



North American Metals Council
Managed by B&C® Consortia Management, L.L.C.

April 23, 2018

Via E-mail

Ms. Julie Thompson
Program Development and Engagement Division
Department of the Environment
Gatineau, Quebec
K1A 0H3

Mr. Michael Donohue
Risk Management Bureau
Department of Health
Ottawa, Ontario
K1A 0K9

Re: Comments on Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999 (*Canada Gazette*, Part I, Vol. 152, No. 7 - February 17, 2018)

Dear Ms. Thompson and Mr. Donohue:

The North American Metals Council (NAMC)¹ and the NAMC Selenium Work Group (NAMC-SWG)² submit these comments on the Environment and Climate Change

¹ NAMC is an unincorporated, not-for-profit group formed to provide a collective voice for North American metals producers and users (*i.e.*, the North American “metals industry”) on science- and policy-based issues that affect metals in a generic way. NAMC members include trade associations as well as individual companies.

² The NAMC-SWG (*See* <http://www.namc.org/selenium.html>) is engaged in technical research on issues pertaining to selenium (Se). Activities include the development of water and tissue-based standards for Se, the implementation of such standards, the development of effects thresholds, and the identification of analytical methods pertinent to such standards. As part of its ongoing efforts, the NAMC-SWG develops papers on these topics and shares them publicly on its website or through the peer-reviewed scientific literature.



North American Metals Council

Ms. Julie Thompson and
Mr. Michael Donohue
April 23, 2018
Page 2

Canada/Health Canada document (ECCC/HC, 2018) Order Adding Toxic Substances to Schedule 1 to the Canadian Environmental Protection Act, 1999 (*Canada Gazette*, Part I, Vol. 152, No. 7 - February 17, 2018) (Schedule 1 Order).

As part of the second phase of the Chemicals Management Plan (CMP), the Government of Canada (*i.e.*, represented by ECCC and HC) conducted a scientific assessment of selenium (Se) and its compounds in Canada under Sections 68 and 74 of the Canadian Environmental Protection Act (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 report (FSAR) for these substances was published in the *Canada Gazette, Part I*, on December 16, 2017 (ECCC/HC, 2017a). These risk assessments have resulted in having met criteria under Sections 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. In parallel with, and following up from this initiative, ECCC and HC have also developed the Risk Management Approach document (ECCC/HC, 2017b; revised from initial Risk Management Scope document; EC/HC, 2015).

In addition to early consultation on the draft screening assessment report (DSAR), the NAMC-SWG has also recently provided comments on selenium-related aspects of the proposed Coal Mining Effluent Regulations (ECCC, 2017), and the latter Risk Management Approach document (ECCC/HC, 2017b).

This submission, also developed by members of the NAMC-SWG, provides comments on the above-mentioned Schedule 1 Order document (ECCC/HC, 2018). We provide the following “Clarifications” (comments, recommendations) and “Key Issues for Consideration” pertaining to scientific/technical aspects of the Schedule 1 Order.

Clarifications

The table below summarizes statements made in the Schedule 1 Order document which, in NAMC-SWG’s view, require clarification, additional detail, or justification.



North American Metals Council

Ms. Julie Thompson and
 Mr. Michael Donohue
 April 23, 2018
 Page 3

Statement in Schedule 1 Order Document (emphasis added with underlining)	NAMC-SWG Comment/Recommendation
<p><i><u>“The screening assessment determined that as a result of human activities, selenium and its compounds are being released into the environment in a quantity or concentration that is harmful to human health and the environment.”</u></i></p>	<p>This general statement needs to be qualified, justified, and supported by specific examples (and references), given the special characteristics of selenium (<i>e.g.</i>, essentiality, confounding variables) in both aquatic and terrestrial systems. For example, in some regions of Canada (<i>e.g.</i>, British Columbia), while there are potential risks due to elevated concentrations in some aquatic ecosystems, soils are known to be deficient in selenium. A more appropriate statement could highlight the localized nature of potential selenium risks.</p>
<p><i>“One of the <u>priorities</u> under the CMP [Chemicals Management Plan] is selenium and its compounds.”</i></p>	<p>It is important to highlight those criteria that were used to prioritize selenium under the CMP. In other words: what triggers resulted in selenium being placed on the priority list? Are these triggers the same as those that resulted from other parameters listed in Schedule 1 (<i>e.g.</i>, asbestos, lead, mercury)?</p>
<p><i>“Selenium is an essential nutrient to human health.”</i></p>	<p>It is also essential to aquatic life and wildlife; this should be included in this statement.</p>
<p>The section entitled <i>“Canadian and international risk management activities.”</i></p>	<p>This section appears to be a listing of international regulations/guidelines: (a) without context (<i>i.e.</i>, why are these various activities/guidelines/regulations listed here?); and (b) human health and environmental guidelines are mixed throughout this section.</p>
<p><i>“Canada also has <u>guidelines recommending a maximum acceptable concentration for selenium in drinking water.</u>”</i></p>	<p>The reference to the revised Health Canada guideline document (HC, 2014) is not provided.</p>



North American Metals Council

Ms. Julie Thompson and
 Mr. Michael Donohue
 April 23, 2018
 Page 4

Statement in Schedule 1 Order Document (emphasis added with underlining)	NAMC-SWG Comment/Recommendation
<p><i>“In Canada, the Metal Mining Effluent Regulations (MMER), under the Fisheries Act, require metal mines to undertake <u>environmental effects monitoring studies with regard to selenium in their effluents.</u>”</i></p>	<p>This has only recently been recommended, and the revised MMERs (which refers to selenium monitoring of fish tissue in EEM studies) have not yet been promulgated. In the current MMERs, selenium is not included as a parameter being monitored.</p> <p>In addition, if this statement is referring to the proposed Coal Mining Effluent Regulations, which is currently still being consulted upon, this should be fully explained and referenced.</p>
<p><i>“... the Environmental Code of Practice for Base Metals Smelters and Refineries recommends <u>particulate matter emissions limits to air and, following CCME, water quality objectives limits of selenium to water.</u>”</i></p>	<p>The document referenced only cites the ambient water quality (aquatic life) quality guideline (1 µg/L), which is NOT an effluent limit, and is severely outdated.</p>
<p><i>“... the Wastewater Systems Effluent Regulations, under the Fisheries Act, include mandatory minimum effluent quality standards of secondary treatment for wastewater effluent, which <u>results in the removal of selenium to varying degrees.</u>”</i></p>	<p>Selenium is not mentioned in these regulations. It appears that this statement was taken from the Risk Management Approach (ECCC/HC, 2017b) document. The specific statement: “which results in the removal of selenium to varying degrees,” requires proper justification and a reference to the appropriate document.</p>
<p><i>“... constitute or may constitute a <u>danger</u> to the environment on which life depends...”</i></p>	<p>This statement is vague, specifically: what constitutes “danger”? Concentrations that exceed guidelines or toxicity benchmarks do not always indicate that there is a risk to the environment.</p>



North American Metals Council

Ms. Julie Thompson and
 Mr. Michael Donohue
 April 23, 2018
 Page 5

Statement in Schedule 1 Order Document (emphasis added with underlining)	NAMC-SWG Comment/Recommendation
<p><i>“The assessment of selenium and its compounds considered the combined exposure to all selenium compounds from natural or anthropogenic sources, whether they are present in water, sediment, soil, air, food, or products available to consumers. The screening assessment concluded that selenium and its compounds meet the <u>criteria for a toxic substance</u> ...”</i></p>	<p>It would seem appropriate to have the text in the document explicitly identify which criteria (for a toxic substance) were met by selenium and based on which information (e.g., provide references, or examples).</p>
<p><i>“The most severe effect resulting from long-term exposure to elevated concentrations of selenium in the food web is reproductive failure in egg-laying vertebrates (fish, water birds and <u>amphibians</u>).”</i></p>	<p>With respect to amphibians referred to in the statement, we note that Masse <i>et al.</i> (2015) observed developmental abnormalities in the African clawed frog, <i>Xenopus laevis</i>, but not at the level of reproductive failure (and not in field situations). It is possible that reproductive failure could occur at higher concentrations (than at those concentrations where observed sublethal effects occur; e.g., eye lens abnormalities), but this has not yet been demonstrated. Moreover, other amphibian species have not been tested yet, so it is not clear whether amphibians in general are sensitive to selenium exposure.</p>



North American Metals Council

Ms. Julie Thompson and
 Mr. Michael Donohue
 April 23, 2018
 Page 6

Statement in Schedule 1 Order Document (emphasis added with underlining)	NAMC-SWG Comment/Recommendation
<p><i><u>“Field studies conducted in Canada and other regions of North America have demonstrated the reproductive effects of selenium on birds and fish when present at sufficiently high concentrations in the food web, as well as potential impacts on fish populations and biodiversity, all of which affect the integrity of various ecosystems.”</u></i></p>	<p>While this statement may be true for “... other regions of North America,” (see above references to Hyco Lake, Belews Lake, and Kesterson Reservoir), for Canada, this statement is not supported by the literature. It is recommended that references be provided to support these statements.</p> <p>We believe that -- for this specific document -- the focus should be on Canada, and it should be stated explicitly what types of effects are observed (e.g., reproductive effects on fish documented, but not clear evidence of population-level effects -- that we are aware of -- and no documented effects on birds -- that we are aware of).</p>
<p><i><u>“Risk quotient analyses were performed by comparing selenium exposure concentrations to predicted no-effect concentrations (PNECs) for fish egg/ovary and fish whole-body tissues, and for the sediment and soil compartments.”</u></i></p>	<p>Which sites/locations are referred to in this statement? It is recommended that data (or references) be provided to support these comparisons.</p>
<p><i><u>“Based on these analyses, concentrations of selenium in the environment may cause ...”</u></i></p>	<p>It should be clarified whether elevated concentrations of selenium ‘in the environment’ are anthropogenically derived or are from natural sources.</p>
<p>The section entitled <i>“Human health assessment.”</i></p>	<p>Drinking water is important as a source of selenium exposure to humans. Evaluation of selenium in drinking water, however, appears to have been excluded from this section of the document. The focus of this assessment appears to be dietary exposure, with an emphasis on fish consumption.</p>



North American Metals Council

Ms. Julie Thompson and
 Mr. Michael Donohue
 April 23, 2018
 Page 7

Statement in Schedule 1 Order Document (emphasis added with underlining)	NAMC-SWG Comment/Recommendation
<p><i>“The assessment also found that <u>selenium whole blood concentrations in some subpopulations of Canadians may exceed levels at which selenosis has been observed in humans.</u>”</i></p>	<p>Again, the exceedance of selenium levels/concentrations -- in this case, in blood -- does not indicate that there is a risk.</p>
<p><i>“Some Inuit who eat traditional foods have been identified as a subpopulation with elevated exposure. Subsistence fishers who consume fish with elevated selenium concentrations (e.g. <u>from lakes around mining operations</u>) and individuals taking multivitamin/mineral supplements providing higher levels of selenium are two additional subpopulations in Canada with the potential for elevated selenium exposure.”</i></p>	<p>To make this a valid assertion, appropriate comparisons need to be made to subsistence fishers that consume fish from lakes that are not downstream of mining operations. In addition, this requires a statistically-robust analysis of the results; this should be justified and referenced accordingly.</p> <p>Moreover, are Inuit actually eating traditional foods that now have higher selenium concentrations due to anthropogenic sources? An important point also not raised is the mitigative effect of selenium on mercury toxicity (e.g., Berry & Ralston, 2008).</p>

Key Issues for Consideration

1. Final Decision on Measure to be taken -- Schedule 1 Order

The document concludes that “... selenium and its compounds were determined to have the potential to cause harm to the environment and human health as defined under paragraphs 64(a) and 64(c) of CEPA.” Based on this, the Schedule 1 Order goes on to state that:



North American Metals Council

Ms. Julie Thompson and
Mr. Michael Donohue
April 23, 2018
Page 8

One of the following measures must be proposed after a screening assessment is conducted under CEPA:

1. taking no further action with respect to the substances;
2. adding the substances to the Priority Substances List [PSL] for further assessment; or,
3. recommending that the substances be added to the List of Toxic Substances in Schedule 1 of CEPA, and where applicable, recommending the implementation of virtual elimination.

Based on some key issues related to the essentiality of, and site-specific behavior of selenium, we recommend that measure 2 listed above (*i.e.*, adding the substance to the PSL for further assessment) is more appropriate than measure 3 (adding selenium to the List of Toxic Substances in Schedule 1).

2. Assertion related to Financial or Compliance Burden on Stakeholders

The document states that:

[A]ddition of selenium and its compounds to Schedule 1 of CEPA would not result in any direct impacts (benefits or costs) on the public or industry, since the proposed [Schedule 1] Order would not impose any compliance requirements on stakeholders. Accordingly, there would be no compliance or administrative burden imposed on small businesses or businesses in general.

We do not concur with this statement. Adding selenium to Schedule 1 gives the federal government a mandate to implement a number of risk management measures, some of which have already been initiated (*e.g.*, proposed Coal Mining Effluent Regulations; ECCC, 2017; revised MMERs). Based on the experience of Canadian members of the NAMC-SWG, it has been observed that these risk *management* measures will significantly increase financial and regulatory burdens, in the form of increased monitoring, reporting, development, and



North American Metals Council

Ms. Julie Thompson and
Mr. Michael Donohue
April 23, 2018
Page 9

implementation of selenium management plans and, potentially, the requirement for selenium treatment, which can be extremely costly.³

3. Assertion related to Effects on the Environment or its Biological Diversity

The document states that: selenium will “...*have or may have an immediate or long-term harmful effect on the environment or its biological diversity*” We believe that this is the key statement that is used as justification of the Schedule 1 Order.

The NAMC-SWG challenges this assertion, however, for the following reasons. Ecologically, “immediate” would not apply to selenium, as selenium has not been demonstrated to be acutely toxic. With respect to “long-term harmful effects,” we acknowledge that there are historical accounts of fish population extirpations over 30 years ago in the United States (*e.g.*, Hyco Lake, Belews Lake, and Kesterson Reservoir), and that selenium hazard and reproductive effects have *been* documented in field-collected fish in Canada (Holm *et al.*, 2005; Muscatello & Janz, 2009; Rudolph *et al.*, 2008; Nautilus Environmental, 2011, *etc.*). It is important, however, to note that evidence of population-level effects (*i.e.*, hazards and/or reproductive effects on fish) due to elevated selenium concentrations in the receiving environment have not been demonstrated in any field studies conducted in Canada.

We believe that the concept of “long-term harmful effects” is likely based only on comparisons of concentrations measured in the field, in certain cases, to thresholds and/or regulatory guidelines; the latter were developed/derived from laboratory-based toxicity tests, rather than actual demonstrated effects in field populations, including changes to biodiversity.

The NAMC-SWG strongly supports the need for reasonable and scientifically-defensible guidelines, regulations, approaches, best available technology -- economically achievable (BATEA), and acceptable risk.

³ See Canadian Mining & Energy, *Elk Valley water plan approved*, available at http://www.miningandenergy.ca/sustainability/article/elk_valley_water_plan_approved/.



North American Metals Council

Ms. Julie Thompson and
Mr. Michael Donohue
April 23, 2018
Page 10

Thank you for the opportunity to provide these comments.

Sincerely,

Guy Gilron, MSc, RPBio, ICD.D
Technical Lead, NAMC-SWG
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037

William J. Adams, Ph.D., Fellow SETAC
Chairman, NAMC
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037



North American Metals Council

Ms. Julie Thompson and
Mr. Michael Donohue
April 23, 2018
Page 11

References

- Berry MJ, Ralston NV. 2008. Mercury toxicity and the mitigating role of selenium. *Ecohealth*, 5(4): 456-459.
- Canadian Council of Resource and Environment Ministers (CCREM). 1987. Canadian water quality guidelines. Task Force on Water Quality Guidelines. Ottawa, ON, Canada.
- Environment and Climate Change Canada (ECCC). 2017. Proposed Approach for Coal Mining Effluent Regulations – Consultation Document, November 2017.
- Environment and Climate Change Canada/Health Canada (ECCC/HC). 2018. Order Adding Toxic Substances to Schedule 1 to the *Canadian Environmental Protection Act, 1999*, available at <http://www.gazette.gc.ca/rp-pr/p1/2018/2018-02-17/html/reg2-eng.html>.
- Environment and Climate Change Canada/Health Canada (ECCC/HC). 2017a. Screening Assessment -- Selenium and its compounds.
- Environment and Climate Change Canada/Health Canada (ECCC/HC). 2017b. Risk Management Approach for Selenium and its Compounds under the Selenium-containing Substance Grouping.
- Environment Canada/Health Canada (EC/HC). 2015. Risk Management Scope for Selenium and its Compounds under the Selenium-containing Substance Grouping.
- Health Canada (HC). 2014. Guidelines for Canadian Drinking Water Quality: Guideline Technical Document -- Selenium. Water and Air Quality Bureau, Healthy Environments and Consumer Safety Branch, Health Canada, Ottawa, Ontario.
- Holm J, Palace VP, Siwik P, Sterling G, Evans R, Baron CL, Werner J, Wautier K. 2005. Developmental effects of bioaccumulated selenium in eggs and larvae of two salmonid species. *Environmental Toxicology & Chemistry*. 24: 2373–2381.
- Masse, A, Muscatello JR, Janz DM. 2015. Dose-Dependent Early Life Stage Toxicities in *Xenopus laevis* Exposed *In Ovo* to Selenium. *Environmental Science & Technology*, 49(22): 13658-13666.



North American Metals Council

Ms. Julie Thompson and
Mr. Michael Donohue
April 23, 2018
Page 12

Muscatello JR, Janz DM. 2009. Selenium accumulation in aquatic biota downstream of a uranium mining and milling operation. *Science of the Total Environment*. 407:1318–1325.

Nautilus Environmental. 2011. Evaluation of the effects of selenium on early life stage development of Westslope cutthroat trout from the Elk Valley, BC. Sparwood (BC): Elk Valley Selenium Task Force. Draft revised report.

Rudolph B-L, Andreller I, Kennedy CJ. 2008. Reproductive success, early life stage development, and survival of Westslope cutthroat trout (*Oncorhynchus clarki lewisi*) exposed to elevated selenium in an area of active coal mining. *Environmental Science & Technology*. 42: 3109–3114.