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Federal Contaminated Site Risk Assessment in Canada

Guidance on Technical Review of Human Health Risk Assessments | Version 3.0

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L'évaluation des risques pour les sites contaminés fédéraux au Canada :
Guide sur l'examen technique des évaluations des risques pour la santé humaine | Version 3.0

To obtain additional information, please contact:

Health Canada
Address Locator 0900C2
Ottawa, ON K1A 0K9
Tel.: 613-957-2991
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
E-mail: publications-publications@hc-sc.gc.ca

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Preface

The Federal Contaminated Sites Action Plan (FCSAP) was established in 2005 as a 15-year horizontal program with funding of $4.54 billion from the Government of Canada. In 2019, the program was renewed for another 15 years, from 2020 until 2035.

The primary objective of FCSAP is to reduce environmental and human health risks from known federal contaminated sites in Canada and their associated federal financial liabilities. To achieve this objective, FCSAP funds federal departments, agencies and Consolidated Crown corporations (collectively referred to as "custodians") to assess, remediate and risk manage the federal contaminated sites for which they are responsible. FCSAP also provides guidance, tools and resources to custodians to ensure that federal contaminated sites are managed in a scientifically sound and a nationally consistent manner. The Federal Approach to Contaminated Sites and the FCSAP Decision-Making Framework provide a 10-step roadmap that outlines the specific activities, requirements, and key decisions to effectively address federal contaminated sites in Canada. The Decision-Making Framework along with other FCSAP-related resources can be found on the FCSAP website.

This guidance document supplements Health Canada's (HC's) human health risk assessment (HHRA) guidance and assists federal custodial departments with a standardized review methodology to allow for consistent assessment of human health risks posed by federal contaminated sites across Canada. This guidance is relevant in the early steps of the DMF but can also be used in the latter steps.

Guidance documents related to HHRA prepared by Health Canada (HC) in support of FCSAP may be obtained by contacting HC at cs-sc@hc-sc.gc.ca or from our website at: https://www.canada.ca/en/health-canada/services/environmental-workplace-health/contaminated-sites.html.

As is common with any national guidance, this document will not satisfy all requirements presented by federal contaminated sites, custodial departments or risk assessors. As the practice of HHRA advances and as FCSAP proceeds, new and updated information on various aspects of HHRA will be published. As a result, it is anticipated that revisions and/or addendums to this document will be necessary from time to time to reflect this new information. Please consult the HC website above to confirm that the version of the document in your possession is the most recent.

HC requests that any questions, comments, suggested additions or revisions to this document be directed to HC at the email address identified above.

Summary of Revisions

The current document entitled *Federal Contaminated Site Risk Assessment in Canada: Guidance on Technical Review of Human Health Risk Assessments* Version 3.0 reflects several revisions relative to the document formerly published under the title of *Federal Contaminated Site Risk Assessment Part III: Guidance on peer review of human health risk assessments for federal contaminated sites in Canada* Version 2.0 (2010a). Significant revisions to this document include the following:

- Changes were made to reflect updated information in the HC (2024) Preliminary Quantitative Risk Assessment (PQRA) guidance from the HC (2010b) PQRA guidance;
- The original HC PQRA guidance was designed to rank sites in a consistent manner with regard to potential human health risks. However, since the results of a PQRA are no longer used within FCSAP to rank and prioritize federal sites for subsequent action and remedial funding, this guidance document has been updated;
- Reference has been made to additional HC guidance documents that were not published in 2010;
- A section was added to address bioavailability in soils and soil-like media, as this was updated in HC (2024);
- A section was added to address assessment of less than lifetime exposures, as this was updated in HC (2024);
- Questions were added to address gender-based analysis plus (GBA Plus) considerations;
- A question was added with regard to climate change considerations;
- The questions have been numbered for ease of reference;
- Some questions from the 2010 version were separated into multiple questions to allow for a yes/no answer.

Abbreviations and Acronyms

CALA	Canadian Association for Laboratory Accreditation
CCME	Canadian Council of Ministers of the Environment
COPC	contaminant of potential concern
CSM	conceptual site model
EDI	estimated daily intake
ESA	environmental site assessment
FCSAP	Federal Contaminated Sites Action Plan
GBA	gender-based analysis
HC	Health Canada
HHRA	human health risk assessment
HQ	hazard quotient
ILCR	incremental lifetime cancer risk
IVBA	*in vitro* bioaccessibility
PAHs	polycyclic aromatic hydrocarbons
PCBs	polychlorinated biphenyls
PCDDs/PCDFs	polychlorinated dibenzo-*p*-dioxins/polychlorinated dibenzofurans
P/T	provincial/territorial
PQRA	preliminary quantitative risk assessment
QA/QC	quality assurance/quality control
RBA	oral relative bioavailability
RBF	relative absorption factors
RPF	relative potency factor
TEF	toxic equivalent factor
TRV	toxicological reference value
U.S. EPA	United States Environmental Protection Agency

1. Introduction

1.1 Background

The objective of this document is to promote the preparation of human health risk assessment (HHRA) reports that are complete, understandable, and transparent.

This document, entitled *Guidance on: Technical Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada,* can be used by both HHRA authors and technical reviewers to identify whether the major elements of an HHRA are included.

To the greatest extent possible an HHRA should be a stand alone document with reference to appropriate documents as required. This document provides guidance to identify common issues, omissions and insufficiencies with HHRA reports. The questions can be used by consultants to ascertain consistency with HC (2024) guidance prior to submission of draft HHRA to custodians. Further, custodians may use the document in review of HHRAs conducted for federal contaminated sites funded by the FCSAP.

An electronic version of the guidance in MS Word can be obtained by request from HC at cs-sc@hc-sc.gc.ca.

HC provides Expert Support review of HHRAs to federal custodial departments for contaminated sites funded under the FCSAP, and has published guidance to assist federal custodians and their consultants. Where major gaps or questions exist, HC will request clarifications, revisions, and/or additional information. This guidance document is a tool to be used by the authors of HHRAs prior to submission for technical review by Expert Support. This will allow the authors of the HHRA to ensure that issues likely to trigger comments from HC are identified and addressed in the HHRA.

The guidance is designed to allow for a response of “yes,” “no,” or “not applicable“ for each question or set of questions.

Although this guidance was designed to be used as a tool to review Preliminary Quantitative Risk Assessments completed using the HC (2024) guidance, it can also be used to review more complex HHRAs that include contamination of multiple media and more areas of potential concern. In addition to this document, HC (2010c) guidance entitled “*Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment*” may be used to review more complex HHRAs.

Guidance on assessment of potential risks to ecological receptors is available from Environment and Climate Change Canada and/or Fisheries and Oceans Canada Expert Support departments.

This guidance is not intended as a regulatory or approval tool or instrument by HC. Under the FCSAP, HC has no regulatory role. HC provides expert guidance, advice and training in the identification, assessment, and management of federal contaminated sites in Canada.

1.2 Purpose

This document provides a standardized approach to technical review of HHRAs in the specific context of FCSAP. The checklist presented here is designed specifically for the assessment of sites that are the property and/or the responsibility of federal agencies.

For properties being divested to a private party or to P/T or municipal government agencies, or for assessments that address human health risks from off-site migration of contamination (e.g., to an adjacent P/T water body or neighbouring private property), HHRAs may have to be completed in accordance with P/T regulatory requirements, with a concomitant review. These local regulatory requirements may differ from the standardized questions identified in this guidance document. When the assumptions, methods and interpretations being employed in such cases vary from those presented here, the differences should be noted in the risk assessment, particularly if they lead to divergence in HHRA conclusions. Although the guidance offered here is prescriptive in nature, it is not designed or intended as a substitute for the professional judgment of a qualified and experienced risk assessment practitioner. It is recognized that many contaminated sites will present unique situations that are not specifically addressed in this document. However, where possible and appropriate, this guidance should be used. Alternative or unique approaches can be documented. HHRAs should be complete and address all relevant risks that may be associated with contamination at a site.

Risk assessment practitioners and site managers are encouraged to review this guidance as the issues identified herein are the most common in HHRA technical review. This guidance provides a standardized method for the technical review that should identify whether the HHRA was conducted and reported in a manner that allows for evidence-based decision making that is transparent, reproducible, defensible, and complete.

1.3 Gender-Based Analysis Plus

In the context of contaminated site HHRA, gender-based analysis plus (GBA Plus) identifies and analyzes the differential impacts of contaminated sites on diverse population groups. The "plus" in GBA Plus acknowledges that GBA goes beyond biological (sex[1]) and socio-cultural (gender[2]) differences. It highlights the pathways on which those differences develop and how they intersect with other determinants to shape health and well-being. It guides the consideration of sex and gender in framing, planning for, and conducting HHRAs for contaminated sites. GBA Plus includes other individual and social identity factors such as race, religion, social position, income, age, ability, and education; this is called intersectionality[3]. The basic steps to applying GBA Plus include gathering appropriate data, understanding context, and asking analytical questions to determine whether there may be disproportionate effects on diverse populations. By working through a GBA Plus analysis, experts can better understand the possible differential effects on distinct groups of people, including on disproportionately affected or impacted populations and populations identified by sex and gender. Considering how a program, policy, plan or product related to assessment and management of a contaminated site might impact groups differently provides an opportunity for all those involved to help address potential pitfalls before they become a problem or to identify opportunities that would not have been otherwise considered.

Key GBA Plus considerations in contaminated site HHRAs noted below are included in the checklist:

- Does the proposed assessment and management of the contaminated site identify the diverse communities who may be directly and indirectly affected by chemical exposure to contamination at the site?
- Are data about potential impacts disaggregated by sex, gender, age, language and other social identities relevant to the local communities?
- Have perspectives and characteristics of affected diverse communities and disproportionately impacted groups been included in the HHRA?

[1] Sex refers to physical and physiological features including chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy. https://cihr-irsc.gc.ca/e/48642.html

[2] Gender refers to the socially constructed roles, behaviors, expressions and identities of girls, women, boys, men, and gender diverse people. https://cihr-irsc.gc.ca/e/48642.html

[3] Government of Canada's Approach Gender Based Analysis Plus. https://women-gender-equality.canada.ca/en/gender-based-analysis-plus/government-approach.html

- Has the toxicity assessment considered all age groups and is it protective of the entire population (i.e., protective of diverse communities and age groups)?
- What are the health disparities from the contaminated site on the well-being of all people that may be affected, including Indigenous peoples and disproportionately affected populations?
- What types of measures are needed to ensure equitable representation during engagement processes and subsequent stages of contaminated site assessment and management?
- What measures are needed to mitigate any adverse effects of the contaminated site on all people that may be affected by contamination, including Indigenous Peoples and disproportionately affected groups?

Identifying the range of concerns and interests of, and impacts on, diverse groups based on social characteristics like gender, age, ethnicity, occupation, and length of residency, for example, can help foster the development of more comprehensive mitigation and enhancement strategies.

2. Technical Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada

Report title: _____
Report author: _____
Report date: _____
Reviewed by: _____
Date reviewed: _____

#	Query	Supplementary Explanation	Yes	No	N/A
2.1 Background and Objectives					
1	Is the purpose of the HHRA clear? (i.e. why is the HHRA being conducted?)	The report should explain how the HHRA will be used in the overall contaminated site management process. If the site is to be risk managed, then HHRA may be used to: direct additional site assessment to address data gaps or assess significant exposure pathways; determine whether site specific data or modeling can result in a more accurate estimation of risk; develop site-specific target levels for remediation; direct risk management; inform and support decision making associated with remedial actions; and/or inform and support option analysis for site management strategies.			
2	Is the scope of the HHRA clear and is the contamination to be assessed in the HHRA described?	The land area, land use and contamination to be assessed in the risk assessment should be described. If there were different contamination sources at the site, the HHRA should include a rationale for the scope of work if any areas are not addressed.			

#	Query	Supplementary Explanation	Yes	No	N/A
3	Does the scope of the HHRA include off-site migration of contaminants?	If off-site migration of contaminants in any media is a possibility, then consideration of off-site land use should be considered as part of the risk assessment process.			
4	Does the report identify the owner of the site?	The report should identify the federal custodian (owner) of the site.			
5	Does the report identify whether there are plans for divestiture of the site and to whom?	The requirements of another regulatory jurisdiction (e.g. provincial) may need to be addressed if the site is being divested by a federal department.			
6	If the site is not federally owned, does the report indicate whether there is a shared responsibility for the site with another jurisdiction, such as a provincial government?	All jurisdictions with shared responsibility for the site should be identified. The requirements of another regulatory jurisdiction (e.g. provincial) may need to be addressed.			
2.1.1 Site description					
7	Are all relevant site characteristics documented such as site identification and location?	Critical aspects of the site identification and characterization that are relevant to assessment of exposure should be summarized in the HHRA text and presented in maps, photos, figures and tables.			
8	Is the historical and current land use identified, including surrounding land use and presence of buildings on-site?	The HHRA should include current site use (and intended use if relevant); surrounding off-site land use; description and size of nearest communities and groundwater use; historical land uses; and built environment (surface cover, buildings etc.).			

#	Query	Supplementary Explanation	Yes	No	N/A
9	Have all environmental site assessments (ESAs) been adequately summarized?	Relevant information from ESAs should be summarized in the text, with reference to reports. All documents should be provided as part of the technical review. Report summary should include, but not be limited to: a brief description of the sampling protocols and design (e.g. number, location, media, and depth of the samples collected); substances analyzed; guidelines used (and referenced) for screening; concentrations of contaminants of potential concern (COPCs); and a description of previous site remediation activities. A site plan, with sample locations, should be included in the HHRA or reference provided to the report where this information is presented.			
10	Have descriptions of previous site management actions been summarized, including but not limited to risk management actions?	If relevant, this addresses a broader scope of actions such as long term monitoring, administrative management (e.g. fencing), or natural attenuation etc.			
11	Does the report include a summary of relevant information to aid with interpretation of fate and transport of contaminants and potential for off-site migration of contaminants?	The report should include a summary from ESAs to aide with technical review of fate and transport, such as: topography; geology (soil types and stratification, bedrock depth and type); groundwater flow direction, depth and uses; surface water bodies and surface water flow, etc.			
12	Does the HHRA include all COPCs associated with current and historical land uses?	Current and historical land use is used to assess whether all COPCs were analyzed.			

#	Query	Supplementary Explanation	Yes	No	N/A
13	Have sources of drinking water on-site and off-site been identified and tested?	The source of potable water for the site, including groundwater wells or surface water, should be identified and tested. Distance from the site will depend on the COPCs and fate and transport considerations.			
2.2 Problem Formulation					
2.2.1 Site characterization					
14	Have all relevant media been tested?	COPCs should be tested in the appropriate areas and media (groundwater, surface water, soil, soil gas, indoor air, and foods) based on the historical land use, and contaminant physical properties.			
15	Have contaminant concentrations been adequately summarized for the site?	Contaminant concentrations should be summarized for each media, including: number of samples; media; date sampled; detection limits; location; depth of sample; minimum and maximum concentration; number of samples below the detection limit.			
16	Were sufficient samples collected from locations known or suspected to be contaminated to identify the areas with highest potential contamination and characterization of contaminants of potential concern (COPCs)?	Targeted sampling, in areas of known or suspected contamination, is common in ESAs to increase the likelihood that contamination is characterized. The HHRA should identify whether the sampling program was adequate to characterize the contamination or if there are missing data (e.g., surface soil vs subsurface soil, groundwater, etc). Rationale for the sampling program, number and locations of samples, should be provided.			

#	Query	Supplementary Explanation	Yes	No	N/A
17	Has the extent of contamination been delineated horizontally and vertically in all impacted media?	Delineation of contaminated areas is important for characterization of human exposure, for risk management and remediation. Location of historical activities and fate and transport should be identified.			
18	If there was more than one area of potential concern does the HHRA provide information on location and COPCs?	The HHRA should include relevant information to describe each area of potential concern (e.g., historical activities, chemicals used, etc.).			
19	Has the extent of contamination been delineated horizontally and vertically in all impacted media?	Delineation of contaminated areas is important for characterization of human exposure, as well as for risk management and/or remediation. Sampling should account for: location of historical activities; transport of COPCs; and areas where people spend time.			
20	Does the list of substances that were selected for analysis include all those typically associated with the historical uses of the site and their potential degradation products?	The HHRA should include a summary of COPCs associated with the current or historical land use. HC (2024) contains a non-exhaustive list of contaminants associated with typical land uses. While this list may be useful in identifying COPCs that may be elevated as a result of historical anthropogenic activity, all substances, including those not presented in HC (2024) should be considered for inclusion in the HHRA. The HHRA should identify whether degradation products are more toxic or mobile in environmental media than parent compounds. For example, when tetrachloroethylene and/or trichloroethylene are COPCs, their degradation products, such as vinyl chloride, (even if not detected) should be included as COPCs, as the concentration of degradation products may increase over time.			

#	Query	Supplementary Explanation	Yes	No	N/A
21	Were samples of media discrete (i.e. not composite)?	HC (2024) recommends use of discrete samples. In situations where only composite samples (≥2 samples combined as one) have been collected, additional sampling may be required to identify contaminated areas.			
22	If the HHRA refers to groundwater monitoring wells, are borehole logs and details of the monitoring well installations provided in the HHRA or referenced with the appropriate documents provided for technical review?	If there are potential exposure pathways via exposure to groundwater or due to volatilization of chemical pollutants, the HHRA should reference information from the ESAs that are relevant to interpretation of fate and transport of contaminants relevant for an HHRA. This includes technical review of the borehole logs (with descriptions of monitoring well installations), depth to groundwater, contour of groundwater flow direction, etc.			
23	If subsurface vapours may impact indoor air, are sufficient data available to estimate human exposure?	HC (2023) supplemental guidance on vapour intrusion provides considerations for the vapour intrusion pathway and to guide assessment of exposure.			
24	Does the HHRA include a description of the environmental sampling quality assurance and quality control (QA/QC) measures employed?	The HHRA should provide a summary of QA/QC employed in sampling, such as duplicate samples; field blanks, etc. and to reference the appropriate reports. Refer to CCME (2016) for data quality objectives for environmental samples. The HHRA should identify concerns with data quality.			
25	Are sampling methods and analytical protocols described and do they follow a standard method?	The HHRA should: identify whether standard sampling methods and analytical methods were used; refer to CCME (2016) and identify if the sample is representative; reduce chemical loss during sampling (for volatile organic chemicals); and prevent contamination of samples.			

#	Query	Supplementary Explanation	Yes	No	N/A
26	Were the chemical analyses completed by a laboratory certified for the analytical methods used?	The HHRA should state if the chemical analyses were performed by a laboratory accredited by the Canadian Association for Laboratory Accreditation, the Standards Council of Canada, or similar, such as the Programme d'accreditation des laboratoires d'analyse in Quebec.			
27	Does the HHRA include or reference laboratory Certificates of Analysis?	Certificates of Analysis should be included in appendices in the HHRA or referenced in environmental site assessment reports available for technical review.			
28	Does the HHRA include a description of laboratory QA/QC measures employed or reference to ESAs with this information?	The HHRA should identify whether the laboratory QA/QC measures were acceptable (refer to HC 2024) and if not, whether corrective action was taken. In cases where the laboratory method is uncertified, the HHRA should identify whether QA/QC procedures such as analyses of standard reference materials and acceptable recoveries specified in the method are met.			
2.2.2 Identification of chemicals of potential concern					
29	Were all COPCs screened using CCME environmental quality guidelines?	Current CCME soil quality guidelines should be human health-based and relevant to site use where available. Guidelines can be restricted to a relevant pathway or pathways (direct ingestion, dermal exposure, indoor infiltration of volatile contaminants, etc.), as long as the most protective value that pertain to site use is used for screening and there are no preclusions for use. If guidelines from another jurisdiction were used, the HHRA should include justification. All guidelines should be fully referenced and reviewed for potential errors.			

#	Query	Supplementary Explanation	Yes	No	N/A
30	If criteria to screen COPCs other than CCME were used, were they appropriate?	HC (2024) identifies considerations for screening of COPCs. Alternate criteria should be fully referenced, with rationale where CCME guidelines are not available.			
31	Were COPCs identified using the maximum measured on-site concentrations?	COPCs are defined as: Those chemicals for which the maximum on-site concentration exceeds the human health based environmental quality criteria, and the local or regional background concentrations; or those chemicals for which no human health-based criteria or background data exist. This applies to one or more exceedances. An exceedance of a guideline is not assumed to be an anomaly and may require delineation, risk management and/or an HHRA. If statistics other than the maximum value are used to screen-out chemicals this may result in an underestimate of health risk and misidentification of areas of environmental concern.			
32	Was the screening process transparent and were screening guidelines used correctly?	The HHRA should include a summary of the screening process for COPCs that are not included in the quantitative HHRA. Chemical concentrations in media samples, along with the associated detection limits, should be listed in tabular form with appropriate screening guidelines. Chemical concentrations should be expressed in the same units as the guideline values. Concentrations that exceed guideline values should be highlighted and summarized in a table which should include sample number, date of sampling, depth (if applicable), units of measurement, and media.			

#	Query	Supplementary Explanation	Yes	No	N/A
33	Do laboratory detection limits exceed guideline values?	Detection limits of chemicals should not exceed guideline values. If detection limits exceed guideline values the chemical should be carried forward in the HHRA.			
34	If chemicals were screened out, was sufficient information provided in the HHRA to evaluate whether the screening was conducted appropriately and correctly?	Historical data should be screened against the most current guidelines. If historical data were screened against guidelines that were current at the time, but are no longer valid, the most current guidelines should be used for screening.			
35	If chemicals were screened out for reasons other than comparison of the maximum measured concentration to screening guidelines, were the reasons for exclusion adequately justified and referenced?	If no guidelines are available, the substance should be included in the quantitative HHRA. Essential elements should be included in the HHRA, unless there is a sufficient rationale to support that elevated concentrations would not pose a human health risk, including a toxicological assessment. Uncertainty related to the health effects of a substance is not sufficient reason to eliminate it in the HHRA.			
36	If chemicals were screened out because their concentrations were below background levels, was the reference location appropriate? Were background concentrations calculated appropriately and used correctly?	If concentrations of substances are equal to or below background concentrations **and** there is no suspected source on site, then substances may be screened out even if generic guidelines are exceeded. Full rationale should be provided. HC (2024) provides Canadian sources of background concentrations. The source of background data for each site should be fully referenced and should not include sampling of areas with elevated anthropogenic concentrations.			

#	Query	Supplementary Explanation	Yes	No	N/A
2.2.3 Receptors and pathways					
37	Have all relevant receptor age groups been identified (e.g. infant, toddler, child, teen, adult)?	All people that may be exposed to contamination should be identified.			
38	Have all potentially sensitive receptor population groups been identified (e.g. toddlers, Indigenous communities, people who are or may become pregnant)?	The HHRA should identify sensitive populations. An HHRA may focus on the most sensitive age group or receptor group (e.g., toddlers have the greatest intake of soil per unit of body weight of any age group). Exposure to bioaccumulative substances requires consideration for subsistence fishing populations, Indigenous communities, and recreational fishers with higher seafood consumption rates. Sensitive populations may be identified for toxicological reasons for substances with developmental effects (e.g., people who are or may become pregnant).			
39	Does the HHRA identify the diverse communities who may be directly and indirectly affected by chemical exposure to contamination at the site?	This aspect is a GBA Plus consideration. All potentially impacted receptors should be identified in the problem formulation and carried forward into the HHRA.			
40	Has the HHRA considered the health disparities from the contaminated site on the well-being of all people that may be affected, including Indigenous peoples and disproportionately affected populations?	This aspect is a GBA Plus consideration. All potentially impacted receptors should be identified in the problem formulation and carried forward into the HHRA.			

#	Query	Supplementary Explanation	Yes	No	N/A
41	Have all relevant exposure pathways been considered?	Indirect and direct exposure pathways are listed in HC (2024). Classifying pathways as incomplete and removing them from further consideration requires a rationale in the HHRA.			
42	If exposure pathways that were excluded from the quantitative HHRA, was their exclusion adequately justified?	Any exclusion of an exposure pathway should be justified. If risk management options are required to ensure future site use is consistent with assumptions regarding relevant exposure pathways, the HHRA should identify this in the executive summary and as part of the remedial action plan.			
43	Have potential effects related to climate change been included as a consideration in the HHRA (e.g., fate and transport of chemicals and/or assumptions for site use)?	Climate change considerations should be addressed, such as permafrost melting, increased precipitation, drought, etc. that may affect fate and transport of substances and/or changes related to land use.			
44	Was a conceptual site model (CSM) provided, summarizing land use, receptor groups, critical receptors, and potential exposure pathways?	A CSM for each land use at the site should describe all of the known or suspected sources of contamination; consider how and where the contaminants are likely to move (pathways), and identify who (receptors) is most likely to be affected by the contaminants (HC, 2024).			

#	Query	Supplementary Explanation	Yes	No	N/A
2.3 Exposure Assessment					
2.3.1 Chemicals of potential concern: exposure estimation					
45	Was an appropriate exposure concentration used to estimate exposures to COPCs from soils and sediment? For example, is the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible for each media given sample size and other factors?	If the ESA's provide sufficient site data of reasonable quality for soils and sediment, it is possible to apply a statistic other than the maximum (mean, upper confidence limit of the mean, specified percentile value, etc.) to estimate the exposure concentration, if supported by scientific rationale. Rationale and statistical evaluation should be scientifically sound and fully documented. Community-wide average concentrations, or other statistics representing central tendency, should not be applied if people have greater exposure to areas of higher contamination (e.g., where part of a community is impacted to a greater extent than the rest of the community). Note that the **maximum** concentration in all media is always used for **screening** COPCs.			
46	Was the maximum concentration used to screen COPCs in groundwater?	The **maximum** concentration in groundwater is always used to estimate exposure where groundwater is a drinking water source and when a contaminant plume requiring vapour intrusion assessment is under all or part of an occupied building or may migrate under a building.			
47	Is a statistical analysis of the data presented, if relevant?	If the maximum concentration was not used then a statistical analysis should be presented for the data for each media.			

#	Query	Supplementary Explanation	Yes	No	N/A
2.3.2 Fate and transport modelling					
48	If models were used to predict the environmental fate and transport of a contaminant from one environmental medium to another, was their use appropriate?	Environmental fate models are often used to predict fate and transport of contaminants. Models should be appropriate for the COPCs and site characteristics. Rationale for their use should be provided, with uncertainties associated with the model (e.g., whether the model has been peer reviewed; performance for different relevant scenarios has been documented; the complexity of the model is supported by peer-reviewed calibration and testing, the extent of site characterization, etc). Models may include, but are not limited to, those that: estimate the groundwater concentration from soils; predict the indoor air concentration of a volatile substance; predict airborne dust concentrations from soils; predict concentrations in foods, etc. The risk assessment should identify whether the complexity of the model is supported by peer-reviewed calibration and testing, the extent of site characterization, and the scope of the risk assessment.			
49	Is the model intended for use for the type of chemicals considered in the HHRA?	Different models may be used to estimate concentrations of substances in different media. The model used should be appropriate for the substance and site characteristics, with rationale provided in the report.			

#	Query	Supplementary Explanation	Yes	No	N/A
50	Were sufficient data available in the ESAs to support the use of the model?	The HHRA should identify whether there are sufficient site data to meet the demands of the model, such as geochemical data. For example, if the assessment has to rely on multiple "default values" for model parameters, its usefulness might be limited. Also, the HHRA should identify whether model results provide more significant digits than the available data can justify.			
51	Were all models fully referenced in the HHRA to allow for technical review?	References should be provided for models, identifying whether the model is readily available.			
52	Has the model been modified from its original published form, or from its commonly used form? If so, was rationale provided with a discussion on the impact of the changes on model predictions?	Model modification may significantly impact the predictions and performance of the model. Models with internal dependences or embedded parameters are particularly sensitive to modifications, and such changes can have hidden impacts on performance. Some models may be slightly modified to reflect site conditions, or to account for model weaknesses, where these are well-understood from comparison of model predictions and relevant empirical data, and any modifications should be clearly documented and implications identified.			
53	Does the HHRA recommend monitoring for current and/or future conditions to address uncertainties with the modelling?	The HHRA report should identify whether the model predictions are likely to overestimate or underestimate concentrations in environmental media as well as to identify whether future sampling is recommended to confirm the results of the modelling.			

#	Query	Supplementary Explanation	Yes	No	N/A
54	Are all model assumptions and equations explained?	All model assumptions should be fully documented and equations, with units, provided. Intermediate calculations (e.g. concentrations at specific locations) should be documented to allow for technical review.			
55	Are intermediate results included and do they make sense?	The HHRA should include intermediate results of modelling, as relevant. For example, modelling vapour intrusion from groundwater to indoor air should include predictions of soil gas contaminant concentrations as well as indoor air concentrations.			
2.3.3 Receptor characterization					
56	Were all receptor exposure characteristics drawn from HC guidance?	The physical and behavioural characteristics of each receptor group should be documented, with references, in the HHRA. HC (2024) provides guidance on receptor characteristics that include, but are not limited to, body weight, inhalation rate, etc.			
57	If HC (2024) receptor characteristics was not used, was this because no Canadian data are published for a specific characteristic?	Alternate sources for exposure characteristics may be used where Canadian published data are not available.			

#	Query	Supplementary Explanation	Yes	No	N/A
58	If the HHRA include a scenario with consumption of foods, was the community consulted or a survey completed?	If people consume foods that may be impacted by contamination, this exposure pathway would be considered operable. The consumption scenarios would be used in the exposure estimate. The HHRA report should identify whether the community was consulted or whether the evaluation included a survey of the community to obtain estimated consumption rates for all foods consumed?			
59	If applicable, were alternate source(s) for exposure characteristics clearly documented?	All alternate sources for exposure characteristics should be fully referenced to allow for technical review.			
60	Were alternate assumptions for receptor characterization appropriate and adequately justified?	All alternate sources for receptor characteristics should be justified. For characteristics not included in HC guidance, the U.S. EPA *Exposure Factors Handbook* (U.S. EPA, 2011, 2017–2018, with ongoing updates) and the U.S. EPA *Child-Specific Exposure Factors Handbook* (U.S. EPA, 2008) may be used as reference sources.			
61	Were assumptions regarding exposure duration and exposure frequency for each receptor appropriate and adequately justified?	Assumptions regarding exposure frequency and duration should be clearly documented in the HHRA along with a rationale to establish their validity for the site. Typical assumptions are provided in HC (2024); however, site specific information can be used to modify default assumptions related to exposure duration and exposure frequency. For less-than-chronic duration exposures, consult (HC 2013; 2024; 2025b).			

#	Query	Supplementary Explanation	Yes	No	N/A
2.3.4 Exposure equations					
62	Were HC (2024) equations used to estimate dose (i.e. exposure)?	Equations for estimating the dose for each pathway are presented in HC (2024) and HC supplemental guidance documents for HHRA at contaminated sites. All relevant equations should be provided in the HHRA.			
63	If alternate equations were used, did they include the same units as HC's equations, and were references provided?	Equations presented in the HHRA should have the same units as those used by HC to avoid mistakes due to errors in unit conversion.			
64	Does the HHRA include sample calculations for estimating the dose via each exposure pathway?	An example sample calculation should be provided for each exposure pathway, as noted in HC (2024) to allow for technical review.			
65	Are equations dimensionally consistent and are all units correct?	The report should provide sample equations with laboratory data and receptor characteristics provided in the correct units. Dimensionally consistent means that the dimensions (and units) are the same on both sides of the "equal" sign.			
66	Can the calculations be reproduced?	The technical review includes a check of the math for each exposure pathway, and to identify whether the calculations can be reproduced for each exposure pathway.			
2.3.5 Bioavailability					
67	Has 100% oral relative bioavailability (RBA) been assumed in the exposure estimate?	Relative absorption factors (RAFs) for ingestion, also called RBA factors are usually assumed to be 100% (HC, 2024). If oral RBA is not included, then 100% is implicitly assumed.			

#	Query	Supplementary Explanation	Yes	No	N/A
68	If the oral bioavailability was assumed to be less than 100%, was the exposure estimate adjusted using an oral RBA based on site-specific tests of on-site soil from *in vivo* testing, or a validated *in vitro* bioaccessibility (IVBA) test that has been accepted by a regulatory authority or HC for the chemical of concern?	In complex HHRAs, IVBA tests that have been developed or accepted by a regulatory agency for specified chemicals (e.g., lead and arsenic) may be used to estimate RBA of site soils (HC, 2017). The IVBA test chosen must be validated for the chemical and the method by a regulatory agency prior to use, and the soil concentrations must be within the concentration range used to validate the method for the chemical of potential concern. Soil samples used for IVBA testing must be sieved to the specified particle size fraction specified in the method. QA/QC requirements specified in the IVBA method must be met for the bioaccessibility results to be considered valid. Site-specific RBA estimates are preferred over default RBA estimates from the literature. If estimates of oral RBA were obtained from the literature, HC should be consulted as to the study's applicability to the site under assessment, and justification for the use of default RBA values or from the literature must be fully justified and referenced.			
69	If the answer to the question above was no, was the RBA value based on published literature with scientific rationale provided?	Use of published literature to estimate site-specific bioavailability is not recommended as there are numerous variables that can influence bioavailability. The uncertainty associated with the assumption should be identified.			
70	Were dermal absorption factors from HC guidance?	Relative dermal absorption factors are listed in (HC, 2025a).			

#	Query	Supplementary Explanation	Yes	No	N/A
71	If the answer to the above question (#70) was no, were the sources referenced?	Values from other jurisdictions or published literature should be referenced.			
72	If the inhalation pathway was evaluated, was absorption assumed to be 100%? If a variable representing inhalation bioavailability is not included, then 100% is implicitly assumed	Relative absorption factors for inhalation are usually 100% because inhalation toxicological reference values (TRVs) are generally based on measured airborne concentration, not absorbed dose. All relative absorption factors less than 100% must be fully explained and referenced.			
73	If the answer to the above question was no, were the sources referenced?	Values from other jurisdictions or published literature should be referenced.			
2.3.6 Less-than-chronic or intermittent exposure					
74	Were exposure scenarios at the site less-than-chronic (e.g, less than 7 days per week, 52 weeks per year) and did the equations present estimates for daily exposure while at the site?	HC (2024; 2025b) guidance stipulates that exposure be calculated for the days people may be exposed (e.g., the exposure that would be experienced on the days at the site).			
75	If the HHRA included dose averaging (e.g, less than 7 days per week, 52 weeks per year), was sufficient scientific rationale provided on a chemical-specific basis?	HC guidance (2024; 2025b) recommends no dose averaging as this may result in underestimation of risk. Chemical-specific rationale is required for any exposure amortization, and this would generally require a more complex HHRA.			

#	Query	Supplementary Explanation	Yes	No	N/A
76	If exposures of less-than-chronic duration are considered for non-carcinogens, was their use appropriate and justified with references?	Less-than-chronic exposures to chemicals should not be "averaged" over a longer time period unless there is a chemical specific and site specific rationale provided as this can underestimate risk (HC, 2024; 2025b).			
77	In calculating lifetime average daily dose for cancer risks, was the assumption of lifetime exposure included?	When less-than-chronic duration exposures are relevant, consult HC (2013; 2024; 2025b). The required level of assessment will normally exceed what is performed in a preliminary HHRA.			
2.4 Toxicity Assessment					
78	Were all TRVs drawn from HC?	HC (2025a) provides a list of TRVs for substances commonly found at federal contaminated sites and is the preferred source. All TRVs and units should be properly referenced to ensure correct transcription.			
79	If the answer to the above question was no, was it because HC had no TRV for the particular COPC?	For chemicals not listed in HC (2025a), TRVs may be obtained from another peer-reviewed source and documented. If alternate values are used when a HC TRV is available, the HHRA should include: justification for not using the HC TRV; description, basis, and reference; method of derivation; level of protection; uncertainty or confidence level; any modification made for consistency with HC.			
80	Are the selected TRVs clearly stated, with references, for each chemical, each pathway, and if relevant, age group?	Selected TRVs should be presented in tabular format in the HHRA, with references.			

#	Query	Supplementary Explanation	Yes	No	N/A
81	Are the health effects associated with each COPC and the basis for the TRV described?	A brief description of the health effects for each chemical and the basis for the selected TRV should be included. For chemicals that are not listed in HC (2025a), effects associated with the TRV should be summarized and referenced.			
82	Were pathway specific TRVs used to calculate risk for each relevant pathways?	Pathway specific TRVs are published in HC (2025a).			
83	If alternate TRVs were used, were risks calculated for both HC and alternate TRVs?	If HC TRVs are available, but alternate values were used, risks should be calculated using both (HC, 2024; 2025a).			
84	If carcinogenic polycyclic aromatic hydrocarbons (PAHs), polychlorinated dibenzo-*p*-dioxins/ polychlorinated dibenzofurans (PCDDs/PCDFs), or certain dioxin-like polychlorinated biphenyls (PCBs) were assessed, was HC guidance used regarding relative potency factors (RPFs) or toxic equivalence factors (TEFs)?	It is recommended that the report include RPFs and provisional RPFs for carcinogenic PAHs as well as TEF for dioxins, furans and some dioxin like PCBs are listed in HC (2025a).			
85	Are ADAFs included in the assessment for carcinogens with a mutagenic mode of action?	HC (2013) recommends the use of ADAFs in risk assessment for contaminated sites for carcinogens with a mutagenic mode of action.			

#	Query	Supplementary Explanation	Yes	No	N/A
86	Has the toxicity assessment considered all age groups and is it protective of the entire population (i.e., protective of diverse communities and age groups)?	This aspect is a GBA Plus consideration. HC (2025a) provides TRVs for the most sensitive populations. If TRVs from other sources are used, identify whether the most sensitive populations were used in derivation of the TRV.			
2.5 Risk Characterization					
87	Are the results of the HHRA clear?	The HHRA should provide a clear summary of the incremental lifetime cancer risk (ILCR) and hazard quotients (HQ) for each chemical, exposure pathway, and critical receptor.			
88	Are data about potential impacts disaggregated by sex, gender, age, language and other social identities relevant to the local communities?	This aspect is a GBA Plus consideration. This information may not be available on a site specific basis; however, if available it should be noted in the risk characterization section.			
89	Have perspectives and characteristics of affected diverse communities and disproportionately impacted groups been included in the HHRA?	This aspect is a GBA Plus consideration. The risk characterization section should identify whether communities were consulted and considerations included in the assessment.			
90	Are measures needed to ensure equitable representation during engagement processes and subsequent stages of contaminated site assessment and management?	This aspect is a GBA Plus consideration. The risk characterization section should identify considerations from community engagement.			

#	Query	Supplementary Explanation	Yes	No	N/A
91	Was a target HQ of 0.2 used in the risk characterization?	HC (2024) identifies that HQs of 0.2 or less as are considered negligible. If the background estimated daily intake (EDI) is included, a target HQ of 1 may be used (see below). If any other agency has been identified as having jurisdiction (for example, provinces for off-site areas), then the target HQ should be documented with references.			
92	If a target HQ of 1.0 was used, were background exposure levels included in the exposure estimate?	The exposures from the site plus the EDI for each substance from background sources, can be added and compared with the applicable target HQ (HC 2024). The HQ including the EDI should be presented in addition to the calculation of the HQ for on-site exposures alone. For substances with no data related to background exposures, on-site exposures are evaluated using a target HQ of 0.2.			
93	Was the target incremental lifetime cancer risks identified as less than 1×10^{-5} for all exposure pathways from the site?	HC (2024) identifies incremental lifetime cancer risks associated with contaminated sites of one in one hundred thousand (1×10^{-5}) or less as essentially negligible. If another agency has been identified as having jurisdiction (for example, provincial jurisdiction for off-site contamination), then the negligible risk level should be documented in the HHRA.			
94	For chemicals and pathways affecting the same target organ, are the HQs summed for non-cancer effects?	HQs should be summed for chemicals that affect the same target organ. Generally, oral and dermal exposures are summed (HC, 2024).			

#	Query	Supplementary Explanation	Yes	No	N/A
95	For carcinogens, have risks been summed for chemicals and pathways causing the same form of cancer?	Risks for chemicals that produce the same form of cancer should be summed. Generally, oral and dermal exposures will be summed (HC, 2024).			
96	Is the uncertainty associated with the HHRA discussed?	The HHRA should provide a qualitative or quantitative evaluation of the uncertainty in the results. The HHRA should identify the sensitive variables and assumptions including: sufficiency of sampling; analytical detection limits; data gaps; QA/QC; seasonal or other environmental factors on sampling; modelling; exposure assessment; toxicological assessment; quality of historical data regarding COPCs, etc.			
97	Do the recommendations identify requirements for further characterization, evaluation or assessment, based on significant uncertainty in certain parameters?	If additional ESA data are required and/or more in-depth site-specific assessment, the HHRA should clearly identify the requirements to assess risk.			
2.6 Risk Management					
98	If HQs exceed 0.2 or ILCRs exceed 1×10^{-5}, does the HHRA identify remedial or risk management measures?	If the calculated risks exceed target risk levels, the HHRA may recommend risk management or remediation measures to reduce exposure.			

#	Query	Supplementary Explanation	Yes	No	N/A
99	Are recommendations to address the human health risk proposed?	Recommendations may include, but are not restricted to: i) the need for a more detailed HHRA or additional ESA data to delineate the contamination or address any critical data gaps, based on significant uncertainty in HHRA parameters; ii) any measures that need to be taken immediately to protect people that may be affected by contamination; iii) measures that reduce or eliminate exposure; iv) measures to remove contamination or reduce contaminant concentrations at the site; v) measures that prevent migration of contamination into other environmental matrices, or prevent migration off the site; vi) identify remedial and/or risk management measures consistent with the spatial scale of the site and the magnitude of the risks; and vii) the need for any ongoing monitoring of environmental media.			
100	Does the report identify what measures are needed to mitigate any adverse effects of the contaminated site on all people that may be affected by contamination, including Indigenous Peoples and disproportionately affected groups?	This aspect is a GBA Plus consideration. Disproportionately impacted populations require consideration in addition to the general public. Risk mitigation measures identified in the HHRA require consideration of all impacted receptors.			
101	Is the responsible department or agency responsible for risk management clearly identified?	The responsible department or agency responsible for risk management should be clearly identified if different from the client department that solicited the HHRA.			

#	Query	Supplementary Explanation	Yes	No	N/A
2.7 Overall Comments					
102	Is the HHRA complete and generally acceptable (i.e. are there only minor issues or no issues) or do major gaps or outstanding issues exist that preclude a generally acceptable evaluation of potential human health risk?	**Minor gaps:** A minor gap consists of issues that require clarification or justification. They do not prevent the evaluation of potential health risk, but may warrant consideration to improve the overall quality of the HHRA. **Major gaps:** Major gaps or outstanding issues may involve missing data that preclude the defensible evaluation of risks, or prevent technical reviewers from verifying the information in the HHRA. Resolution of major gaps may require recalculation of risk estimates. Minor or major gaps may be discussed under separate cover to the HHRA if a revised HHRA is not feasible. Both minor and major gaps may be associated with a "no" response to one or more questions. However, this does not exclude other issues specific to the assessment under review being discussed. Any concerns, outstanding issues, required explanations, and/or data requirements should be discussed.			
103	Are there other comments not identified in the questions above that require attention? If so, provide the comments in a separate letter.				

Note: N/A, not applicable

3.0 References

CCME. 2016. Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment Volume 1–4. Canadian Council of Ministers of the Environment, Winnipeg, Canada.

Health Canada. 2010a. Federal Contaminated Site Risk Assessment in Canada: Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0 (2010)

Health Canada. 2010b. Federal Contaminated Site Risk Assessment in Canada: Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0. Contaminated Sites Division, Healthy Environments and Consumer Safety Branch, Health Canada, Ottawa.

Health Canada. 2010c. Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment. Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

Health Canada. 2013. Federal Contaminated Site Risk Assessment in Canada: Interim Guidance on Human Health Risk Assessment for Short Term Exposure to Carcinogens at Contaminated Sites. Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

Health Canada. 2017. Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment on: Oral Bioavailability of Substances in Soil and Soil-like Media. Contaminated Sites Division, Safe Environments Directorate. Health Canada, Ottawa.

Health Canada. 2021. Federal Contaminated Site Risk Assessment in Canada: Overview of Health Canada Guidance Documents Related to Human Health Risk Assessment of Federal Contaminated Sites. Contaminated Sites Division, Safe Environments Directorate. Health Canada, Ottawa.

Health Canada. 2023. Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance for Soil Vapour Intrusion Assessment at Federal Contaminated Sites, version 2.0. Contaminated Sites Division, Safe Environments Directorate. Health Canada, Ottawa.

Health Canada. 2024. Federal Contaminated Site Risk Assessment in Canada: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 4.0. Contaminated Sites Division, Healthy Environments and Consumer Safety Branch, Health Canada, Ottawa.

Health Canada. 2025a. Federal Contaminated Site Risk Assessment in Canada: Toxicological Reference Values (TRVs) Version 4.0. Contaminated Sites Division, Health Environments and Consumer Safety Branch, Health Canada, Ottawa.

Health Canada. 2025b. Federal contaminated site risk assessment in Canada: Interim Guidance on Human Health Risk Assessment of Non-cancer Effects Resulting from Less-Than-Chronic Exposures at Federal Contaminated Sites. Contaminated Sites Division. Healthy Environmental and Consumer Safety Branch, Health Canada, Ottawa.

U.S. EPA (United States Environmental Protection Agency). 2008. Child-Specific Exposure Factors Handbook. EPA/600/R-06/096F. National Center for Environmental Assessment. Office of Research and Development U.S. EPA, Washington, DC. Accessed June 17, 2024 at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=199243

U.S. EPA. 2011. Exposure Factors Handbook. EPA/600/R-09/052F, 2011 and updates. National Center for Environmental Assessment. Office of Research and Development. United States Environmental Protection Agency, Washington, DC. Accessed June 17, 2024, at https://www.epa.gov/expobox/about-exposure-factors-handbook