and metal mining**

Mines vary significantly in the nature of the ore and waste rock they extract. Mines therefore have varied levels of selenium in their effluent, ranging from insignificant to potentially high enough to be a source of concern.

#### **3.2.1.1 Coal mining**

Environment and Climate Change Canada is developing a potential regulatory approach for selenium discharges from the coal mining sector. This will be the subject of stakeholder consultation as part of the regulatory process.

#### **3.2.1.2 Metal mining**

For metal mines, a significant amount of information on selenium releases is already collected under the Metal Mining Effluent Regulations (MMER) reporting requirements and additional licensing requirements associated with Nuclear Safety and Control Act applicable to uranium mining and milling. Information was also shared by the mining industry during the 10-year review of the MMER. Proposed amendments to the MMER enhance the current environmental effects monitoring requirements to inform a future compliance requirement under the regulation. The proposed amendments add a new fish tissue study for selenium if a threshold effluent concentration is exceeded. The proposed amendments were published in the Canada Gazette, Part I, on May 13, 2017 for a formal 60-day public consultation period.

### **3.2.2 Base metals smelting and refining**

Facilities within the base metals smelting and refining sector vary significantly due to their different feedstocks, processes and products. It is therefore expected that these facilities would have varied levels of selenium in their effluent, ranging from insignificant to potentially high enough to be a source of concern. Smelters and refineries that report to the MMER (six of the 12 facilities in Canada) would likely be captured as part of the potential regulatory controls for metal mining, as described above. However, for the remaining six facilities that do not report to the MMER, Environment and Climate Change Canada is proposing to work with these facilities to gather additional data on selenium effluent concentrations through a voluntary initiative. If the voluntary initiative is not feasible, Environment and Climate Change Canada will examine other data collection methods, such as a mandatory section 71 notice under CEPA. This will allow Environment and Climate Change Canada to determine what risk management measures should be developed, if any, for these facilities that do not report to the MMER.

While the focus of risk management action is the release of selenium to water, atmospheric emissions from smelters and refineries are also identified as potentially significant contributors to the environmental loading of selenium near these facilities.

In October 2012, the Canadian Council of the Ministers of the Environment, with the exception of Québec, agreed to implement a Canada-wide Air Quality Management System (AQMS). The AQMS is a comprehensive approach that relies on several interrelated elements to reduce air pollution in Canada (Canadian Council of Ministers of the Environment, 2014a). Base-level industrial emission requirements (BLIERs) comprise one of those elements. The Government of Canada, in collaboration with stakeholders, has recently developed BLIERs for smelters and refineries, and is now working towards their implementation via Environmental Performance Agreements with companies in the sector.

Between 2005 and 2015, particulate matter emissions and sulphur dioxide emissions were reduced by 51% and 46% respectively. It is expected that, upon implementation of BLIERs, particulate matter emissions will be further reduced and sulfur dioxide emissions will be reduced by about 50% from 2015 levels by 2019. Particulate matter contains most of the metals and metalloids emitted to air, such as selenium. It is thus anticipated that selenium emissions would also be reduced as a co-benefit of particulate matter emission reductions. Moreover, gas-scrubbing control technologies used to remove contaminants from off-gases containing sulfur dioxide are also expected to capture selenium. Levels of selenium reduction will vary depending on the selected control technology. While selenium will not be specifically monitored in the emissions or in the environment as part of the BLIERs program, selenium reductions may be reflected in the annual emissions data reported by smelters and refineries to the National Pollutant Release Inventory (NPRI).

### **3.2.3 Power generation**

The potential for risk of exposure to selenium from power generation has been identified in the context of coal-fired power plants co-located with coal mines. Sampling sites did not allow for measurements to be attributed solely to the power generation sector, because coal power plants are generally located in the vicinity of coal mines.

Notwithstanding uncertainties on source apportionment from power generation, other federal actions to address the sector will provide a co-benefit for selenium releases. The Government of Canada published the Reduction of Carbon Dioxide Emissions from Coal-Fired Generation of Electricity Regulations in September 2012. The regulations set a stringent performance standard for new coal-fired electricity generation units and those that have reached the end of their useful life. The implementation will cause a permanent shift to lower- or non-emitting types of electricity power generation. By phasing out traditional coal-fired electricity units, the regulation will also reduce the potential risk for selenium releases associated with coal-fired electricity generation over time. The performance standard requirements under the regulations came into effect on July 1, 2015. Furthermore, as announced in November 2016, the federal government

intends to accelerate this phase out of traditional coal-firing by amending these regulations to attain phase out by 2030; this will further reduce the potential risk for selenium over time.

### **3.2.4 Agriculture**

In light of the potential risk identified in the final screening assessment for this sector, Agriculture and Agri-Food Canada will collaborate with other government departments and industry on appropriate science initiatives as needed.

### **3.2.5 Publicly owned wastewater treatment**

The data used in the assessment represent a small sample of the numerous publicly owned wastewater treatment plants in Canada. On the basis of the available information, the risk for the wastewater sector is low and limited to potentially very few facilities.

Selenium is not used in the treatment of wastewater; it is released to wastewater systems from upstream sources. Selenium can also be naturally present in the wastewater entering the wastewater treatment facilities.

In 2012, Environment Canada published the Wastewater Systems Effluent Regulations (WSER), which set standards, achievable through secondary wastewater treatment, for the quality of effluent discharged from wastewater treatment facilities. As wastewater systems with no treatment or primary treatment are upgraded to achieve at least the standards of these regulations, a reduction in selenium releases to the environment is anticipated over time. It is expected that selenium released via wastewater effluent from upstream sources, such as various industries that send their effluent to publicly owned wastewater treatment facilities and the consumer use of products containing selenium that are washed down the drain, may be addressed by the regulations.

If actions are deemed necessary to address an identified risk following the effect of the WSER, Environment and Climate Change Canada will prioritize measures that aim to reduce selenium releases from the original emitter(s).

### **3.2.6 Natural health products**

Following the publication of the draft screening assessment and the risk management scope, the NNHPD proposed a lower maximum daily dose allowed for selenium under the NNHPD's Selenium and Multi-Vitamin/Mineral Supplements monographs. These monographs were subjected to a 30-day public comment period which ended on March 9, 2016; and the NNHPD has taken into consideration comments made and information provided by stakeholders in the preparation of the final version of the revised monographs. The maximum daily dose to be allowed under these monographs has been proposed to be reduced from 400 to 200 µg/day, based on the daily average 95<sup>th</sup> percentile dietary intake for the different age groups falling within the adult

subpopulation (i.e., 19-71+ years). The Institute of Medicine (IOM) has identified, for adults, a Tolerable Upper Intake Level (UL) of 400 µg/day for selenium, representing total intake from food, water, and supplements. The current Estimated Average Requirement (EAR) and Recommended Dietary Allowance (RDA) for selenium in adults, excluding pregnancy and lactation, have not changed, set at 45 and 55 µg/day, respectively. Health Canada will continue to work towards finalizing the revised maximum daily dose allowed for selenium under the Natural and Non-prescription Health Products Directorate (NNHPD)'s Selenium and Multi-Vitamin/Mineral Supplements monographs.

### **3.2.7 Other initiatives**

The performance measurement of some of the environmental risk management instruments will rely in part on data reported to the NPRI. Environment and Climate Change Canada has already lowered the reporting threshold for selenium and its compounds under the NPRI in 2011 (from 10 tonnes to 100 kg manufactured, processed or otherwise used). As presented in the final screening assessment, the new threshold has increased reporting and should better indicate the extent of the releases of selenium to the environment. For this reason, the year 2011 will be used to establish a baseline for the performance measurement of some of the environmental selenium risk management activities.

### **3.3 Food consumption advice for specific sub-populations**

Although Health Canada does not issue advisories for foods hunted or gathered for personal consumption (referred to as traditional or country foods), Health Canada will, upon request from relevant public health authorities (such as provinces or territories), provide health risk assessments and opinions on the potential risks posed by chemical substances in specific traditional foods or in the interpretation of biomonitoring results. Any subsequent risk management advice developed from these assessments, such as a consumption advisory, would be issued by the relevant public health authority. Health Canada will continue to proactively communicate with relevant public health authorities and implicated stakeholders about selenium and its compounds.

### **3.4 Risk Management Information Gaps**

To further inform risk assessment and decisions on proposed environmental risk management, additional information is being sought on the following:

**Base metals smelters and refineries that do not report to the MMER:** effluent volumes at discharge points, concentrations of total selenium in the effluent, in the environment upstream and downstream of discharge points.

**Coal-fired power plants not co-located with coal mines:** effluent volumes at discharge points, concentrations of total selenium in the effluent, in the environment upstream and downstream of the discharge point(s), and in tissues of fish living in the

receiving water body; and information on electricity specific sector contribution to those releases and information on fly-ash disposal, wastewater treatment and monitoring practices.

**Wastewater treatment facilities:** As the Wastewater Systems Effluent Regulations come into effect (the first timeline to upgrade is the end of 2020), and actions are deemed necessary, samples of influent, effluent, downstream and upstream of publicly-owned wastewater treatment plants may need to be collected to determine the effect of the regulations on total selenium levels.

## **4. Background**

### **4.1 Current Uses and Identified Sectors**

Selenium is a naturally-occurring element widespread in environmental media (e.g. water, air, soil, and plants). Selenium and its compounds can be used in plastics (as a component of pigments), rubber (accelerator in rubber vulcanization), agriculture (soil supplement, animal feed, and pesticides), paints (as a component of pigments), ceramics and glass (as a component of pigments), electronic material, drugs including natural health products (as a medicinal ingredient in multi-vitamin/mineral supplements and anti-dandruff shampoos), supplemented foods, specific foods for special dietary uses, cosmetics, consumer products, lubricants, and metallurgical applications. Selenium can also be released due to human activities (e.g., mining and burning of fossil fuels). The information collected on these uses and sectors was reviewed and presented in detail in the final screening assessment. The sections below provide a summary of the uses and sectors where a potential risk was identified in the final screening assessment.

#### **4.1.1 Selenium production**

In Canada, no metal mine produces selenium exclusively. Selenium can be either recovered to be refined for its market value or it can be present in ores as a contaminant. Between 2005 and 2012, Canadian selenium production fluctuated between levels of 97 000 kg in 2010 and 191 000 kg in 2008 (Natural Resources Canada, 2014).

#### **4.1.2 Coal mining and metal mining**

As a natural element of the terrestrial crust, selenium may be found in metal ores and selenium-rich rock formations. Underground and open-pit coal mining and metal mining are anthropogenic activities having the potential to release selenium to the environment during the extraction and processing of ores and the subsequent management of the resulting wastes. Due to technical and economic constraints, selenium is not recovered from coal (U.S. Geological Survey, 2014; Fthenakis, Kim, & Wang, 2007).

### **4.1.3 Base metals smelting and refining**

Ore concentrates, from Canadian mines or imported, that contain selenium are processed in some smelters and refineries, with the recovery of selenium as an intermediate product, a residue or as a main product (Environment and Climate Change Canada, 2017d).

### **4.1.4 Manufacture, import and uses of selenium and selenium-containing substances, products and manufactured items**

Based on a literature review, sectors or activities that may be using or producing selenium or its compounds worldwide are varied and numerous. In Canada, the identity and volume of manufactured products and items containing selenium substances in commerce is largely unknown. Limited data on the use of specific selenium compounds in Canada was obtained through two notices under section 71 of CEPA. The sectors identified below are limited to the ones where a potential risk was identified in the final screening assessment from the use of selenium and its compounds.

#### **4.1.4.1 Agriculture**

Selenium-containing products and products enriched in selenium are available to ensure that livestock receive essential nutrients. Agricultural feedlots can use dietary supplements rich in selenium. Selenium amendments can also be applied onto soils that are deficient in selenium (Environment and Climate Change Canada, 2017g).

#### **4.1.4.2 Natural health products**

Selenium is listed with a medicinal role in the Natural Health Products Ingredients Database (NHPID), and identified as a medicinal ingredient in the NNHPD's Selenium and Multi-Vitamin/Mineral Supplements monographs. The monographs outline various source materials/ingredients for selenium's use in natural health products. Selenium is also listed with a homeopathic role in the NHPID. Selenium sulfide is listed with a medicinal role in the NHPID, and identified as a medicinal ingredient in the NNHPD's Anti-Dandruff Products monograph. Selenium compounds are present as such in currently licensed natural health products, with the most common products, among others, being multi-vitamin/mineral supplements, anti-dandruff shampoos, and homeopathic medicines (Health Canada, 2016b; Health Canada, 2016a).

### **4.1.5 Incidental manufacture and presence in the environment**

Data on the incidental manufacture or presence of selenium in several sectors was gathered in part through reporting to the NPRI and through environmental monitoring and studies of selenium levels in fish eggs and ovaries, fish tissues, and surface water near known point sources.

Selenium is naturally or incidentally present in raw material processed during coal mining, metal mining, and power generation. A potential risk was found from the resulting releases of selenium to the environment from a subset of these activities. A potential risk was also found due to the presence of selenium in the influent of publicly owned wastewater treatment facilities and the resulting releases of selenium to the environment.

Selenium and its compounds present in wildlife, either due to natural or anthropogenic sources, create the potential for higher exposure in populations who consume certain traditional foods or diets (e.g., Inuit and subsistence fishers).

## **5. Exposure Sources and Identified Risks**

### **5.1 Natural Sources**

Selenium (symbol: Se) is a naturally-occurring element in the terrestrial crust. Typically, selenium is associated geochemically with sedimentary rocks, and more specifically with ferrous oxide formations and black shale. Selenium can be found in minerals such as pyrite, chalcopyrite, pyrrothite and sphalerite (Reimann & de Caritat, 1998). Selenium is also naturally found in crude oil, coal and copper deposits, and wood.

Natural releases of selenium include volcanic activity, wildfire, weathering of selenium-rich soils and rocks, sea salt spray and volatilization from plants and water bodies (Mosher & Duce, 1987; Nriagu, 1989; Presser, Sylveste, & Low, 1994). These natural emissions of selenium have been estimated to represent about 60% of global emissions of selenium to the atmosphere (Nriagu, 1989; Mosher & Duce, 1987); this indicates that anthropogenic emissions are not negligible relative to natural sources and that the natural cycle of selenium is perturbed by human activities (Environment and Climate Change Canada and Health Canada, 2017).

### **5.2 Anthropogenic Releases to the Environment**

Anthropogenic releases of selenium to the environment have been identified in the final screening assessment as posing a risk in some sectors which are identified below, particularly when released directly to the aquatic environment.

#### **5.2.1 Coal mining**

As of November, 2016, 8 coal mining facilities reported releases to the NPRI of 13 360 kg of selenium to water in 2014. These facilities also reported the on-site disposal of 28 802 kg of selenium; this data includes selenium contained in tailing products and coarse coal rejects (National Pollutant Release Inventory, 2014).

Any human activity that disturbs or exploits selenium-rich rock formations or soils will mobilize selenium. The extraction of coal can be a major contributor of selenium to the environment when selenium is present in rocks associated with coal. Selenium may be

released with coal mining effluents because selenium and coal can be found in similar geological environments. Moreover, potential run-off of water from mine wastes following precipitation may end up in nearby water bodies. Leaching and direct transport of selenium-enriched waters into regional ponds, reservoirs, lakes, and rivers can also occur from the disposal of the waste rocks (Environment and Climate Change Canada, 2017a).

Available and selected studies on selenium levels in the vicinity of coal mines were mostly conducted in Alberta and British Columbia, where most of the Canadian facilities are located. High selenium concentrations in fish eggs and ovaries, in fish tissues, and in sediments near some coal mining sites show a potential risk to harm aquatic and benthic organisms.

### **5.2.2 Metal mining**

As of November 2016, 59 metal mines and mills (including uranium production) reported releases to the NPRI of 3579 kg of selenium to water, 856 kg to air, and 84 kg to land in 2014. These facilities reported the on-site disposal of 1 244 935 kg of selenium. Disposal data includes the disposal of tailings and waste rock, which tend to be disposed of on-site (National Pollutant Release Inventory, 2014). Note that these numbers do not reflect the one-time accidental release from Mount Polley mine that occurred in 2014.

In addition to the documented releases from mining operations, potential run-off of water from mine wastes following precipitation may end up in nearby water bodies (Environment and Climate Change Canada, 2017c).

In that regard, important distinctions exist between operating, closed, and abandoned or orphan mines.

To comply with the Metal Mining Effluent Regulations (MMER) under the Fisheries Act, modern operating metal mines must meet effluent quality limits, and study the environmental effects of their effluents.

Once mineral resources are exhausted or operations are no longer profitable, a mine undergoes closure. Properly closed mines involve the orderly, safe, and environmentally sound conversions of operating mines to a closed state. However, mining sites can continue to release effluent into the environment long after they cease operations. To mitigate these releases, treatment and monitoring of contaminated water at the site's final discharge point(s) are often conducted as part of post-closure activities. In the case of closed mines, a known owner is still responsible for compliance with laws and regulations (Government of Canada, 2013b).

Orphaned or abandoned mines are sites where advanced exploration, mining or mine production has ceased without rehabilitation having been completed, and whose ownership has reverted to the Crown, either provincially or federally depending on the

jurisdiction, because the last owner was financially unable or unwilling to properly close the site or because no owner could be found. Orphaned or abandoned mines are of particular concern as they may not have been properly decommissioned and, as a result, their effluent could have higher levels of contaminants (Mackasey, 2000; Government of Canada, 2013b; Castrilli, 2007). Abandoned mines are a result of irresponsible closures prior to the implementation of current laws and regulations.

Under present requirements, proponents must provide mine closure plans, with funds to support them, to regulators before commencing any mining activities. Regulators will use closure plans and funds to rehabilitate the sites should the proponents be unable to do so in the future (Cowan Minerals Ltd., 2010).

Measured concentrations of selenium in environmental media in the vicinity of metal mines across Canada were gathered from a variety of reports, studies and databases. Sources of information included the reports submitted to Environment and Climate Change Canada's Environmental Effects Monitoring (EEM) Program under the MMER. This information, which is presented in the final screening assessment and its supporting documentation, indicates that selenium releases from mining operations and on-site waste management are likely the cause of the elevated selenium levels found near these sites. For this sector, selenium in fish eggs and ovaries, in fish tissues, and in sediment near sources of releases may exceed predicted no-effect levels for aquatic organisms and benthic organisms (Environment and Climate Change Canada, 2017c).

### **5.2.3 Base metals smelting and refining**

Selenium can be released to surface water and air as a result of base metals smelting and refining. As of December 2016, 11 base metals smelting and refining facilities reported releases to the NPRI of 2 398 kg of selenium to water and 9 068 kg to air in 2014. These facilities also reported the on-site disposal of 738 kg and off-site disposal of 39 279 kg of selenium contained in residues (National Pollutant Release Inventory, 2014).

Measured concentrations of selenium in environmental media in the vicinity of smelters and refineries across Canada are available in a variety of reports, studies, and databases. There are indications that some base metals smelters may be contributing to elevated concentrations of selenium in soil and sediments following several years of releases to water and through atmospheric emission and deposition. There are also indications that the high levels of selenium in water bodies and in fish tissues near some smelters and refineries may be associated with their operations (Environment and Climate Change Canada, 2017d). A potential risk to aquatic, terrestrial, and benthic organisms was therefore identified for this sector.

### **5.2.4 Power generation**

As of November, 2016, 13 power generating stations reported releases to the NPRI of 16 kg of selenium to water and 821 kg to air in 2014. These facilities also reported the

on-site and off-site disposal of 11 123 and 5 694 kg, respectively (National Pollutant Release Inventory, 2014).

The combustion of coal can generate volatile and particulate forms of selenium that escape to the atmosphere. Emission control measures in coal-fired power plants increase the removal rate of fly ash and sulfur, and these measures capture selenium alongside sulfur. Wastewater from wet stack scrubbers as well as run-off or effluents from waste piles and fly ash settling ponds are potentially major sources of dissolved or particulate-adsorbed selenium to aquatic environments (Environment and Climate Change Canada, 2017e). In Canada, some coal-fired facilities prevent discharges of wastewater to the environment by using a closed loop system, whereby contaminated water is treated and recirculated in the process (Submission sent to the Chemicals Management Program, 2015; unreferenced).

Concentrations of selenium measured in sediment and in surface water at the Wabamun Lake in Alberta were used to assess releases from coal-fired power plants co-located with coal mining operations. Due to the absence of other major industries in the vicinity of the lake, these levels were attributed to the activities of the power plants and related coal mining activities together. Fish tissue concentrations were also gathered from the National Fish Contaminants Program and other studies conducted across Canada. Selenium concentrations in some of these fish tissue samples exceeded the predicted-non effect level concentrations. A potential risk was therefore identified for aquatic and benthic organisms (Environment and Climate Change Canada, 2017e).

### **5.2.5 Agriculture**

As of November 2016, total releases reported to the NPRI of selenium from all agricultural chemical manufacturers and other farm supplies wholesalers and distributors were less than one kg in 2014 (National Pollutant Release Inventory, 2014). Diffuse releases of selenium to water from agricultural activities can occur from the use of animal feed and application of manure, fertilizers and biosolids, and subsequent leaching and run-off from agricultural soils, which are not captured under the NPRI (Environment and Climate Change Canada, 2017g).

Selenium is a naturally-occurring element present in higher concentrations in the soil from the Canadian prairies and in western Canada (National Research Council, 1983). Selenium run-off due to natural precipitation and to irrigation of agricultural soils could increase selenium concentrations in water bodies located in the vicinity of intensive agricultural areas (Environment and Climate Change Canada, 2017g). Run-off from agricultural feedlots using dietary supplements enriched in selenium can be of particular concern (Lemly, 2004). Similarly, application of selenium amendments can produce short-term elevation of selenium concentrations in run-off (Wang, Alfthan, Aro, Lahermo, & Vaananen, 1994). The application of manure and biosolids to replenish essential nutrients in soils can also be an important source of selenium (Environment and Climate Change Canada, 2017g).

Measured concentrations of selenium in fish tissues collected near agricultural areas under the Fish Contaminants Monitoring and Surveillance Program show a potential risk for aquatic organisms (Environment and Climate Change Canada, 2017g). In addition, a model was used to estimate the contribution of several simultaneous sources of selenium to agricultural soils. In the model, the largest sources of selenium were predicted to be manure followed by biosolids. Fertilizers and atmospheric deposition were predicted to be minor sources. This model was also used to predict concentrations of selenium in soils of Canadian Prairies, which revealed a potential but low risk to terrestrial organisms (Environment and Climate Change Canada, 2017g).

### **5.2.6 Publicly owned wastewater treatment**

In general, wastewater treatment is a common point of entry for substances to water and a potential point of entry to soil through the subsequent management of biosolids. Releases of selenium from publicly owned wastewater treatment facilities come from consumer products and industrial releases discharged into their influents. As of November 2016, 9 publicly owned wastewater treatment facilities that reported to the NPRI in 2014 reported releases of 1 360 kg of selenium to water (National Pollutant Release Inventory, 2014).

Raw influent, primary and final effluent samples, as well as sludge and biosolids samples were collected at wastewater treatment systems that participated in the Chemicals Management Plan Monitoring Program. (Environment and Climate Change Canada, 2017f).

Of the 25 wastewater treatment systems that participated in the CMP Monitoring and Surveillance Program, five also reported releases of selenium to the NPRI. The limited overlap between the two monitoring programs for wastewater systems can be explained by their respective characteristics. The 25 sites selected by the CMP Monitoring and Surveillance Program were chosen to form a representative sample of facilities across Canada. The information collected aims to characterize the ecological exposure of multiple substances of interest under the CMP, not only selenium. As for the NPRI, facilities are only required to report their releases of selenium if they meet certain reporting thresholds.

### **5.2.7 Iron and steel, oil sands extraction and processing, and glass manufacturing**

For the iron and steel sector, the oil sands extraction and processing sector, and the glass manufacturing sector, the potential risk from selenium and its compounds to aquatic, benthic or terrestrial organisms is low, as identified in the final screening assessment. Furthermore, the risk was not found to be representative of the activities of those sectors, nor could the risk be attributed solely to them, thus making their contribution to the risk unclear. Environment and Climate Change Canada is therefore not proposing risk management measures for these sectors.

## 5.3 Human Health Exposure Pathways

Selenium is an essential nutrient for human health. All Canadians are exposed to selenium, mostly through food. Selenium intake levels in Canadians are considered adequate to meet nutritional requirements.

At elevated levels above what the body needs to function, selenium can become harmful to health. Selenosis is the critical health effect of chronic exposure to elevated levels of selenium. Symptoms of selenosis include hair loss, nail loss, nail deformities, weakness, decreased cognitive function and gastrointestinal disorders. Selenosis is the basis for many international regulatory reference values including the Tolerable Upper Intake Level (UL) established by the Institute of Medicine for United States and Canadian populations.

Total selenium measured in blood provides a measure of integrated exposure, from all routes (oral, dermal, and inhalation) and all sources, including environmental media, diet and products. Based on blood measurements, elevated selenium exposures were not identified in the general Canadian population, including children, or in First Nations populations living on reserve, south of the 60<sup>th</sup> parallel.

However, three subpopulations discussed below were identified in the assessment as having elevated exposures based on blood measurements (2-28% of Inuit) or as potentially having elevated exposures based on other exposure estimates (subsistence fishers and Canadians taking certain multi-vitamin/mineral supplements). Note that having elevated exposures does not mean that clinical signs of selenosis or other effects are occurring. Other factors may influence whether effects occur (e.g., form of selenium to which people are exposed and dietary exposure to other nutrients).

### 5.3.1 Inuit populations

Two to 28% of Inuit living in various communities in northern Canada had selenium blood concentrations above 480µg/L, a blood level considered equivalent to the UL of 400µg/day, while up to 7% had selenium blood concentrations exceeding 1000 µg/L, a level where selenosis has been observed in human populations. These increased exposures are likely due to the consumption of traditional foods, as selenium bioaccumulates in the aquatic food web and several species such as ring seal, beluga whale and narwhal have been identified as having high concentrations.

### 5.3.2 Subsistence fishers

Subsistence fishers including First Nations who consume fish caught downstream of some industrial operations (e.g. coal mining, metal mining, smelting and refining and electricity generation co-located with coal mining), where fish have elevated selenium levels due to industrial activities, may have elevated exposures. Fish consumption advisories are in place for some locations where a risk had been identified as outlined in section 7.2.1. Risk management activities to decrease levels in water and/or fish, as described in section 3.2, are expected to decrease these exposures.

### **5.3.3 Canadians taking multi-vitamin/mineral supplements**

Canadians with typical exposures from food and drinking water and who also take multi-vitamin/mineral supplements providing high levels of selenium are considered as having potential elevated exposures (see section 3.2.6).

## **6. Risk Management Considerations**

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

For the sectors of ecological concern where selenium is incidentally present, it is not expected that chemical alternatives or alternate process technologies would be a practical approach to minimize releases of selenium. Instead, additional effluent control technologies (e.g., additional on-site or off-site effluent treatments) would likely be effective approaches for most sectors, as appropriate and economically feasible.

Selenium may have positive effects on plant processes, but it has not been confirmed to be essential to plants (Canadian Council of Ministers of the Environment, 2009a; Germ, Stibilj, & Kreft, 2007). However, it is an essential micronutrient to animals because of the role of selenocysteine, an essential amino acid (Stadtman, 1996). Therefore, in agricultural areas where soils are deficient in selenium and, more importantly, where the livestock do not have sufficient intake of selenium as part of their diet, there are no alternatives to selenium-enriched products.

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

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

## **7. Overview of Existing Risk Management**

### **7.1 Related Canadian Risk Management Context**

### **7.1.1 Coal mines and metal mines**

In Canada, environmental protection is a shared responsibility between the different levels of governments. Natural resource management falls under the jurisdiction of the provinces. Territories can also have similar authorities if federal powers are devolved to them. As described below, provincial and territorial laws play an important role in mitigating environmental impacts from mining activities.

Despite many variations, provincial and territorial laws across the country exhibit similar structures. For instance, most mining acts require proponents to seek permits for the various stages of a mining project (e.g., exploration, construction, operation, reclamation). The request for a permit must often be accompanied with prescribed information, such as: a description of the intended activities, the proposed environmental program, and a reclamation plan (Castrilli, 2007; Badlwin & Fipke, 2010).

As part of, or in conjunction with, the application procedure for a permit, provincial environmental protection and environmental assessment acts can require the proponent to conduct an environmental impact assessment. Due to the nature and magnitude of their activities, mining projects are usually subject to that requirement.

If the anticipated impacts of a proposed project are too significant, a permit can be refused. Measures can also be taken by regulators to minimize impacts on the environment when a permit is granted by imposing conditions. These can take many forms, ranging from reporting requirements to release limits (Castrilli, 2007; Badlwin & Fipke, 2010).

Finally, it is important to note that many other ancillary permits and licenses may be required for the exploration, development and operation of a mine. Waste discharge permits, permits to alter, destroy or damage wildlife and water licenses are a few examples (Badlwin & Fipke, 2010). The legal requirements associated with obtaining these additional permits can also help control environmental impacts.

In addition to meeting the requirements of the applicable provincial acts, the proponents may also be required by the Canadian Environment Assessment Act, 2012 to explain environmental effects related to areas of federal jurisdiction, such as Aboriginal peoples, inter-provincial impacts, fisheries and migratory birds (Hart & Hoogeveen, 2012).

Under the Fisheries Act, the federal government has authority to regulate the effluents of any sector, including coal mining and metal mining.

For metal mining activities, the Metal Mining Effluent Regulations (MMER), under the Fisheries Act, authorize the deposit of the deleterious substances listed in Schedule 4 into natural fish bearing waters within regulated limits. Furthermore, the regulations require metal mines to undertake Environmental Effect Monitoring (EEM) studies as defined in Schedule 5 of the regulations to determine effects, if any, on fish, fish habitat and fisheries resources. EEM studies consist of biological monitoring, effluent characterization, water quality monitoring studies, and sublethal toxicity testing.

Although not required by the regulations, mines are also encouraged to study and implement possible corrective actions for the cause of effects (Environment and Climate Change Canada, 2015).

While not permitted to be released under the Schedule 4, selenium is listed in Schedule 5 of the MMER, and has been identified as being present at potentially significant concentrations in effluent from some facilities.

In 2012, Environment Canada commenced a 10-Year review of the MMER. By the end of the pre-consultation period in 2015, several proposals had been discussed, including how to best manage selenium releases from metal mines, and whether the scope of the regulations should be broadened to encompass other types of mines, such as coal mines. Following the consultations, the proposed amendments to the MMER were published on May 13, 2017, and were subject to a 60-day public comment period that ended July 12, 2017. For metal mines, data will continue to be gathered under the MMER while for coal mines, a separate regulatory approach is being explored.

#### **7.1.1.1 Uranium mines**

Like other metal mines, uranium mines are subject to the requirements of the MMER under the Fisheries Act. However, because uranium is a nuclear substance, the activities of uranium mines are also managed under the Nuclear Safety and Control Act (NSCA) which requires additional regulatory controls.

The NSCA establishes the regulatory framework for nuclear matters in Canada. When it came into force in 2000, it created the Canadian Nuclear Safety Commission (CNSC). To protect the environment and the health and safety of persons from nuclear activities, the CNSC is required by the Act to license regulated nuclear activities, including uranium mining (Government of Canada, 2016a). The licensing process and obligations of licensees for every stage of the life cycle of uranium mines are prescribed by the Uranium Mines and Mills Regulations (Government of Canada, 2016b). As part of its regulatory oversight, the CNSC also conducts compliance activities for operating and decommissioned mines (Government of Canada, 2015).

To meet its mandate, the CNSC has the authority and responsibility to manage hazardous substances as well as nuclear substances (Canadian Nuclear Safety Commission, 2014). As early as 2004, the CNSC identified that selenium releases had the potential to impact fish populations downstream of certain uranium mines and mills effluent discharge points. This resulted in the initiation of a series of industry, CNSC and academic risk assessments and studies which informed the uranium mining and milling sub-sector assessment (Environment and Climate Change Canada, 2017b) and have greatly enhanced understanding of selenium behaviour in the environment (Janz et al., 2014).

The CNSC regulatory approach for selenium requires all existing and proposed uranium mines and mills to include selenium in their licensed environmental protection program.

As a result, selenium must be assessed in a site-specific ecological risk assessment, incorporated into the effluent and receiving environment monitoring programs, and risk managed within an environmental management system. Selenium site-specific risk management activities currently range from routine effluent and environmental (e.g., water, sediment, fish tissue) monitoring to the addition of selenium treatment systems, as necessitated by the site-specific environmental protection program.

As a result of CNSC regulatory over-sight selenium releases at uranium mines and mills are controlled and have been substantially reduced in order to protect the environment. Releases and environmental concentrations are reported as part of the annual “Regulatory Oversight Report for Uranium Mines and Mills in Canada” presented by CNSC Staff to the Commission during a live web cast public meeting. These reports are available for download at [the CNSC web page](#).

### **7.1.2 Base metals smelting and refining**

In 2006, a Notice Requiring the Preparation and Implementation of Pollution Prevention Plans in Respect of Specified Toxic Substances Released from Base Metals Smelters and Refineries and Zinc Plants was published in the Canada Gazette. The Notice outlines the requirements to prepare and implement pollution prevention plans in respect of specified toxic substances released from these facilities. The notice includes annual release limits for particulate matter, which contain most of the metals and metalloids emitted to air, such as selenium. Annual release limits also target sulfur dioxide. The notice requires facilities to take into consideration a number of factors including the [Environmental Code of Practice for Base Metals Smelters and Refineries](#), which recommends particulate matter and sulfur dioxide emission limits to air. The code of practice also recommends following the Canadian Council of Ministers of the Environment (CCME) water quality objectives for chemical parameters and certain metals. A limit of 1 µg/L is listed for total selenium.

### **7.1.3 Power generation**

In January 2003, Environment Canada released the New Source Emission Guidelines for Thermal Electricity Generation under CEPA. These guidelines provide limits for emissions of sulfur dioxide (symbol: SO<sub>2</sub>), nitrogen oxides (symbol: NO<sub>x</sub>) and particulate matter (PM) from new fossil-fuel fired steam-cycle combustion units (Environment Canada, 2003).

On October 11, 2006, the CCME endorsed Canada-wide Standards for Mercury Emissions to significantly reduce mercury emissions from the coal-fired electric power generation sector. The 2012 progress report describes an increasing mercury capture rate, from 28 to 56% since the 2003 baseline year, and a resulting total reduction of mercury emissions of nearly 70%. Reductions in selenium emissions, as co-benefits, are expected, but will depend on the nature of the technology chosen to reduce mercury emissions. For instance, the installation of activated carbon injection and a fabric filter is expected to reduce emissions of other metals, organics, and particulate matter.

Selenium emissions have not been documented in the progress report (Canadian Council of Ministers of the Environment, 2014b).

The Reduction of Carbon Dioxide Emissions from Coal-fired Generation of Electricity Regulations, which came into force in 2015, will set a stringent performance standard for new coal-fired electricity generation units and those that have reached the end of their useful life. The regulations are expected to generate co-benefits for the releases of metals, including selenium, to varying degrees depending on the actions taken by the facilities (e.g., closure, installation of carbon capture and storage technologies, or transition to low-emission fuels). Furthermore, as announced in November 2016, the federal government intends to accelerate this phase out of traditional coal-firing by amending these regulations to attain phase out by 2030; this will further reduce the potential risk for selenium over time.

#### **7.1.4 Agriculture**

Selenium is an essential animal nutrient. Background levels of selenium in some Canadian regions are insufficient for the production of forage containing selenium concentrations adequate for livestock requirements. This can be addressed through the supplementation of selenium to animal feeds or soils.

Selenium soil supplements may be directly applied to deficient soils; however, they are generally applied with fertilizers. When the selenium is blended into a fertilizer prior to import or sale it is regulated under the Fertilizers Act (2014 email from Canadian Food Inspection Agency to Existing Substances Risk Assessment Bureau, Health Canada; unreferenced).

Under the 1983 Feeds Regulations<sup>5</sup>, selenium can be added to a complete feed, as defined under the regulations, at concentrations up to 0.3 mg/kg, depending on the livestock for which it is intended (Government of Canada, 1983). Selenium can be added to feeds at concentrations of up to 0.3 mg/kg for chickens, turkeys, swine, growing dairy cattle, beef cattle, sheep, goats, ducks and geese, and at concentrations of 0.1 mg/kg for salmonid fish and rabbits (Canadian Food Inspection Agency, 2015)

The CFIA's fertilizer and supplement metals standards were developed to ensure that products regulated under the Fertilizers Act and Regulations, pose a minimum risk of adverse effects to human, plant, animal health and the environment. They are predicated on the maximum total cumulative metal addition to soils over a 45 year time period, as opposed to the metal concentration in the product per se. The maximum total cumulative metal addition from fertilizers and supplements to soils over a 45 year is 2.8 kg/ha of selenium

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<sup>5</sup> The Canadian Food Inspection Agency (CFIA) is in the pre-consultation phase of a complete modernization of the Feeds Regulations, which includes a review of maximum nutrient levels such as selenium allowed in livestock feeds. As part of this process, the CFIA is working with the Food Directorate of Health Canada to establish levels in feeds that are protective of Canadian foods.

The application and use of fertilizers and supplements, including manure, processed wastewater (biosolids) and compost, is under provincial jurisdiction. In Ontario, for example, the application of fertilizers is controlled by the Nutrient Management Act and its regulations, which sets maximum application rates and minimum distances between areas of application and sensitive receivers such as wells and surface water (Government of Ontario, 2014).

The CCME recommends water quality guidelines for the protection of agriculture, which are 20 µg/L for continuous irrigation, 50 µg/L for intermittent irrigation and 50 µg/L for livestock feed water (Canadian Council of Resource and Environment Ministers, 1987). The recommended limit for selenium in agricultural soils is 1 mg/kg dry weight (Canadian Council of Ministers of the Environment, 2009b).

### **7.1.5 Publicly owned wastewater treatment and other sectors**

The Wastewater Systems Effluent Regulations (WSER), established under the Fisheries Act, include mandatory minimum effluent quality standards that can be achieved through secondary wastewater treatment (Environment Canada, 2013). While the WSER do not directly target selenium, the requirement of additional treatment at some publicly owned WWTPs is expected to generate co-benefits for industrial sectors that send their effluent to a publicly owned WWTP. Concentrations of selenium measured in biological sludge and treated biosolids sampled at various WWTPs across Canada by the Chemicals Management Plan's Monitoring and Surveillance Program support this assumption.

## **7.2 Products**

### **7.2.1 Food**

Under the Food and Drug Regulations, selenium cannot be added to food, except for infant formula, formulated liquid diets, in foods represented for use in a very low energy diet or in meal replacements and nutritional supplements. Minimum and maximum amounts of selenium which can be added are specified for these types of foods (Government of Canada, 1978). Supplemented foods may also contain added selenium but only after review by Health Canada and provided they meet compositional and labelling requirements (2015 email from Foods Directorate to Safe Environments Directorate, Health Canada; unreferenced).

Health Canada often participates in environmental assessments of proposed development projects, such as mines that are subject to the Canadian Environmental Assessment Act, 2012. Within that context, Health Canada is asked to review among other things, the proponent's human health risk assessments for fish and other traditional foods, including exposure scenarios, methodologies, toxicological reference values, rationales, and provides expert information and knowledge to the decision makers.

Additionally, Health Canada has, upon request, reviewed information and supported the assessment of selenium data in fish in Canadian water bodies that contain elevated selenium concentrations, which supports any decisions of the appropriate authority(ies) regarding risk management strategies, such as fish consumption advisories (2014 personal communication from Food Directorate to Safe Environments Directorate, Health Canada; unreferenced)

Fish consumption advisories have been issued by entities other than Health Canada for Beaverlodge and Martin Lakes in the Eastern Athabasca Region of Saskatchewan since 2003 due to high concentrations of selenium in fish resulting from historical uranium mining operations (Canadian Nuclear Safety Commission, 2013a; Canadian Nuclear Safety Commission, 2013b; Saskatchewan Ministry of Environment, 2014). The advisory limits consumption of fish for subsistence fishers to one serving (0.375 kg) over one to four weeks dependent on the type of fish (Saskatchewan Ministry of Environment, 2014).

Though not conducted by Health Canada, the need for fish consumption advisories have also been evaluated at other mining sites in Canada, including the North Saskatchewan River and the Elk Valley in British Columbia, where elevated selenium levels have been found in fish and water (Jacques Whitford Axys Ltd. and Intrinsic Environmental Sciences Inc., 2009; Teck Resources Limited, 2013a; Teck Resources Limited, 2013b).

British Columbia has established human consumption screening values for fish consumption for selenium. For high (0.22 kg/day), moderate (0.11 kg/day) and low (0.03 kg/day) fish consumption, screening values are 1.8 µg Se/g (ww), 3.6 µg Se/g (ww) and 18.7 µg Se/g (ww), respectively. If these screening values are exceeded, the Ministry of the Environment will inform the Ministry of Health, who will determine what action and public communication is necessary (British Columbia Ministry of Environment, 2014).

In Ontario, the Guide to Eating Ontario Fish mentions selenium as a metal found in fish tissue but only occasionally at levels requiring consumption restrictions (Ontario Ministry of the Environment and Climate Change, 2017).

Quebec's Criteria for Surface Water Quality includes a maximum concentration of 4.2 mg/L for selenium in water in order to prevent the contamination of fish for consumption (Quebec Minister of Sustainable Development, Environment and the Fight against Climate Change, 2013; Quebec Minister of Sustainable Development, Environment and the Fight against Climate Change, 2002).

The Northern Contaminants Program (NCP) was established in 1991 in response to concerns about human exposure to elevated levels of contaminants in wildlife species that are important to the traditional diets of northern Aboriginal peoples. The NCP allocates funds for research and related activities in five main areas: human health research; communication, capacity and outreach; national/regional coordination and Aboriginal partnerships; community-based monitoring research and environmental

monitoring and research. A number of research projects under the NCP have considered selenium, including as a protective nutrient in relation to mercury exposures (Government of Canada, 2013c). Health Canada participates in the Science Management Committee of the NCP (2014 personal communication from Food Directorate to Safe Environments Directorate, Health Canada, unreferenced).

### **7.2.2 Pest control products**

In Canada, selenium is a component of formulants in pest control products regulated under the Pest Control Products Act. Product types include rodenticides, antifouling paints and hard surface sanitizers.

### **7.2.3 Health Products**

Selenium, selenium sulfide and sodium selenite are listed in the Drug Product Database as ingredients in veterinary drugs, while selenium is also listed as a human drug for use in intravenous electrolyte solutions (Health Canada, 2017). Drugs are authorized for sale in Canada once they have successfully gone through the drug review process to assess safety, efficacy and quality (Health Canada, 2015).

The NNHPD's Selenium and Multi-Vitamin/Mineral Supplements monographs note a proposed maximum daily dose of 200 µg/day based on the IOM's UL for adults which applies to selenium intake from food, water, and supplements (Health Canada, 2007; Health Canada, 2016a) (2016 email from the Natural and Non-prescription Health Products Directorate to Safe Environments Directorate, Risk Management Bureau, unreferenced). The NNHPD's Anti-Dandruff Products monograph notes a maximum concentration of 2.5%.

### **7.2.4 Cosmetics**

Selenium and its compounds, excluding selenium sulfide (7488-56-4), are described as prohibited for use in cosmetic products on the List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the Cosmetic Ingredient Hotlist or simply the Hotlist), an administrative tool that Health Canada uses to communicate to manufacturers and others that certain substances, when present in a cosmetic, may contravene the general prohibition found in section 16 of the Food and Drugs Act or a provision of the Cosmetic Regulations (Health Canada, 2014)

### **7.2.5 Other**

The Cribs, Cradles and Bassinets Regulations, Toys Regulations and Expansion Gates and Expandable Enclosures Regulations, under the Canada Consumer Product Safety Act specify that paints and other surface coating materials on these products must not contain any compound of selenium if more than 0.1% of the compound dissolves in 5% hydrochloric acid after being stirred for 10 minutes at 20°C (Health Canada, 2016c; Health Canada, 2011; Health Canada, 2016d).

## **7.3 Guidelines**

### **7.3.1 Federal, provincial and territorial environmental quality guidelines**

Most provincial and territorial guidelines on selenium refer to the CCME water quality guidelines, which recommend 1µg/L for freshwater, 20µg/L for continuous irrigation, 50µg/L for intermittent irrigation, and 50µg/L for livestock feed water (Canadian Council of Ministers of the Environment, 2009b; Canadian Council of Resource and Environment Ministers, 1987).

British Columbia is a notable exception. In 2014, the British Columbia Ministry of the Environment published its updated water quality guidelines for selenium. The updated guidelines provide fresh and marine water quality guidelines (2 µg/L), whole-body fish tissue guidelines (4µg/g, dry weight), fish egg/ovary guidelines (11 µg/g, dw), and muscle tissue guidelines (4 µg/g, dry weight) (British Columbia Ministry of Environment, 2014).

### **7.3.2 Drinking water**

The Guidelines for Canadian Drinking Water Quality, prepared by the Federal-Provincial-Territorial Committee on Drinking Water and published by Health Canada has established a maximum acceptable concentration of 0.05 mg/L (50 µg/L) for selenium in drinking water (Health Canada, 2013). Each province and territory uses this as a basis for establishing their own enforceable limits or regulations for drinking water quality.

## **7.4 Pertinent International Risk Management Context**

### **7.4.1 United States**

In June 2016, the United States Environmental Protection Agency (U.S. EPA) published the final national aquatic life criterion for selenium. The limits for chronic exposure are: 15.1 mg/kg dry weight in fish eggs or ovaries, 8.5 mg/kg dry weight in fish whole-body, 11.3 mg/kg dry weight in fish muscle, 1.5 µg/L in lentic aquatic systems, and 3.1 µg/L in lotic aquatic systems (United States Environmental Protection Agency, 2016) . It should be noted that the U.S. EPA considers selenium to be a bioaccumulative substance.

The IOM is an independent, non-profit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. The IOM is the health arm of the National Academy of Sciences in the United States (Institute of Medicine, 2013). The IOM has set, for adults, an Estimated Average Requirement (EAR) of 45µg/day, a Recommended Dietary Allowance (RDA) of 55µg/day and a Tolerable Upper Intake Level (UL) of 400µg/day for selenium. The United States Food and Drug Administration (U.S. FDA) has also adopted, for adults a UL of 400 µg/day for selenium intake from food, water and supplements (2014 email from Natural and Non-

prescription Health Products Directorate to Safe Environments Directorate, Risk Management Bureau, unreferenced).

Minimum and maximum levels of selenium for infant formula are set out in the Code of Federal Regulations (U.S. Department of Health and Human Services, 2016)

The U.S. EPA set a drinking water limit of 50 µg/L (United States Environmental Protection Agency, 2012).

The U.S. FDA permits the use of selenium yeast in chicken, turkey, swine, beef cattle, and dairy cattle feed at levels not exceeding 0.3 ppm of added selenium (U.S. Department of Health and Human Services, 2013).

The U.S. EPA has fish consumption screening values for selenium of 20 µg Se/g (w/w) for recreational fishers and 2.5 µg Se/g (w/w) for subsistence fishers (United States Environmental Protection Agency, 2000).

#### **7.4.2 Other countries**

The European Union (EU) and a few other countries, including several member states, recommend a drinking water limit of 10 µg/L for selenium (Ireland Environmental Protection Agency, 2011; Northern Ireland Environment Agency, 2011; Gdańsk University of Technology, 2006; The Council of the European Union, 1998; Government of India, 2012; Australian Government, 2011).

Under the EU Cosmetics Regulations, all selenium compounds with the exception of selenium sulfide are banned from all cosmetic products. Selenium sulfide can be used in anti-dandruff shampoos in concentrations of less than 1% by weight, and must be labelled (The European Parliament and the Council, 2009).

The United Kingdom set a daily upper intake level of 450 µg, with 350 µg allowed from dietary supplements (Expert Group on Vitamins and Minerals, 2003).

Australia and Singapore allow 150 to 200 µg/day in dietary supplements (2014 email from Natural and Non-prescription Health Products Directorate to Safe Environments Directorate, Risk Management Bureau, unreferenced).

Australia and New Zealand have developed a joint guideline for fresh and marine water quality with a trigger value of 11 µg/L (total selenium) for the protection of 95% of freshwater species. These guidelines are currently under review (Governments of Australia and New Zealand, 2000).

South Africa established a chronic effect value<sup>6</sup> of 5 µg/L for the toxic effects of selenium on aquatic organisms (Department of Water Affairs and Forestry, 1996).

India's standard for the maximum selenium concentration in all industrial effluents to surface waters, marine and coastal areas, and to public sewers is 50 µg/L (Government of India, 2012).

### **7.4.3 World Health Organization**

Due to uncertainties inherent in the scientific database, the World Health Organization suggests a provisional guideline value of 40 µg/L for selenium in drinking water (World Health Organization, 2011).

## **8. Next Steps**

### **8.1 Public Comment Period**

Industry and other interested stakeholders are invited to submit comments on the content of this risk management approach or other information that would help to inform decision-making (such as outlined in sections 3.4). Please submit additional information and comments prior to February 14, 2018.

Comments and information submissions on the risk management approach should be submitted to the address provided below:

Environment and Climate Change Canada  
Chemicals Management Division  
Gatineau Quebec K1A 0H3  
Tel: 1-800-567-1999 or 819-938-3232  
Fax: 819-938-3231  
Email: [eccc.substances.eccc@canada.ca](mailto:eccc.substances.eccc@canada.ca)

Stakeholders who have an interest in selenium and its compounds are encouraged to identify themselves. Stakeholders will be informed of future decisions regarding selenium and its compounds and may be contacted for further information.

Following the public comment period on the risk management approach, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the risk management approach

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<sup>6</sup> Defined as that concentration or level of a constituent at which there is expected to be a significant probability of measurable chronic effects to up to 5 % of the species in the aquatic community.

will be taken into consideration in the selection or development of these instrument(s). Consultation will also take place as instrument(s) are developed.

## **8.2 Timing of Actions**

Electronic consultation on the risk management approach: December 16, 2017 to February 14, 2018

Submission of additional studies or information on selenium and its compounds: on or before February 14, 2018

Publication of responses to public comments on the risk management approach: on or before December 2019

Publication of the proposed instrument(s), if required: at the latest, 24-months from the publication of the final screening assessment

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

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

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## ANNEX A. Selenium-containing Substances on the Domestic Substances List

CAS RN	Substance Name	Substance Category
7446-08-4	Selenium oxide (SeO <sub>2</sub> )	inorganic
7446-34-6	Selenium sulphide	inorganic
7783-00-8	Selenious acid	inorganic
7791-23-3	Seleninyl chloride	inorganic
10102-18-8	Selenious acid, disodium salt	inorganic
56093-45-9	Selenium sulfide	inorganic
5819-01-2	Dodecane, 1,1'-selenobis-	organometallic
7488-56-4	Selenium sulfide (SeS <sub>2</sub> )	inorganic
13410-01-0	Selenic acid, disodium salt	inorganic
21559-14-8	Selenium, bis(diethylcarbamodithioato-S,S')-	organometallic
12002-86-7	Silver selenide (AgSe)	inorganic
12069-00-0	Lead selenide (PbSe)	inorganic
12214-12-9	Cadmium selenide sulfide (Cd <sub>2</sub> SeS)	inorganic
12626-36-7	Cadmium selenide sulfide (Cd(Se,S))	inorganic
12656-57-4	C.I. Pigment Orange 20	UVCB-Inorganic
58339-34-7	C.I. Pigment Red 108	UVCB-Inorganic
67711-98-2	Slags, dore furnace	UVCB-Inorganic
129618-35-5	Electrolytes, copper-manufg.	UVCB-Inorganic
152923-45-0	Slimes and Sludges, mercury conc. roasting off gas condensate	UVCB-Inorganic
69029-73-8	Leach residues, tellurium	UVCB-Inorganic
121053-28-9	Electrolytes, cobalt-manufg.	UVCB-Inorganic
10214-40-1	Selenious acid, copper(2++) salt (1:1)	inorganic
12137-76-7	Palladium selenide (PdSe)	inorganic
20405-64-5	Copper selenide (Cu <sub>2</sub> Se)	inorganic
1306-24-7	Cadmium selenide (CdSe)	inorganic
3425-46-5	Selenocyanic acid, potassium salt	inorganic
7782-49-2	Selenium	inorganic
7783-07-5	Hydrogen selenide (H <sub>2</sub> Se)	inorganic
144507-49-3	Slimes and Sludges, sulfuric acid manuf., sulfur dioxide cooling tower, selenium-contg.	UVCBs-inorganic