CEAA 44

Initial Reviewer Question (HC-IR-8 Round 1 Part 2, June 29 2016)

Section 2.8.3 presents the proposed magnitude (i.e. acceptability) of risk for both non-carcinogens and carcinogens. However, the proposed 'acceptable' risks are not consistent with Health Canada guidance. The report identifies that for non-carcinogens, a low and likely to be negligible risk is defined as being a hazard quotient of 1.0 to ≤10 and a potentially elevated risk is defined as a hazard quotient >10.

The report identifies that for carcinogens, a low and likely to be negligible risk is defined as an incremental lifetime cancer risk (ILCR) of 1x10-5 to ≤1x10-4, and a potentially elevated risk is an ILCR >1x10-4.

These values are higher than Health Canada's acceptable target hazard quotient of <1 and Health Canada's acceptable ILCR of <1x10-5. No rationale was provided by the consultant to identify how levels above the targets identified by Health Canada would be protective of health.

Initial AECOM Response:

• AECOM wishes to clarify that section 2.8.3 is not to be considered a revision of Health Canada policy on acceptable risk. In section 2.8.2, AECOM provides a discussion of Health Canada policy on risk levels that are referenced within federal policy. AECOM also provides in section 2.8.2 federal rationale for the present case that a hazard quotient of 1.0, rather than 0.2, is appropriate (i.e., because of consideration of multiple dietary and non-dietary sources of metals intake). These federal policies are not disputed in section 2.8.2 or in 2.8.3. However, in section 2.8.3, AECOM presents its position on risk interpretation from its perspective as the HHRA author with unique appreciation for conservatism inherently applied through various risk assessment assumptions. We consider this useful insight to the reviewer and stakeholders. To this end AECOM has articulated its professional opinion by considering both federal policy (as discussed in section 2.8.2) , and the numerous conservative assumptions applied throughout the risk analysis (e.g., numerous air modelling conservative assumptions, receptor bioavailability assumptions, dust deposition assumptions., etc) to provide meaningful interpretive categories for the ensuing risks and their magnitudes. To reiterate the example of Hazard Quotient categories, AECOM is of the confident opinion that given the considerable conservative assumptions applied for the HHRA:

- HQ < 1.0 will be negligible
- 1.0>HQ≤10 will be low and likely negligible
- HQ>10 is a potentially elevated risk

CEAA Follow-up Comment, October 28 2016)

Following the review of CEAA 44 (Round 1 – Part 2), in order to understand the effects to the health of Indigenous groups, Health Canada recommends the following as acceptable standards to use in the determination of significance of an effect on human health: <1.0 for a HQ for non-carcinogens; <1.0E-5 (<1 x 10^{-5}) for incremental increases in lifetime cancer risk (ILCR) associated with project-related activities. For non-cancer risks, where HQs >1.0 currently exist in the baseline scenario, the predicted change as a result of the project should be discussed with a narrative and compared to baseline conditions to determine significance (e.g. baseline HQ is 1.4 and future HQ is predicted to be 1.6). For carcinogens, the incremental increase in lifetime cancer risk associated with project activities should be evaluated; if that incremental increase exceeds 1 x 10^{-5}, additional mitigation should be presented, as appropriate.

Specific Request to Address Comment

Provide a discussion for the predicted potential effects to human health as a result of the Project for non-cancer risks where HQs >1.0 currently exist in the baseline scenario and are predicted to increase as a result of project activities. Compare prediction to baseline conditions when determining significance (e.g. where baseline HQ is 1.4 and future HQ is predicted to

be 1.6). Update effects assessment conclusions and the recommended mitigation measures where elevated non-carcinogenic risks are predicted as a result of project activities, where applicable.

Evaluate the incremental increase in lifetime cancer risk associated with Project activities. If that incremental increase exceeds 1.0E-5, indicate whether additional mitigation measures that will be implemented, as well as present a revised environmental effects analysis.

AECOM Follow-up Response

In responding to request CEAA 44, we have consolidated and attached the numerical risk results in Tables 1, 2 and 3 for convenience in viewing numerical risk estimates for the Baseline, Project and Cumulative scenarios. These tables provide HQ and ILCR for threshold effect endpoints and carcinogenic endpoints, respectively. In the present case the results for *threshold* effect endpoints are limited to the Toddler receptor because this receptor elicits a greater exposure rate than Adults; cancer risks expressed as ILCR reflect a composite receptor as previously requested by CEAA . These tabulated results incorporate previous revisions (relative to those originally filed in the HHRA) that were communicated to CEAA in September 2016 (i.e., account for revised inhalation and water ingestion rates by Toddlers). The tables provide the following insight:

- Table 1 addresses predicted hazard quotients for the Toddler receptor and indicates:
    - With the exception of arsenic, all *HQs greater than unity in the Baseline scenario are predicted to remain unchanged or decrease in the Project and Cumulative scenario*.
    - HQ for mercury remains unchanged because it is driven by measured fish tissue levels which are not expected to change due to the mine water management plan.
    - HQs for iron, lead and manganese decrease because the modelled future Project and Cumulative scenarios use predicted exposure point concentrations (based on peer-reviewed published metal transfer factors) rather than Baseline empirical data for berries, small game birds and small mammal game
    - In the case of arsenic the Baseline total HQ = 2.7. The risk estimate is primarily driven by dietary As (HQ m= 1.2) modelled from caribou meat consumption in which the tissue concentration was the maximum reported from several published studies of tissue quality from other parts of Canada (see original HHRA technical report). The secondary As contributor to the total HQ is berry consumption (HQ = 0.8; however analyzed As in berries was non-detectable and this HQ was derived by use of a soil-to-berry transfer factor for Baseline) and the tertiary is fish consumption (HQ = 0.43). The As total HQ increases marginally by 0.4% for the Project and Cumulative scenarios, with differences between the Project and Cumulative results being too insignificant to detect in our calculations. The change is attributed to modelled future berry consumption and associated dry dust deposition. The increment is a calculated (theoretical) result and in our opinion beyond resolution of prospective HHRA which inherently includes uncertainty and conservative assumptions.
- Table 2 addresses ILCR for arsenic intake via combined intake from ingestion and dermal absorption, and indicates:
    - The Baseline ILCR for arsenic via ingestion and dermal absorption is 5.80E-4
    - The Project scenario ILCR for arsenic via ingestion and dermal absorption is 5.82E-4, yielding a predicted incremental increase in Project ILCR of 2.27E-6, which is considered a negligible increment according to Health Canada Guidance on Human Health Risk Assessment. (The calculation has been refined using the media value to reflect the most probable long-term mass of arsenic deposition to berry surfaces following 30day with no precipitation)
    - The Cumulative scenario ILCR for arsenic via ingestion is 5.84E-4, yielding a predicted incremental increase in Project ILCR of 3.44E-6, which is considered a negligible increment according to Health Canada Guidance on Human Health Risk Assessment. (The calculation has been refined using the median value to reflect the most probable long-term mass of arsenic deposition to berry surfaces following 30day with no precipitation)
- Table 3 addresses ILCR for carcinogen exposures (As, Be, Cr) via inhalation and indicates:

- ILCRs for Baseline, Project and Cumulative scenarios are all less than 1E-5
- Incremental increases in ILCRs for the Project scenario are less than 1E-5.
- The above ILCRs and their predicted changes are negligible.

Mitigation and/or Monitoring:

The Proponent recognizes that:

- The calculated Baseline risks reported herein are predicated on conservative exposure assumptions and such assumptions are a widely practiced precautionary approach to managing potential human health risk of new projects.
- The calculated Project and Cumulative scenarios reported herein yield negligible *incremental* risk (HQ<1.0, or incremental ILCR<1E-5), and that the total potential risk, although in some cases considered significant, are driven by the estimated Baseline risk.

In light of the above, the proponent does not propose *additional* mitigative efforts beyond those described in the EIS and supplemental in responses to previous CEAA questions. Instead the Proponent proposes to focus their resources on monitoring as a first step to improve/validate exposure assumptions intrinsic to the estimated human health risks and resolving if additional mitigation is warranted. The scope of monitoring is summarized as follows:

- The Proponent is committed to duplicating the country food sampling program, conducted in summer/fall 2015 for the Howse Property EIS, 2 years after the commencement of the Howse Operations phase and, subsequently, every 5 years for the duration of the operations phase. Please refer to Supporting Study D of the Howse Property EIS for a full description of the sampling methods.
  - Results would be reported during Health and Safety Committee meetings (held 3-4 per year) and a copy of these reports will be submitted to Health Canada.
  - In the event of increases of contaminants in any of these foods, the proponent will conduct a new Human Health Risk Assessment. Subsequently, a targeted action plan (results-dependent) will be implemented.
- The Proponent is committed to conducting air quality monitoring, including total suspended matter and associated chemistry to inform/update assumptions associated with direct (inhalation) and indirect (food quality, dust, soil) exposure pathways. The details of the air quality monitoring program are provided in the Environmental Impact Statement Volume 1, Appendix XXIV.

Table 1. Predicted Hazard Quotients and percent change from baseline scenario () for Toddler Receptor.

	PCOC	Soil Ingestion	Particulate Inhalation	Soil Dermal Contact	Surface Water Ingestion	Berry Consumption	Labrador Tea Consumption	Game Bird Consumption	Small Mammal Consumption	Large Mammal Consumption	Fish Consumption	Total
Baseline Assessment	Arsenic	1.74E-01	7.20E-05	4.48E-03	6.06E-02	7.97E-01	0.00E+00	4.85E-02	3.18E-03	**1.18E+00**	4.30E-01	**2.70E+00**
	Barium	8.36E-05	4.96E-07	1.03E-04	6.00E-04	7.11E-02	0.00E+00	2.01E-04	2.39E-03	0.00E+00	1.69E-03	7.62E-02
	Berylium	6.28E-07	3.72E-08	7.71E-05	1.82E-04	1.72E-05	0.00E+00	1.13E-05	1.80E-07	0.00E+00	1.82E-03	2.11E-03
	Chromium (2017)	1.21E-03	3.85E-05	7.98E-03	9.09E-02	8.87E-02	0.00E+00	3.53E-05	2.67E-02	0.00E+00	3.64E-02	2.52E-01
	Cr (Sept-2016)	1.26E-05	4.02E-07	8.34E-05	9.09E-02	9.27E-04	0.00E+00	3.53E-05	3.59E-04	0.00E+00	3.64E-02	1.29E-01
	Iron	3.40E-01	1.41E-04	2.93E-02	5.61E-02	4.95E-01	0.00E+00	1.01E-01	1.39E-02	2.32E-01	3.74E-02	**1.30E+00**
	Lead	8.37E-02	3.47E-05	7.20E-02	9.09E-03	1.60E-01	0.00E+00	4.03E-01	3.05E-02	8.25E-01	3.64E-02	**1.62E+00**
	Manganese	1.68E-03	1.74E-05	3.61E-02	2.78E-02	**1.71E+00**	0.00E+00	5.47E-03	8.01E-03	0.00E+00	6.23E-03	**1.79E+00**
	Mercury	1.94E-03	8.05E-07	1.67E-03	9.09E-03	7.05E-02	0.00E+00	1.54E-02	3.32E-03	7.95E-01	**5.73E+00**	**6.62E+00**
	Molybdenum	4.72E-07	1.96E-10	4.06E-09	7.91E-07	3.01E-05	0.00E+00	8.74E-07	4.92E-08	0.00E+00	7.91E-07	3.31E-05
	Selenium	6.26E-07	2.60E-10	5.38E-09	8.80E-06	1.52E-06	0.00E+00	7.40E-05	5.77E-07	8.88E-05	8.74E-04	1.05E-03
Project Assessment	Arsenic	1.74E-01	2.11E-04	4.48E-03	6.06E-02	8.00E-01	0.00E+00	5.48E-02	3.19E-03	**1.18 (0%)**	4.30E-01	**2.71 (0%)**
	Barium	8.38E-05	1.19E-06	1.03E-04	6.00E-04	4.77E-04	0.00E+00	2.14E-05	2.96E-04	0.00E+00	1.69E-03	3.27E-03
	Berylium	6.29E-07	1.69E-07	7.73E-05	1.82E-04	1.81E-05	0.00E+00	1.14E-05	1.81E-07	0.00E+00	1.82E-03	2.11E-03
	Chromium	1.21E-03	9.32E-05	7.99E-03	9.09E-02	9.01E-02	0.00E+00	1.20E-03	2.68E-02	0.00E+00	3.64E-02	2.55E-01
	Cr (Sept-2016)	1.46E-05	6.68E-05	9.69E-05	9.09E-02	1.01E-02	0.00E+00	4.18E-05	5.05E-04	0.00E+00	3.64E-02	1.38E-01
	Iron	3.41E-01	9.33E-04	2.94E-02	5.61E-02	1.58E-01	0.00E+00	9.61E-02	7.45E-03	2.32E-01	3.74E-02	0.95 (-27%)
	Lead	8.38E-02	8.37E-05	7.20E-02	9.09E-03	1.61E-01	0.00E+00	1.82E-02	3.06E-02	8.25E-01	3.64E-02	**1.24 (-24%)**
	Manganese	1.68E-03	2.43E-05	3.61E-02	2.78E-02	1.23E-01	0.00E+00	1.70E-04	2.65E-03	0.00E+00	6.23E-03	**0.20 (-89%)**
	Mercury	1.94E-03	2.31E-04	1.67E-03	9.09E-03	7.05E-02	0.00E+00	2.75E-04	3.33E-03	7.95E-01	**5.73 (0%)**	**6.61 (0%)**
	Molybdenum	4.72E-07	3.39E-10	4.06E-09	7.91E-07	3.01E-05	0.00E+00	3.44E-07	4.93E-08	0.00E+00	7.91E-07	3.26E-05
	Selenium	6.26E-07	3.13E-10	5.38E-09	8.80E-06	1.52E-06	0.00E+00	2.43E-06	5.78E-07	8.88E-05	8.74E-04	9.77E-04
Cummulative Assessment	Arsenic	1.74E-01	5.53E-04	4.49E-03	6.06E-02	8.07E-01	0.00E+00	5.52E-02	3.21E-03	**1.18 (0%)**	4.30E-01	**2.71 (0%)**
	Barium	8.42E-05	2.98E-06	1.03E-04	6.00E-04	4.97E-04	0.00E+00	2.18E-05	3.01E-04	0.00E+00	1.69E-03	3.30E-03
	Berylium	6.31E-07	4.72E-07	7.75E-05	1.82E-04	1.89E-05	0.00E+00	1.15E-05	1.84E-07	0.00E+00	1.82E-03	2.11E-03
	Chromium (Jan-2017)	1.21E-03	2.34E-04	8.02E-03	9.09E-02	9.19E-02	0.00E+00	1.22E-03	2.72E-02	0.00E+00	3.64E-02	2.57E-01
	Cr (Sept-2016)	1.91E-05	2.08E-04	1.27E-04	9.09E-02	5.66E-02	0.00E+00	5.60E-05	8.28E-04	0.00E+00	3.64E-02	1.85E-01
	Iron	3.43E-01	2.70E-03	2.95E-02	5.61E-02	1.64E-01	0.00E+00	9.78E-02	7.58E-03	2.32E-01	3.74E-02	**0.97 (-27%)**
	Lead	8.39E-02	2.10E-04	7.22E-02	9.09E-03	1.63E-01	0.00E+00	1.84E-02	3.08E-02	8.25E-01	3.64E-02	**1.24 (-24%)**
	Manganese	1.68E-03	5.01E-05	3.61E-02	2.78E-02	1.24E-01	0.00E+00	1.71E-04	2.65E-03	0.00E+00	6.23E-03	**0.20 (-89%)**
	Mercury	1.94E-03	7.18E-04	1.67E-03	9.09E-03	7.06E-02	0.00E+00	2.75E-04	3.33E-03	7.95E-01	**5.73 (0%)**	**6.61 (0%)**
	Molybdenum	4.73E-07	7.70E-10	4.07E-09	7.91E-07	3.02E-05	0.00E+00	3.45E-07	4.95E-08	0.00E+00	7.91E-07	3.27E-05
	Selenium	6.26E-07	5.95E-10	5.38E-09	8.80E-06	1.52E-06	0.00E+00	2.43E-06	5.79E-07	8.88E-05	8.74E-04	9.77E-04

Note: Percent change only calculated for HQ's which exceed the de Minimis value of HQ=1.

Table 2. Predicted Arsenic Incremental Lifetime Cancer Risk via Combined Ingestion and Dermal Contact for a Composite Receptor.

Exposure Scenario	ARSENIC Oral Cancer Slope Factor (mg/kg bw/day)-1	Revised Total Oral Dose (mg/kg bw/day)				Weighted Cancer Risk Estimate				**TOTAL ORAL ILCR (Sept 2016)**	**Incremental Change from Baseline**
		Toddler	Child	Teen	Adult	Toddler	Child	Teen	Adult		
		Fraction of 80 yr. lifetime				Fraction of 80 yr. lifetime					
		0.06	0.09	0.1	0.75	0.06	0.09	0.1	0.75		
Baseline	1.8	8.09E-04	3.89E-04	2.17E-04	2.89E-4	8.73E-05	6.31E-05	3.90E-05	3.91E-04	**5.80E-04**	
Project	1.8	8.12E-04	3.91E-04	2.17E-04	2.91E-4	8.77E-05	6.33E-05	3.91E-05	3.92E-04	**5.82E-04**	2.27E-06
Cumulative	1.8	8.14E-04	3.92E-04	2.18E-04	2.91E-4	8.79E-05	6.35E-05	3.92E-05	3.93E-04	**5.84E-04**	3.44E-06

Table 3. Predicted Incremental Lifetime Cancer Risks of As, Be and Cr via Inhalation for a Composite Receptor.

COPCs/Exposure Scenario	Inhalation Cancer Slope Factor (mg/kg bw/day)-1	Revised Total Inhalation Dose (mg/kg bw/day)				Weighted Cancer Risk Estimate				**REVISED TOTAL INHALATION ILCR**	**Incremental Change from Baseline**
		Toddler	Child	Teen	Adult	Toddler	Child	Teen	Adult		
		Fraction of 80 yr. lifetime				Fraction of 80 yr. lifetime					
		0.06	0.09	0.1	0.75	0.06	0.09	0.1	0.75		
Baseline											
Arsenic	27	2.16E-08	1.89E-08	1.12E-08	1.00868E-08	3.50E-08	4.60E-08	3.03E-08	2.04E-07	3.16E-07	NA
Berylium	7.3	7.44E-10	6.52E-10	3.87E-10	3.47496E-10	3.26E-10	4.29E-10	2.82E-10	1.90E-09	2.94E-09	NA
Chromium	46	3.85E-08	3.37E-08	2.00E-08	1.79571E-08	1.06E-07	1.40E-07	9.19E-08	6.20E-07	9.57E-07	NA
Project											
Arsenic	27	6.33E-08	5.55E-08	3.29E-08	2.95519E-08	1.03E-07	1.35E-07	8.88E-08	5.98E-07	9.25E-07	6.09E-07
Berylium	7.3	3.38E-09	2.96E-09	1.75E-09	1.57587E-09	1.48E-09	1.94E-09	1.28E-09	8.63E-09	1.33E-08	1.04E-08
Chromium	46	9.32E-08	8.16E-08	4.84E-08	4.34793E-08	2.57E-07	3.38E-07	2.23E-07	1.50E-06	2.32E-06	1.36E-06
Cumulative											
Arsenic	27	1.66E-07	1.45E-07	8.61E-08	7.73707E-08	2.69E-07	3.53E-07	2.32E-07	1.57E-06	2.42E-06	2.11E-06
Berylium	7.3	9.44E-09	8.27E-09	4.90E-09	4.40511E-09	4.13E-09	5.43E-09	3.58E-09	2.41E-08	3.73E-08	3.43E-08
Chromium	46	2.34E-07	2.05E-07	1.22E-07	1.09263E-07	6.46E-07	8.49E-07	5.59E-07	3.77E-06	5.82E-06	4.87E-06