Public Comments Summary for Selenium and its Compounds

Comments on the draft screening assessment report (dSAR) and risk management scope (RMS) document for selenium and its compounds to be addressed as part of the Chemicals Management Plan (CMP) were provided by: Assembly of First Nations, Association of International Customs and Border Agencies, Cameco Corporation & AREVA Resources Canada Inc., Canadian Electricity Association, Canadian Vehicle Manufacturers' Association, Canadian Nuclear Safety Commission, Coal Association of Canada, Consumer Health Products Canada, Council for Responsible Nutrition, Government of British Columbia (Health), Government of Northwest Territories (Health and Social Services), Jamieson Laboratories Ltd., Mining Association of Canada, North American Metals Council, SaskPower, Teck Resources Limited, SHEQ - Compliance & Licensing Cameco Corporation-Operations Centre, Université Laval and several private citizens.

A summary of comments and responses is included below, organized by topic:

TOPIC	Summarized/Rolled-up Comment	Summarized/Rolled-up Response
General comments	The screening assessment report (SAR) is very technical, and difficult to interpret for those without a scientific knowledge base.	A plain language summary is available in the Selenium Information Sheet posted on the CMP website.
	Clarify if the documents were developed to assess whether selenium meets the criteria of section 64 of the Canadian Environmental Protection Act, 1999 (CEPA 1999) or to develop a guideline for selenium. Also, the assessment should clearly communicate its purpose at the beginning of the document, and indicate that the precautionary principle was used during the assessment.	The introduction indicates that the purpose is to "focus on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA 1999, by examining scientific information to develop conclusions by incorporating a weight-of-evidence approach and precaution."
	A number of comments were related to errors in French translation.	Errors in the French translation were corrected.
Methodology	The whole-body predicted no effect concentration (PNEC) value is below background concentrations and there are flaws in the way it was derived. Use only PNEC values that are above background concentrations, based on appropriate data.	The whole-body PNEC calculation was revised. The revised value is above typical background concentrations.
	Follow the Canadian Council of Ministers of the Environment (CCME) protocols to derive PNEC values.	The PNEC calculation was updated to better align with the CCME (2007) protocol for endpoint selection, and the related statements were revised.
	Provide details concerning search criteria, comprehensiveness, time frames, and data validity (i.e., Robust Study Summary (RSS) forms), and clearly identify which studies were evaluated, and which were deemed not suitable and why. Overall, a standard approach to evaluating data in all aspects of the risk assessment document should be used.	A standard approach for evaluating data is applied throughout the assessment. Completed RSS forms were made available for effects and bioaccumulation studies, and data for measured environmental concentrations were evaluated with certain quality criteria (e.g., field sampling method, location and timing, type of laboratory analysis, detection limits.)
	Provide the rationale for characterizing exposure concentrations using mean, median or geometrical mean. An additional metric could also be used (whether it is an upper percentile or 95th Upper Confidence Limit of a Mean).	Raw data were not available from all sources; references typically only reported measures of central tendency.
	Revise the data tables using consistent methodology. In particular, ensure accuracy and consistency of the data presented in the tables for Environment and Climate Change Canada (ECCC) supporting documents EC (2014b), EC (2014c), and EC (2014d) to include and/or update the following data characteristics and parameters: locations, sample collection dates, sampling periods, concentration ranges, mean or median from the range, number (N) values and meaning, correct references and spelling of reference names.	The supporting documents were revised for consistency by applying a methodology for the reporting of the specified parameters. Improvements were made to the presentation of data, notably for medium characteristics and the partitioning of reference and impacted data into separate tables. Due to confidentiality, locations sampled for the Environmental Effects Monitoring (EEM) data of the Metals Mining Effluent Regulations (MMER) remains masked. References were added or corrected where appropriate.

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	Clarify the methodology for converting dry weight to wet weight for exposure data. Fish tissue concentrations of selenium may be overestimated using the current method (80% water content, unreferenced). Other referenced values are available, such as Suter (2000), which cites a value of 75% moisture.	The use of this conversion method was clarified and additional context was added to footnotes in the supporting documents.
Information and data updates	Reviewers indicated that most of the comments submitted by experts were rejected. From the introductory statement on page 2 "The ecological and human health portions of this assessment have undergone external, written peer review and/or consultation." Update this statement because it is misleading to imply that the expert reviewers support the conclusions.	Many changes were made to the SAR upon consideration of comments from peer reviewers. The introduction was also updated to indicate that while external comments were taken into consideration, the final content and outcome remains the responsibility of the Government of Canada.
	The data presented are robust, but there are likely a number of outliers in some of these sites, and potentially other unreliable data.	To minimize the impact of potential outliers, the median or mean was used to characterize exposure.
	The study on Inuit youth in Nunavik in Saint-Amour et al. (2006) should be cited properly and the author should be contacted to get the proper interpretation of the study.	Data in Saint-Amour et al. (2006) were re-evaluated and referenced.
	Research supported by industry should not be used to support the conclusions.	Studies cited in the SAR are peer reviewed. No change was made.
	Consider the human health risk assessment for selenium-contaminated fish conducted by Lawrence and Chapman (2007).	Lawrence and Chapman (2007) was considered in the SAR.
	Reflect that sediment and fish tissue concentrations may take time to recover despite selenium discharges being decreased or stopped (see Janz et al. 2014).	The Risk Management Approach (RMA) was revised based on the reference provided
	The fish tissue concentrations from Beaverlodge Lake reported in section 7.2.2.5 of the SAR are higher than the maximum value in Figure 6-4. However, the data are old and may not be representative of current fish tissue concentrations.	The Beaverlodge Lake fish tissue data are now included in Figure 6-4. While recent data are preferred for risk characterization and were included where available, older data may also be considered.
	Include more data from the First Nations Food, Nutrition and Environment Study (FNFNES study), which measures selenium levels in traditional foods in several First Nation communities across Canada. First Nations may also be identified as subsistence fishers. Also include more data on selenium concentrations in traditional food from around point sources, in particular those found in the First Nations Biomonitoring Initiative (FNBI).	FNs are identified as subsistence fishers in the SAR. In addition, the SAR now includes selenium concentrations in traditional foods from the FNFNES British Columbia study (the only FNFNES study to determine selenium concentrations in traditional foods). That study does not identify where traditional foods were collected. Thirteen communities participated in the FNBI. Names and locations of these communities were not included in the FNBI findings.
	Consider updating the health effects assessment with current knowledge of hazard effects associated with selenium.	Updates were made to consider recent knowledge of hazard effects associated with selenium.
	Several comments were received to request inclusion of more information on risks and benefits of dietary exposure.	The SAR was updated to include additional information dietary exposure.

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	Add appropriate studies that describe the interaction of selenium with heavy metals, especially mercury and methyl mercury.	More recent and relevant studies regarding interactions between selenium and heavy metals are included.
	Provide additional detail on how screening values for human consumption are used, and information regarding consumption advisories in Canada or the U.S.	The Risk Management Scope (RMS) document and RMA contain information on consumption advisories in Canada. Selenium consumption advisories in the U.S. are available online at http://fishadvisoryonline.epa.gov/General.aspx.
	Include the provided information regarding hazards and regulations associated with occupational exposures and information on elevated selenium exposures in Taiwan steel workers that identify elevated levels of exposure associated with various health effects such as: proteinuria, irritability, gastro-intestinal irritation, abnormal liver function and upper respiratory complaints.	CMP assessments focus on the general Canadian public. Information on Taiwanese steel workers is not relevant for this assessment and was not included. Hazard information from occupational settings relevant to the Canadian general public, in particular epidemiological information, is considered in the risk assessment.
	Statements about the water solubility of selenium-containing substances are inconsistent and over-generalized, and should be adjusted.	The statements were adjusted for consistency and accuracy.
	Remove Klavercamp et al. (2002) from the bioaccumulation factor (BAF) model given that the wrong target tissues (liver and kidney) were analyzed.	The distributions used to calculate the generic BAF values for lentic (standing water) and lotic (flowing water) environments contain only BAFs derived from muscle and whole-body tissue. Therefore, Klavercamp et al. (2002) is not present in either BAF distribution.
	Consider additional supporting documents on selenium: Metal Industry Air Metals Emissions and Hazard Rankings, Hagelstein, (February 2007), and Hagelstein (March 2017).	Submitted information was considered in preparing the final SAR and RMA.
	The uranium mining and milling supporting document on the Environment and Climate Change Canada (ECCC) website seems to use only select publications even though other sources of monitoring data are obtainable (e.g., EEM, provincial monitoring reports, and ECCC regulatory reporting requirements).	A variety of data sources were used to characterize measured environmental concentrations of selenium, including peer-reviewed literature, federal monitoring data and provincial monitoring reports.
	Many of the references in the uranium mining and milling supporting document are not present in the bioaccumulation database or the effects data collection supporting documents. Please add the references where appropriate.	The references from the uranium mining and milling supporting document were evaluated and added to the bioaccumulation database, where appropriate. None of these references contained appropriate information to add to the supporting document on effects data.
	Revise text in the uranium mining and milling supporting document to more accurately reflect the variety of mining and processing methods used.	The description of uranium mining, milling, and processing methods in the supporting document provides a brief overview and is appropriate to the purpose of this document.
	Reference numbering differs between the SAR and risk management document, and should be reconciled.	Supporting document references in the RMA are aligned with those of the SAR.

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	Consider revising some statements in the SAR to more accurately reflect current knowledge of selenium in the environment. Also use correct terminology and proper chemical formula for selenate and selenite to reflect the different oxidation states.	In consideration of comments received during the public review period, statements in Sections 4.2, 5.1, 5.2, and 6.2 were revised where appropriate. Terminology and chemical formulas were also revised.
	Reanalyze the EEM 2012 dataset for quality assurance, using annualized means, accounting appropriately for non-detect values, and augmented with additional data from 2013–2014.	The EEM 2012 dataset was augmented with 2013 data and reanalyzed. Non-detects were substituted with half the method detection limit (MDL). Due to the presence of multiple MDLs, certain ranges had substituted non-detects as maxima. This was replaced with the highest detect value and documented in the footnotes.
	Report non-detect data in supporting documents EC (2014b), EC (2014c) and EC (2014d) as values less than the detection limit and provide the number of non-detects for a given dataset. When incorporating these values into summary statistics, use a standard and consistent approach (e.g., half the detection limit).	The treatment of non-detect data was clarified in the supporting documents. Where the minima of environmental concentration ranges are non-detects, they are represented as less than the limit of detection (<LOD). The standard approach for substituting non-detect values, is to take one half of the LOD (½ LOD), as applied in the supporting documents. Calculations of central tendency that use substituted values are provided in footnotes where appropriate. The concentration ranges were reviewed and revised.
	Revise text in the SAR and supporting document to more accurately reflect the base and precious metals mining sector in Canada.	The text relating to the mining sector was revised in the SAR and supporting documents to reflect this comment.
	Data from Lemly 1997, discussed in Section 6.1, should be presented as wet weight.	The original presentation in dry weight (Lemly 1997) is more relatable to the whole body PNEC value which is also expressed in dry weight.
	The SAR should include data from the Saskatchewan Regional Health Authorities on concentrations of selenium in women from Northern Saskatchewan.	Representative data from the recommended source is considered in the SAR.
	Background information was provided on the exposure guidance values from various organizations, including from the Institute of Medicine (IOM), the European Commission's Scientific Committee on Food and its Expert Group on Vitamins and Minerals.	The guidance values from various national and international agencies were considered.
Sources and Releases	Contact the Geological Survey of Canada to acquire and include information related to selenium in various rock formations throughout Canada.	Geological distribution of selenium is discussed and background concentrations of selenium are noted as highly variable, depending on underlying geology (Reimann and de Caritat, 1998). Measured concentrations from reference areas were considered where available.

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	Consider revising some statements to more accurately reflect current knowledge of selenium in the environment.	In consideration of comments received during the public review period, Sections 4.2, 5.1, 5.2, and 6.2 were revised where appropriate.
	The SAR suggests that all or most metal mines release selenium. Few metal mines encounter elevated selenium concentrations as extensive data demonstrates (Section 4.2.1, Selenium Production).	Section 4.2.1 was revised, to identify the potential for incidental production (and release) of selenium from mining activities.
	Selenium is not a chemical additive in metal mining and coal processes, and therefore these sources should be excluded from the assessment.	The SAR appropriately addresses incidental production and release of selenium from metal mining, coal mining, and the pulp and paper sector.
	Several references included in the base and precious metals mining supporting document and in the metals smelting and refining supporting document contain monitoring data from Junction Creek, which receives potential releases of selenium from multiple sources. Therefore, it is difficult to attribute the measured concentrations solely to these sectors.	Section 6.6.4 was revised to note uncertainties regarding selenium releases from multiple sources at certain sites. Footnotes were added to the relevant supporting documents to clarify monitoring data from Junction Creek.
	Section 2 of the base metals smelting and refining supporting document should acknowledge the potential reasons for changes in reported releases due to factors such as facility closures and openings, changes in production, in addition to the change in the National Pollutant Release Inventory (NPRI) reporting threshold (already acknowledged in the text).	Section 2 was revised to acknowledge these additional factors.
	Based on data from the NPRI, uranium mines and mills should not be highlighted in the SAR since they only contribute 4% of the total selenium discharged.	Data from the NPRI were used in the SAR for context and to identify sectors that may require additional research and risk characterization.
	The majority of selenium releases reported to the NPRI refers to on-site waste rock storage and not to actual releases.	Waste rock disposal may refer to on-site and/or off-site disposal, where waste rock is discarded or stored and further managed to reduce or prevent releases (EC 2014). The disposal amount refers to the total quantity of selenium estimated to be contained in the waste, not the amount of selenium released.
	Correct the NPRI total release to water in the uranium mining and milling supporting document.	The value presented is correct and represents non-rounded values from NPRI Detailed Substance Reports (available online).
	In Section 2 of the uranium mining and milling supporting document, the statement regarding an increasing time trend in the releases reported to the NPRI should be removed, because reported releases of selenium reflect very low concentrations of selenium in effluent.	The text was revised to reflect the addition of 2013 and 2014 NPRI data.

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	Manganese imported for use in the production of aluminum alloys is contaminated with selenium. The selenium will be volatilised during the production process and released to air, or if captured will become a contaminant in the waste/recycling stream.	As of the 2014 NPRI data, no releases of selenium to air or water were reported from the aluminum sector (NPRI 2016).
	Section 4.2.1 of the SAR is supposed to be about selenium production. Address releases in a separate section.	Section 4.2.1 was revised. The revised statements accurately introduce the potential for incidental production (and release) of selenium.
	In Section 4.1.3 of the RMS document, page 10, modify the text to be consistent with the sector description in section 3.2.2 and stakeholder comments on supporting document 4.4, to clarify that only some facilities process or release selenium.	The proposed changes were accepted.
	Not all facilities have potential selenium issues, and selenium is typically a site-specific issue. In Section 2.1 of the RMS, page 2, revise the second full paragraph to clarify that not all facilities in the named source sectors release selenium to water (in elevated concentrations) and that risks are "potential."	The RMA was updated to reflect that not all facilities in the sectors of concern pose risks or potential risks to the environment.
	In Section 5.2.3of the RMS document, page 13, reword the last sentence as: "There are also indications that the high levels of selenium in water bodies near some smelters and refineries may be associated with their operations (Environment Canada, 2014d)."	The SAR was updated with the recommended changes.
	Revise the RMS to note the limited data available for publicly owned wastewater treatment, and list all sources of selenium releases discussed in the assessment for these facilities.	The SAR was revised to acknowledge the limited data available on publicly owned wastewater systems, and to note sources of selenium releases. The supporting document also notes that data used in the SAR is a small sample size in the context of all wastewater treatment systems in Canada.
	Clarify if the 25 wastewater treatment plants participating in the CMP Monitoring and Surveillance Program included those that reported releases of selenium to the NPRI	The RMA was updated to note that these 25 sites were selected as a representative sample of facilities across Canada to characterize ecological exposures for several other CMP priority substances. Five of these treatment systems reported selenium releases to the NPRI.
	It is agreed that power generation accounts for a small proportion of the total environmental releases of selenium and its compounds, as noted in the RMS.	Noted.
Environmental Fate and Behaviour	Highlight in the SAR that the use of a generic BAF may not accurately reflect site-specific bioaccumulation.	Substance screening assessments under CEPA 1999 are not intended to be site-specific evaluations; rather they are based on available information that represents a range of potential exposure scenarios in Canada.

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	Differentiate between lentic and lotic systems in Section 5 of the SAR, and explain the meaning of estimated BAFs.	The difference between lotic and lentic environments is found in Section 5 in discussions regarding environmental fate, bioavailability and bioaccumulation. Separate representative BAFs are also presented for lotic and lentic environments.
	The assessment report should capture a broad range of BAFs presented in both lentic and lotic environments.	The median BAF for each environment was reported. This minimizes over and under estimation of bioaccumulation, providing reasonable scenarios for risk characterization. Limitations of this approach are acknowledged in Section 6.6.4.
	Fish tissue concentrations should not be calculated from water concentration where measured tissue concentrations are available. In Table 4.4-B, remove the following references: Belize et al. (2006), Weber et al. (2008), Pyle et al. (2005), and Stantec Consulting Ltd (2009).	Risk quotients were based on measured tissue concentrations when these were available. Calculated tissue concentrations (Table 4.4-C) are retained and the references in the supporting document were not removed because they support the weight of evidence and validity of the approach.
	The supporting document EC (2014l) does not contain Arctic air concentrations as cited in the SAR.	Arctic air concentrations were added to the supporting document.
	Data in EC (2014l) correspond to areas not impacted, and provide no connection to long-range transport of selenium. Revise the SAR text to ensure it is based on facts and not assumptions.	When a substance is detected in remote areas with no local and known sources, some type of transport mechanism is assumed. However a conclusion for long-range transport potential of selenium based on data from EC 2014l cannot be determined because it is not known if measured concentrations were from natural or anthropogenic sources.
	Regarding the phrase in Section 5.3.3.1: “selenium is expected to be essential for plant growth, but there are no data to confirm this (CCME 2009),” refer to Germ et al. (2007) for additional information.	The SAR text was revised to reflect the submitted comment.
	The reported endpoint values for the following species are too low: fathead minnow, Westslope cutthroat trout, brown trout, largemouth bass, bluegill, and rainbow trout.	The endpoint values for fathead minnow, Westslope cutthroat trout, brown trout, largemouth bass, bluegill, and rainbow trout were revised considering the submitted comments, the endpoint selection principles of the CCME (2007) protocol, and additional information available from United States Environmental Protection Agency (US EPA) (2015).
	Benthic invertebrates are less sensitive than fish to selenium. The SAR should conclude that benthic organisms are not at risk if an appropriate fish PNEC is developed.	The sediment PNEC calculation was revised. Since there is sufficient uncertainty on the relative species sensitivities of invertebrates, a PNEC for sediment was developed and used for this assessment, in addition to the revised fish PNECs.
	The soil PNEC of 1 µg/g dw is not scientifically sound and does not take into account benefits of soil supplementation. A soil PNEC should not be calculated.	The soil PNEC of 1 µg/g dw aligns with the Canadian Soil Quality Guideline for the Protection of the Environment and Human Health (SQG), in CCME (2009).

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	Include the predicted environmental concentration (PEC) characterization results of the detailed human health and ecological risk assessment in SARA (2009), which determined that selenium concentrations in soil are unlikely to cause direct toxic effects on terrestrial wildlife populations in the Greater Sudbury area.	The SARA (2009) soil concentrations were included in the PEC characterization for the base metals smelting and refining sector. Exceedances in comparison to the selected soil PNEC (Canadian Soil Quality Guideline, 2009) were noted.
	Revise the text in Section 6.3.4 of the SAR to indicate that the link between avian effects and selenium is only assumed, and that other factors such as a mixture may affect measured endpoints.	Text associated with Table 6-3 was revised.
	Bioaccumulation is a concern when it causes effects in populations and this has not been demonstrated.	To clarify this point, text in Section 6.6.2 was revised to read, "As a result, biological diversity and population-level effects may occur and potentially affect the stability of the food webs in certain areas in the Canadian environment."
Ecological Exposures	Due to historical inputs from mining activity and current inputs from wastewater effluent, measured environmental concentrations of water, fish tissue, and sediment cannot be attributed to local smelters alone. Replace the Schist Lake data with data from Phantom Lake or Big Island Lake found in Stantec (2009).	The Schist Lake data were retained because they show the highest exposure from the local smelter effluent releases and air emission combined. Phantom Lake and Big Island Lake only receive air emissions. Due to data limitations from the base metals smelting and refining sectors, the Schist Lake data are important to the overall weight of evidence. Tables in supporting document EC 2016d (previously EC 2014d) were updated with additional related information.
	Revise the water compartment discussion in section 6.6.4 to reflect that some of the measurements are dated, and may not represent recent/current exposure concentrations, especially where active management of selenium releases occurs.	The discussion concerning the water compartment in section 6.6.4 was revised. While recent data is preferred for risk characterization and was included where available, older data may also be considered.
	Some of the monitoring studies in the supporting documents for the base and precious metals mining sector and the smelting and refining sectors do not contain an adequate number of environmental or specimen samples to properly characterize exposure. In some cases, the sample size is unknown, which affects the robustness of the exposure characterization.	While larger datasets are preferable, small datasets are considered because they contribute to the overall weight of evidence. Sample sizes and data points from available studies are reported in the supporting documents.
	Make it clearer in the RMS document that only some mining operations have the potential to increase selenium concentrations in fish.	This point is reflected in the RMA.
	In Section 4.1.5 of the RMS document, page 11, adjust the text to reflect that the risk is a potential risk.	This point is reflected in the RMA.
	Using the provided text, update Section 5.2.2 of the RMS document, page 12-13, to clarify that not all coal mining regions of Canada encounter selenium enrichment.	Most of the proposed changes were made. However, the SAR still notes that releases of selenium from coal mines may pose a risk to both aquatic and sediment-dwelling organisms.
	Provide additional context in the SAR for naturally elevated levels of selenium in	Section 6.3.5 was updated with additional context for naturally elevated selenium

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	fish tissues in selenium enriched areas.	levels in fish tissues.
	Laliberté (2008) shows no significant difference in selenium fish tissue concentrations between impacted waterbodies and reference waterbodies. Further, fish tissue data from a reference waterbody contains the highest observed concentration. This is also the case for fish egg data in McDonald (2010), although in this study the median for impacted waterbodies is significantly higher than for the reference waterbody.	The Laliberté (2008) data were reconsidered and reference waterbodies and impacted waterbodies were reclassified. A footnote was added to supporting document tables to note where maximum fish tissue concentrations for reference water bodies in Laliberté (2008) and McDonald (2010) exceeded the range for the exposed waterbodies.
	The upper bound PECs for metal mining in Figure 6-3 should be modified to remove the Canadian Nuclear Safety Commission (CNSC) 2006 data and to replace the upper bound with that in Muscatello et al. (2006), or MacDonald et al. (2010).	Figure 6-3 incorporates data from a variety of fish species in order to account for variations in selenium uptake and sensitivity. Therefore, the CNSC 2006 data, which contains Lake Whitefish data, was retained and contributes to the overall weight of evidence. Where recent data is not available, older data may be used.
	Confirm the origin of the median estimated fish tissue value in Figure 6-5 for the mining sector.	The median estimated fish tissue value was derived from the surface water data in Lemieux et al. (2004).
	The base metals smelting and refining graph in Figure 6-5 contains data from a single reference. Based on sample size, this value should not be considered adequate to characterize selenium exposure.	No change was made because this reference contributes to the overall weight of evidence.
	A single high value in a given data set can have significant impact on figures in the SAR. Consider applying a different exposure metric to large datasets (for example, averages) to minimize the impact of a large dataset.	Figures 6-3 through 6-7 summarize exposure concentrations by displaying the range (error bars) and the minimum and maximum median or mean (solid bars) for a given sector. Although this does not show distribution of concentrations, greater context is provided in the supporting documents. No change was made.
	Regarding the coal mining and base and precious metals mining supporting documents, the implication that tailings may be uncontrolled is inappropriate and should be removed.	No change was made because the text in the supporting documents presents the potential for accidental releases, which were reported previously in Canada.
	Further consideration of bioaccumulation and persistence of selenium and its various species must be incorporated into the SAR.	The selenium moiety, and thus all species of selenium found in the environment, meets criteria set out in the Persistence and Bioaccumulation Regulations of CEPA 1999.
	Clarify how an assessment of the potential long-term effects could be captured through a PNEC.	The PNEC for selenium is derived from chronic (long-term), sensitive reproduction-based endpoints for multiple fish species. This is further detailed in the Synopsis.
	The assessment may not properly account for research on selenium that identifies concern regarding environmental effects on fish reproduction and developmental deformities.	The scientific consensus is that freshwater fish are the most sensitive aquatic organisms to selenium. Reproductive and developmental effects studies were evaluated for several fish species.

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	Revise the characterization of ecological risk in Section 6.6 of the SAR based on comments provided on PNECs and environmental concentrations.	The section on characterization of ecological risk was revised following revisions to PNECs. PEC values were revised, and risk quotient (RQ) values for measured and estimated data were recalculated in Table 6-4.
Human Health Exposures	The risks associated with subsistence fishing are overstated and should not be associated solely with the mining industry. The work conducted by Lawrence and Chapman (2007) should be included. The only fish consumption advisory in Canada associated with a decommissioned mine, does not reflect current mining operations. Also, selenium blood concentrations for populations specifically downstream of metal mines were not presented in the SAR.	The elevated fish concentrations associated with several sectors and more information on fish consumption advisories in Canada was added. Information presented in Lawrence and Chapman was considered. Risks for subsistence fishers are based on measured concentrations in fish around mines and a health-based screening value for high fish consumption.
	Consider potential exposure from high end consumption of fish, in addition to average consumption.	The risk characterization section was revised with information regarding risks to high end consumers across several sectors.
	The fish consumption advisory for Beaverlodge Lake relates to a mine that operated from 1952 to 1982 that was decommissioned in 1985, and is not reflective of modern mines.	The RMA reflects that this consumption advisory relates to historical mining.
	Focus on the main environmental sources of selenium exposure in humans, rather than on natural health products.	The assessment considers total selenium (all forms) measured in humans, from environmental media, as well as in food, drinking water and products.
	Include more information on the presence of selenium in products, specific to different industries.	Products or scenarios that may result in high exposures are identified. Selenium levels in blood (used in the assessment to estimate population exposure) capture exposure from daily and frequent use products.
	Show that the best biomarker of selenium varies based on the source of selenium exposure and the form of selenium.	More information regarding the forms of selenium in different food sources and their biomarker suitability is now included.
	The reversibility of selenosis in humans should be more accurately characterized and an uncertainty factor (UF) of 1 or 1.1 should be used instead of the current UF of 2. This is further supported by the fact that selenosis has not been found in populations with elevated selenium blood concentrations.	UF greater than 1 is used because the toxic effects may not be reversible. Also, global populations with high exposures to selenium (i.e. China or India) show selenosis to be present. There is no available data for selenosis in Arctic general populations where very high selenium levels were detected.
	People can experience various adverse health effects when exposed to excess selenium through oral, dermal and inhalation routes. Take into account the toxicity of different forms of selenium and how it is distributed in the body in the human health assessment.	The exposure assessment focuses on systemic exposure to selenium, regardless of the route of exposure. The Toxicokinetic section was updated to account for distribution of different forms of selenium in the body. It is unclear whether different forms of selenium have differing toxicity in humans.
	The general public is unaware of the potential for selenium toxicity, because the wellness industry only promotes the beneficial health effects of selenium.	Noted. Human health risks associated with high levels of exposures to selenium among general populations are communicated to the general public through

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		various media including the SAR and the public summary.
	Reflect that the research by Yang et al. was primarily on adults, because very few children were included in the study, and the research is insufficient to rule out the occurrence of selenosis in children.	It is noted that the data set from Yang et al. is too small to rule out the occurrence of selenosis in children. Studies showing selenosis in children from other seleniferous regions such as India were referenced.
	The potential adverse effects of prolonged selenium exposure are particularly concerning due to the large number of First Nations communities across Canada that rely heavily on a traditional diet comprised primarily of fish and marine mammals. Give greater consideration to First Nation consumers, especially where traditional hunting/harvesting areas are near large sources and emitters of selenium.	First Nations were identified as a sub-population that has elevated exposure to selenium. The SAR was updated with additional data from the FNFES regarding selenium concentrations in traditional foods. This data and the potential for elevated exposure helped to determine the CEPA 1999 conclusion, harmful to human health.
	For Inuit in Nunavik, show that maximum values for selenium blood concentrations were found in adults, and not in children.	Maximum values of selenium blood concentrations for Inuit are now included.
	The Inuit Health Survey uses a blood concentration guideline of 1000 ppb. This is the level at which selenosis was observed in **other** human populations.	Noted.
	Several commenters were concerned that Health Canada was lowering the IOM Tolerable Upper Intake Level (UL). Clarify if the Government of Canada intends to change the recommended UL, Recommended Dietary Allowance (RDA), or Dietary Reference Intakes (DRIs) values for selenium.	Health Canada participated on the the National Institute of Medicine IOM UL review committee and did not propose lowering the IOM UL for selenium. The maximum daily dose of 400 µg/day based on the IOM's UL was applied in the assessment.This is for prevention of excess selenium exposure and associated health risks among general Canadian and U.S. populations.
	The safe level for selenium supplementation should be 300 µg per day based on dietary selenium intake of 100 µg per day and a UL of 200 µg per day, as derived by applying a UF of 1.0 to a (no-observed-adverse-effect-level (NOAEL)) of 200 µg from the clinical trial data.	Although the IOM had identified a UL of 400 µg per day for selenium, the proposed supplement limit is 200 µg per day to account for dietary intake.
	The DRI set for the general population in Canada and the U.S. should undergo a comprehensive review and be revised if needed based on data from the Canadian Community Health Survey Cycle 2.2 Nutrition, the Canadian Health Measures Survey as well as other relevant studies. Selenium is an essential nutrient, and this should be considered more in the assessment. Available epidemiological studies suggest that there is a beneficial effect of selenium on chronic health effects such as certain types of cancers and type II diabetics.	The Government of Canada’s key priority for food safety and nutrition encompasses healthy diets. However, no changes were made to the DRI because the purpose of CMP assessments is to determine toxicities associated with exposures to substances that may result in adverse effects to ecological and human health.
	The IOM UL is too conservative. Consider a higher effect level and/or a smaller uncertainty factor. It is unlikely adverse effects would occur with exceedances of	The IOM UL is considered to be an appropriate endpoint for the Canadian populations. It is adequate to protect exposure variations for individuals and

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	the IOM UL.	among sensitive sub-populations.
Risk Characterization	Several commenters recommended a different critical health endpoint for risk characterization, because they considered data from non-Canadian populations not relevant to the Canadian context, particularly Inuit populations. Inuit are exposed to a different form of selenium from traditional foods.	Selenosis occurs in many different populations around the world, beyond the Chinese population. This endpoint is considered to be relevant to Canadian populations, including Inuit populations in northern Canada.
	Include a broad discussion on selenium speciation and the associated risks for each species rather than moiety based conclusion.	Relevant information regarding selenium speciation, including factors such as natural variation in pH, temperature, hydrology, and biotic activity, was updated and discussed along with the toxicokinetics of various forms of selenium in humans. A moiety approach was applied for risk characterization because the toxicological effects of different forms of selenium in humans are not clear, and exposure data for selenium in humans and environment media is measured as total selenium.
	Review the proposed PNEC values and calculation methods to ensure they inform development of accurate and sound risk management tools. The PNEC value should be based on reproductive impairment, rather than the current whole-body PNEC, which is unreasonably low and is based on unreliable and questionable studies.	The egg-ovary PNEC was updated. Species mean values for multiple species were corrected. Unreliable studies were removed from the dataset, and one additional species was added. The whole-body PNEC is now calculated from the same reproductive egg-ovary endpoints using species-specific conversion factors developed by the US EPA (US EPA 2015).
	In the base metals smelting and refining supporting document, distinguish between stand-alone smelters and refineries and those which share a contiguous site with activities considered “mining or milling,” such as tailings disposal. Stand-alone smelters and refineries do not produce tailings or waste rock. By overlooking that aspect, the risk characterization of smelters and refineries incorporates risk characterization of metal mines and may confuse subsequent consideration of the need for risk management.	Stand-alone smelters and refineries are now defined separately from those that are located on mining sites (and are therefore subject to the MMER. The RMA for stand-alone facilities differs from the RMA for facilities subject to the MMER.
Conclusion	Several public commenters disagreed with the proposed human health conclusion.	Noted.
	The assessment concludes that despite the risk of harm to organisms and biodiversity, there remains no risk to the broad integrity of the environment. This conclusion requires further explanation and clarification. Cumulative effects must be a consideration if a risk assessment is to be accurate and relevant.	The species sensitivity distribution was revised to include only studies that identify a link between selenium exposure and eco-toxicological effect. An aggregate exposure approach and consideration of effects data for the selenium moiety were applied.
	Clearly explain that Inuit are exposed to selenium from natural sources and if the	The SAR acknowledges that Inuit are exposed to selenium from natural sources.

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	Inuit sub-population was extracted from the study, there would be no basis for 64(c) of CEPA 1999 toxic conclusion.	The extent of contribution to accumulation of selenium in the environment from human activity has not been fully investigated. The conclusion is based on the potential risk of elevated exposures and related risks for three sub-populations in Canada: 1) some Inuit populations in Northern Canada maintaining a traditional diet of marine mammals; 2) subsistence fishers consuming fish with high concentrations of selenium; and 3) those taking vitamin/mineral supplement with the maximum permissible level of selenium. The Government of Canada will address the concerns identified in the draft Screening Assessment report, including those identified in specific sub-populations.
	The information presented in the risk characterization section does not support the statement "Accordingly selenium and its compounds may be harmful to human health."	Information was added to the risk characterization section to increase the transparency for the evidence used to support the harmful to human health conclusion.
	The conclusion for human health on selenium may discourage consumption of country foods when risks from consumption of these foods are minimal. More information should be included to encourage the consumption of country foods.	The focus of the assessment is to identify and evaluate environmental and health risks related to exposures to elevated levels of selenium, and does not discuss the benefits of consuming country foods. However, the benefits of consuming country foods are recognised as many (e.g. nutritional, social, cultural, etc.), and these benefits would need to be weighed against the risks by appropriate health experts or regulators such as Health Canada's Health Products and Foods Branch, and/or provincial / territorial health authorities.
Risk Management	Characterize the types of rules and regulations that would be put in place for those working with selenium in the capacity of the health and nutritionals industry (i.e., mandatory use of personal protective equipment).	CMP outcomes may influence occupational health and safety regulations developed by other federal authorities, as well as provincial and territorial governments. However, risk management is not proposed for occupational exposures because risks relating to these types of exposures were not identified in the assessment. The Canada Occupational Health and Safety Regulations provide information on protection from hazardous substances in federally regulated occupational settings. In general, rules and regulations for minimising health risks associated with occupational use of selenium in the health and nutritional industry are likely to be specified under provincial and territorial legislation.
	The regulation of selenium supplements should consider the forms of selenium.	Several studies observed that the following common selenium supplements were absorbed in greater amounts: L-selenomethionine, sodium selenate, sodium selenite, and selenium yeast. The Food and Drug Regulations regulate the amount of selenium permitted or required in special dietary foods, such as meal

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		replacements and formulated liquid diets.
	The human health objective does not apply to all age groups as the recommended UL is lower for younger age groups. Senior citizens who are deficient in selenium should also be considered in the assessment.	The objective in the RMA was updated to reflect the comment. Dietary intake estimates for different age groups and genders are outlined, with an average intake of 200 µg per day within adult subpopulations.
	A science-based risk assessment is needed before changes are made to the maximum allowed level in vitamin/mineral supplements.	Potential risks are identified for Canadians who consume food and drinking water with typical levels (e.g. 200 µg/day) of selenium, and who also take multi-vitamin/mineral supplements that are high (e.g. 200 to 400 µg/day) in selenium. Based on information and public comments regarding regulatory proposals from Health Canada (2015 to 2016), the maximum allowed level of selenium in vitamins/mineral supplements has been proposed to be reduced from 400 to 200µg/day.
	Health Canada should plan to put warnings on packages of Brazil nuts because they contain a high level of selenium.	Health Canada does not plan to add warnings on Brazil nut package labels regarding selenium because they make a very minor contribution to overall dietary exposures to selenium in Canada
	Indicate if there will be new labeling or importing requirements for selenium-containing compounds or products.	There are no proposed changes to the labeling requirements for ingredient listing, or requirements for importing selenium, selenium compounds, or products containing selenium, other than certain high selenium vitamins/mineral supplements which are already labelled. However, risk management instruments are subject to change upon review of any new information and further consultation with stakeholders.
	Include a timeline for requested changes or implementation of restrictions to manage some of the identified sources that pose minimal risk.	A timeline for proposed actions regarding selenium is included in the RMA. If needed, additional regulations or instruments will be developed within these timeframes or afterwards. For regulations or instruments proposed under the CEPA 1999, any planned public consultations will be announced in the Environmental Registry and/or the Canada Gazette, Part I.
	Provide an electronic mechanism to alleviate the additional administrative and financial burden to importers that may result if new selenium reporting requirements are implemented.	There are no current plans to develop an electronic mechanism for selenium importers, because the RMA does not propose to create new importing requirements for selenium or any products containing selenium.
	Indicate if the MMER will apply to coal mines, in the interim, while new regulatory approaches for coal mines are considered.	The MMER do not apply to coal mines. For coal mines and other sectors that do not have prescribed risk management instruments for selenium, the Fisheries Act general prohibitions for managing selenium releases and disposal will apply.

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	The CNSC, under the authority of the Nuclear Safety and Control Act (NSCA), has been managing selenium releases from uranium mines mills to protect human health and the environment for more than a decade. To avoid regulatory overlap, uranium mining and milling should be excluded from risk management actions under CEPA 1999.	The RMA was revised to document the existing legal framework for the CNSC to manage selenium releases from uranium mines and mills. The CNSC will continue managing releases of selenium from uranium mines and mills, and work with ECCC by monitoring selenium releases, to determine if additional measures are required.
	The environmental objective in the RMS document should align with the benchmark used in the SAR, as well as with the human health objective.	The environmental objective was revised to reflect the intent of the CEPA 1999, and references important considerations for risk management activities, including selenium levels in the environment that may contribute to adverse effects.
	It is important to maintain consideration for economic and socioeconomic factors throughout the risk management process.	The Government of Canada is committed to consulting stakeholders, including on economic and socioeconomic factors, before applying risk management measures or refining/developing risk management proposals and instruments.
	It is encouraging that economic feasibility and appropriateness are mentioned alongside the discussion of additional control technologies as a risk management consideration to releases.	Noted.
	The RMA should recognize that the fish consumption advisory is related to decommissioned facilities, and that the EEM, under the MMER, provides broad protection to fish populations.	The RMA was revised to reflect these comments.
	The Government of Canada should demonstrate how the Wastewater Systems Effluent Regulations (WSER) reduce selenium releases from wastewater systems. Furthermore, the capacity of wastewater systems used by metal mines should be recognized as a risk management measure for selenium, especially since the MMER requires testing for selenium in mine effluent and downstream monitoring programs.	Detection of selenium in sludge and biosolids supports the assumption that selenium releases to surface water can be reduced, to a certain extent, by primary and secondary treatment.
	If it is acceptable to wait decades to curb selenium emissions from coal fired power plants, the same timeline should be provided for other emitters.	Based on available information and characteristics of risks identified for each source, the proposed action may involve different requirements and timelines.
	Data from the NPRI show that municipalities are among the highest emitters of selenium to water in Canada. The Government of Canada should collect additional information on wastewater systems and present it in the next version of the SAR and the risk management document. Wastewater systems should be given the same scrutiny as the other high emitting sectors.	Information for characterizing risk and developing proposed measures for managing wastewater systems in municipalities is collected using public sources, reporting requirements under the WSER, the CMP's Monitoring and Surveillance Program, and other sources of information as required. Where appropriate, new information for refining the risk characterization or proposed actions for this sector is found in the related documents. No new information was added to the assessment.

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	Incinerating old prescriptions that may contain selenium under the Medicines Return Program does not contribute to environmental concerns.	Incinerated medical waste was not identified as a key ecological exposure scenario in this assessment.
	Where the run-off of water from mines tailings and waste rocks is discussed, the supporting document on oil sands (EC 2014g) is referenced. It should be replaced with an appropriate reference.	The references in the RMA were updated.
	A submitter provided information on operation of their coal-fired power plants, including waste management, to explain how their facilities do not release selenium to the environment through the use of closed-loop systems.	The RMA was revised to reflect that certain wastewater management processes for coal-fired power plants in Canada potentially reduce environmental discharge of contaminants, including selenium.
	Stakeholders should have access to selenium information collected under the Fish Contaminants Monitoring and Surveillance Program (FCMSP).	Data generated by the FCMSP are summarized throughout the SAR and supporting documents. This data is available upon request from a database stored at the Canada Centre for Inland Waters in Burlington, Ontario.
	Include in the RMA an overview of oversight provided by provincial and federal regulatory authorities for the mining, smelting and refining sectors. Mandatory environmental assessments for most industrial sectors should also be covered.	The RMA was updated with the suggested information.
	Update the CCME agriculture guidelines for selenium, which were published in 1987, to reflect recent scientific findings.	Although the CCME may reference CMP results when developing and approving water and soil quality guidelines, it is not the responsibility of the CMP to determine CCME priorities.
	In the RMS document, effluent regulations for metal mines are discussed but not the co-benefits of effluent treatment. Co-benefits of existing regulations on selenium releases should be reflected fairly for all sectors.	The RMA was revised to provide clarification.
	The Quebec surface water quality guideline referred to in the RMS document is adopted from the US EPA. The original source should be referenced.	While Quebec adopted the US EPA guideline, the text reflects the decision of the province. Therefore, no changes were made to the documents.
	The risk management document should be revised with updated draft selenium criterion that was released for public comment by the US EPA in 2015.	The RMA was updated with the information published in the US EPA 2015 draft.
	Develop a regulatory tool under the Fisheries Act to manage the releases of selenium from coal mines. The coal mining regulations should account for sound science, recognize existing provincial and territorial policies and permits, and consider the cost and effectiveness of control technologies. Furthermore, the regulations should use a tiered, site-specific or area-based approach focusing on fish health.	The Government of Canada will consider all feedback and information received while developing a regulatory approach for selenium releases from coal and metal mines. The Government continues to encourage stakeholder participation to inform decisions.
Stakeholder and	The agricultural sector has not reported releases to the NPRI. Data should be	The Government of Canada has requested new information from stakeholders to

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Public Consultations	requested, or research conducted, to quantify the influence of agriculture practices on selenium concentrations in surface water. Include this information in the next version of the SAR and in the revised RMS.	help quantify the contribution of agricultural practices to selenium levels in the environment. All CMP assessed substances are subject to future evaluation if new, significant information is provided that indicates a need for further consideration.
	A submitter recommended that it not be subject to additional risk management for selenium, based on results of recent environmental monitoring data.	Environmental performance information provided by facilities will be considered if a risk management instrument is developed.
	Public consultation must be part of Federal Environmental Quality Guidelines (FEQG) development and publication, and the public should be informed of the Government of Canada's future work on selenium. The published RMA should be followed by another consultation period, and a daily recommended intake review be undertaken if proposing changes to the tolerable UL.	Development of FEQG for selenium and changes to the UL are not intended at this time. However, consultation with stakeholders is an essential part of the risk management process, and the Government of Canada will consult with all affected stakeholders when developing risk management guidance and requirements. Stakeholders who wish to be informed of future decisions are encouraged to complete and submit a Declaration of Stakeholder Interest. The published RMA will be subject to a 60-day public comment period.
	Outcomes of the selenium sub-group discussions during the 10-Year Review of the MMER should be taken into consideration when developing a regulatory approach for the release of selenium from coal and metal mines.	The Government of Canada will consider comments and information gathered during consultation periods, including outcomes from the 10-Year Review of the MMER when refining the regulatory approach for selenium discharges from metal mining and coal mining.

References

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