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Dec. 15, 2021

Sent by e-mail to: Lachlan.Maclean@iaac-aeic.gc.ca and boatharbour@iaac-aeic.gc.ca

Subject: Health Canada's Technical Review of the Proponent's Responses to the Round One (Part Two) Information Requirements for the Boat Harbour Remediation Project

Dear Lachlan MacLean:

Thank you for your email dated November 15, 2021 requesting Health Canada's technical review of the proponent's responses to the Round One (Part Two) Information Requirements (IRs) issued by the Impact Assessment Agency of Canada (IAAC) on October 19, 2021 for the Boat Harbour Remediation Project (BHRP). Health Canada is participating in the environmental assessment process as a Federal Authority under the *Canadian Environmental Assessment Act, 2012*.

Health Canada has reviewed the proponent's responses to IRs IAAC-33, 36, 37, 39, and 62c and provided detailed technical comments for IAAC's consideration in the attached table. In summary, Health Canada identified the following major issues in the proponent's responses:

- Insufficient rationale to support the soil allocation factors used in the calculation of the site-specific target levels for vanadium and dioxins/furans;
- Insufficient rationale to support the exclusion of human consumption of terrestrial game mammals as an operable exposure pathway;
- Insufficient information on plant/berry tissue sampling, and lack of clarity regarding the operability of the country foods exposure pathway in the Upland Areas.

Should you have any questions regarding Health Canada's comments, please contact the undersigned.



Health
Canada

Santé
Canada

Sincerely,

<Original signed by>

Chantal Roberge

National Director, Environmental Health and Internationally Protected Persons Programs,
Regulatory Operations and Enforcement Branch (ROEB), Health Canada

cc:

Kathleen Buset, Director, Chemicals and Environmental Health Management Bureau,

Healthy Environments and Consumer Safety Branch (HECSB), Health Canada

Beverly Ramos-Casey, A/Atlantic Regional Manager, EHP, ROEB, Health Canada

Heather Jones-Otazo, A/Manager, Environmental Assessment and Contaminated Sites
(EACS) Division, HECSB, Health Canada

Ninon Lyrette, Senior Environmental Health Specialist, EACS, HECSB, Health Canada

Dae Young Lee, Impact Assessment Specialist, EHP, ROEB, Health Canada

Attachment: Health Canada's Technical Review of Additional Response to (November 15,
2021) Information Requirements – Boat Harbour Remediation Project

Technical Review of Additional Response to (November 15, 2021) Information Requirements – Boat Harbour Remediation Project

Use column 1 to link any new comments that arise from your review of the proponent responses to February 2021 IRs (now considered IR-1). Please continue to follow the naming scheme from IR-1 for any further potential IRs. For example, if in reviewing the response to the original IR (e.g. IR-53), you have an IR directed to the proponent, name it IR(2)-53. If multiple IRs arise from reviewing the response, use letters to demarcate further (e.g.: IR(2)-53a, IR(2)-53b, and so on).

The Agency believes that in some instances uncertainties can be resolved either through questions directed at the proponent, or by imposing follow-up measures to verify the proponents’ predictions. In these instances, the Agency would appreciate suggestions for follow-up measures in column 6 where there are uncertainties.

As mandated by the Government of Canada, in order facilitate the online posting of tables in an accessible HTML format, please note the inclusion of column headers in each field. Please leave this pre-entered information intact and include your entry on the line below it. If you require additional rows, please copy and paste to maintain formatting.

1	2	3	4	5	6	7
IR -1 Reference # (Original IR #)	IR #2 Number	Project Effects Link to CEAA 2012	Reference to EIS (including appendices)	Context and Rationale	Specific Question/ Proposed Follow-up Measure	Requires Technical Discussion
IR #: IAAC-33	IR Number: IR(2)-33	Project Effects Link to CEAA 2012: 5(1)(c)(i) Aboriginal Peoples Health/ socio-economic conditions Choose an item.	Reference to EIS: Appendix A Section 6.4.3 , PDF p. 166 The proponent’s response to IRs Section 2.2.2, pdf p.104 The proponent’s additional response to IRs Section 3, pdf p.6	Context and Rationale: Insufficient information/rationale is provided to support the soil allocation factors (SAFs) used in the calculation of the site-specific target levels (SSTLs) for vanadium and dioxins/furans. a) Vanadium The proponent’s response states, “[a]n SAF of 1 was applied for vanadium, since background exposures (i.e., estimated daily intake or EDI) were included in the evaluation of risk for this contaminant.” The EDI represents the total background exposure to a chemical and is not related to potential exposures to contaminants at the site. Any risks posed by contamination at the site should be determined by considering the SAFs. The inclusion of the EDI in the calculation of the SSTL is not related to the use of a specific SAF value. The SAF is the relative proportion which it is allowable for soil (or sediment) to constitute in the Residual Tolerable Daily Intake (RTDI = TDI - EDI) from various environmental pathways. When a contaminant of potential concern (COPC) is present in all five media (i.e., air, soil/sediment, food, water, and consumer products), a SAF of 0.2 should be applied. If defensible contaminant-specific evidence exists demonstrating that the contaminant is not present in a given medium, the RTDI may be distributed amongst fewer media and the SAF may be increased from 20% to a value given by: SAF = 100% / (number of	Specific Question/ Request for Information: Health Canada recommends that the proponent address the following comment in a revised project document: a) Update the SAF and SSTL for vanadium, including water and air as applicable exposure media. Alternatively, provide an updated rationale/explanation for why water and air media were excluded. b) Update the SSTL for dioxins/furans using one of the two Health Canada recommended alternative methods (see Context and Rationale column). Alternatively, should another method be used, provide a detailed rationale/explanation for any deviation from the approaches recommended.	Requires Technical Discussion: No

				<p>applicable exposure media)^{Error! Bookmark not defined.}. As noted by Health Canada during the EIS review (February 2021), the proponent excluded water and air from applicable exposure media for vanadium as levels in groundwater/surface water are below the guidelines and levels in soil are below the background concentration (Appendix A of the EIS). The proponent concluded that, “the only applicable exposure media remaining at the Site for vanadium are sediment and food.” When calculating a SAF, all environmental media in which the contaminant is present (even if it exists at levels below background concentrations and/or the applicable guidelines) should be considered. Given the potential exposures via ingestion of water and inhalation of airborne soil particulates at the site, water and air should be considered as applicable exposure media for vanadium, in addition to sediment and food.</p> <p>b) Dioxins/Furans Regarding the SAF for dioxins/furans, the proponent’s response states, “[s]ince the EDI associated with background exposure to dioxins/furans is greater than the tolerable daily intake (TDI), theoretically, residents/Pictou Landing First Nation (PLFN) cannot be safely subjected to any increased exposure. As a result, the Health Canada and CCME default SAF of 0.2 was assumed for dioxins/furans.” The proposed approach is not consistent with the Canadian Council of the Ministers of the Environment (CCME) protocol followed for the derivation of soil quality guidelines in cases where EDI > TDI. When the EDI is greater than the TDI, Health Canada recommends the following alternative methods for the derivation of an SSTL;</p> <ul style="list-style-type: none"> • Set the SSTL to background concentration¹; or • Calculate provisional SSTLs based on 20% of the TDI, as well as based on 10% of the EDI, in the equations used to calculate the SSTL^{2,3}. Select the lower of the two provisional SSTL values as the SSTL. If the SSTL value is lower than background concentration, set the final SSTL to background concentration. When using this approach, chemical-specific scientific rationale should be provided to verify whether the derived SSTL is protective of human health and has considered relevant toxicological data. 		
IR #: IAAC-36	IR Number: IR(2)-36	Project Effects Link to CEAA 2012: 5(1)(c)(i) Aboriginal Peoples Health/ socio-economic conditions	Reference to EIS: Appendix A Section 4.2.5.2, pdf p.73 Table C-2.3, pdf p.484	Context and Rationale: Insufficient information/rationale is provided to support the selection of plant species used as surrogates to establish background concentrations.	Specific Question/ Request for Information: Health Canada recommends that the proponent address the following comment in a revised project document:	Requires Technical Discussion: No

¹ CCME. 2006. A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines. Available at: <https://ccme.ca/en/res/a-protocol-for-the-derivation-of-environmental-and-human-health-soil-quality-guidelines-en.pdf>

² CCME. 2015. Scientific Criteria Document for the Development of the Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health: Nickel. Available at: <https://ccme.ca/en/res/2015-ni-csqg-scd-1540-en.pdf>

³ CCME. 2018. Scientific Criteria Document for the Development of the Canadian Soil Quality Guidelines for Zinc, Protection of Environmental and Human Health. Available at: <https://ccme.ca/en/res/2018-zinc-csqg-scd-1577-en.pdf>

		Choose an item.	<p>The proponent's response to IRs Section 2.2.5, pdf p.108</p> <p>The proponent's additional response to IRs Section 4, pdf p.6</p>	<p>a) Section 4.2.5.2 of the Appendix A outlines an overview of the plant samples collected at the project site, which include a single species of cattails, 4 species of herbaceous plants, and 4 species of berries. However, based on data in Table C-2.3 of the Appendix A, Health Canada understands that only two plant species (i.e., cattails and bugleweed) sampled from the reference wetland were used to establish background concentrations. It remains unclear how the two species can serve as adequate surrogates to establish background levels for all the plant species (land and wetland-based) sampled at the project site, including fruit-bearing plants (e.g., berries) and the remaining 3 species of herbaceous plants.</p> <p>b) Uncertainties regarding the quality of plants that may be consumed by Indigenous peoples could be addressed through the implementation of a follow-up monitoring program, which would help to ensure that people are not exposed to unacceptable levels of COPCs.</p>	<p>a) Provide a rationale for the selection of the plant species and tissues used as surrogates to establish background concentrations in all plant species/tissues sampled, including a discussion on uncertainties associated with the selected species.</p> <p>b) Given the uncertainties associated with screening of COPCs of edible plant tissues, develop a detailed follow-up program, in consultation with Indigenous peoples and other stakeholders, to monitor changes to the quality of edible plants relative to baseline/background conditions, including information on:</p> <ol style="list-style-type: none"> 1) the changes in contaminant levels in edible plant tissues relative to baseline/background levels that would require implementation of additional mitigation/risk management measures; and 2) the mitigation/risk management measures to be implemented if monitoring results show that the contaminant concentrations of edible plant tissues reach or exceed the predetermined changes in contaminant levels identified in 1). 	
IR #: IAAC-37	IR Number: IR(2)-37	<p>Project Effects Link to CEAA 2012: 5(1)(c)(i) Aboriginal Peoples Health/ socio-economic conditions</p> <p>Choose an item.</p>	<p>Reference to EIS: Appendix A Figure 12, pdf p.273 Table 6.3, pdf p.149</p> <p>The proponent's response to IRs Section 2.2.6, pdf p.108</p>	<p>Context and Rationale:</p> <p>Insufficient information/rationale is provided to support the exclusion of human consumption of terrestrial game mammals as an operable exposure pathway.</p> <p>The proponent's response (Section 2.2.6) states that, "[t]errestrial game animals were not included in the HHERA since there were no soil COPCs carried through the HHERA. Further, concentrations of the primary contaminants within the Study Area (i.e., dioxins/furans) in soils at the Site are less than CCME background levels for soils across Canada. Concentrations in terrestrial game animals are expected to be consistent with background levels and much lower compared to aquatic wildlife that are directly exposed to the elevated concentrations of dioxins/furans in the sediment and the aquatic food items that have bio-accumulated contaminants from the sediments."</p> <p>a) It is inappropriate to screen out COPCs for the country foods pathway based on soil quality guidelines not being exceeded. The</p>	<p>Specific Question/ Request for Information:</p> <p>Health Canada recommends that the proponent address the following comment in a revised project document:</p> <ol style="list-style-type: none"> a) Update the conceptual site model for Human Receptors and the quantitative risk assessment to include consumption of wild game as an operable pathway. b) Given the uncertainties associated with exclusion of the game animal consumption pathway in the HHERA, develop a detailed follow-up program, in consultation with Indigenous Peoples and other stakeholders, to monitor changes to the quality of game animals relative to baseline/background conditions, including information on: 	<p>Requires Technical Discussion:</p> <p>No</p>

				<p>Canadian Council of Ministers of the Environment (CCME) dioxins and furans soil quality guidelines for the protection of human health⁴ are only protective of human health from incidental soil ingestion (and not necessarily protective of the food consumption pathway). In the absence of guidelines/standards/criteria available for screening an environmental medium (e.g., country foods), the COPCs should be carried forward into a quantitative risk assessment to determine whether there may be health risks associated with the predicted concentrations⁵. Health Canada recommends that, if receptors may be exposed to COPCs through multiple pathways, all potential exposure pathways should be included, regardless of the COPCs levels as they can still contribute to the overall project-related exposure and associated risks to human health.</p> <p>It is also unclear why the “Operable/Non-Operable” column of Table 6.3 (Appendix A) states that the exposure pathways for both terrestrial game meat and organs are non-operable, given that the “Rationale” column states that COPCs are carried forward for game organs.</p> <p>c) Uncertainties with the quality of game animals that may be consumed by Indigenous peoples could be addressed through the implementation of a follow-up monitoring program, which would ensure that people are not exposed to unacceptable levels of COPCs.</p>	<p>1) the changes in contaminant levels in game animals relative to baseline/background levels that would require implementation of additional mitigation/risk management measures; and</p> <p>2) the mitigation/risk management measures to be implemented if monitoring results show that the contaminant concentrations of game animals reach or exceed the predetermined changes in contaminant levels identified in 1).</p>	
IR #: IAAC-39	IR Number: IR(2)-39	Project Effects Link to CEAA 2012: 5(1)(c)(i) Aboriginal Peoples Health/ socio-economic conditions Choose an item.	Reference to EIS: The proponent’s additional response to IRs Section 5, pdf p.8	<p>Context and Rationale:</p> <p>Insufficient information/rationale is provided to support the proposed exclusion of operable exposure pathways based on COPC concentrations.</p> <p>Health Canada has clarified in IR(2)-37 that potentially operable exposure pathways, especially country food pathways, should not be excluded from further consideration in the human health risk assessment based on screening of contaminant levels against the quality criteria for other environmental media (e.g., soil, sediment, water). Health Canada is of the view that the issue can be sufficiently addressed by following Health Canada’s general technical guidance described in IR(2)-37 and specific recommendations provided in IR(2)-42/43 and 62a)b)/63/65 submitted to IAAC on November 30, 2021.</p>	Specific Question/ Request for Information: No further comment.	Requires Technical Discussion: No
IR #: IAAC-62 c)	IR Number: IR(2)-62c	Project Effects Link to CEAA 2012:	Reference to EIS:	Context and Rationale:	Specific Question/ Request for Information: No further comment.	Requires Technical Discussion: No

⁴ CCME. 2002. Canadian Soil Quality Guidelines for the Protection of Environmental and Human Health POLYCHLORINATED DIBENZO-p-DIOXINS AND POLYCHLORINATED DIBENZOFURANS (PCDD/Fs). Available at: https://ccme.ca/en/res/polychlorinated-dioxins-and-furans-pcdd_fs-canadian-soil-quality-guidelines-for-the-protection-of-environmental-and-human-health-en.pdf

⁵ Health Canada. 2019. Guidance for Evaluating Human Health Impacts in Environmental Assessment: Human Health Risk Assessment. Available at: <https://publications.gc.ca/site/eng/9.870475/publication.html>

		<p>5(1)(c)(i) Aboriginal Peoples Health/ socio-economic conditions Choose an item.</p>	<p>The proponent's additional response to IRs Section 6, pdf p.13</p>	<p>Insufficient information/rationale is provided to support the use of background contaminant concentrations from crab, lobster, and mussels as screening criteria for contaminants in clam.</p> <p>As acknowledged by the proponent, there remains uncertainties associated with metal concentrations in clam tissue and limited background (or reference) data. Health Canada is of the view that the issue can be sufficiently addressed through Health Canada-recommended risk assessments questions in IR(2)-62a)b)/63/65 and a follow-up country foods monitoring program in IR(2)-40 submitted to IAAC on November 30, 2021.</p>		
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