Ministry of Health

British Columbia Guidance for Prospective Human Health Risk Assessment

Version 2.0

April 2022

Health Protection Branch
Population and Public Health Division

VERSION CONTROL HISTORY

Version #	Date (YYYY-MM)	Modification
1.0	2021-04	Original document
2.0	2022-04	Updates

Version 2.0 of the Ministry of Health's "*British Columbia Guidance for Prospective Human Health Risk Assessment*" has been updated to reflect current regulations and policy development and incorporate feedback received on Version 1.0. Going forward, the guidance document will be reviewed every five years. Any minor edits or changes to the guidance document needed between the scheduled updates will result in version numbering as 2.1, 2.2, etc.

Any comments or suggestions on Version 2.0 of the guidance document can be emailed to HHRAComments@gov.bc.ca

ACKNOWLEDGEMENTS

This document was prepared by the Ministry of Health, with contributions from a technical advisory group:

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B.C. Office of the Provincial Health Officer
B.C. Centre for Disease Control
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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

GLOSSARY

"absorbed dose" means the amount of a contaminant penetrating the absorption barriers (the exchange boundaries) of an organism via either physical or biological processes. For the purpose of this document, this term is synonymous with internal dose.

"additive toxicity" means that the combined toxic effects of contaminants are equal to the sum of the effects of each individual contaminant.

"air" means the atmosphere but does not include the atmosphere inside a human made enclosure that is not open to the weather or an underground mine.

"antagonistic toxicity" means that the combined toxic effect of contaminants is less than the sum of the toxic effects of the individual contaminants.

"background concentration" means the current concentration of a substance in an environmental medium in a geographic area but does not include any contribution from local human-made point sources.

"baseline concentration" means the currently existing concentration of a substance in environmental medium in a geographic area that may be due to natural or anthropogenic sources but does not include contributions from proposed projects or development.

"bioaccumulation" means the progressive increase in the amount of a substance in an organism or part of an organism, which occurs because the substance's rate of intake exceeds the rate at which the organism is able to degrade or eliminate the substance.

"bioavailability" is a measure of a chemical's ability to enter the general systemic circulation following administration or exposure; generally expressed as the fraction of the chemical that enters general systemic circulation.

"bioconcentration" is accumulation of a substance in an organism resulting in a higher concentration of the substance in an organism compared to the concentration of the substance in the environmental media to which the organism is exposed.

"biomagnification" means the incremental process within a food chain by which progressively higher contaminant concentrations are attained in organisms located at respective higher trophic levels (i.e., in organisms located) at higher levels in the food chain.

"carcinogen" is a substance that promotes the formation of cancer and has no defined threshold for health effects (i.e., non-threshold).

"conceptual site model" [CSM] means a qualitative model of how health risks may develop based on hypotheses describing contaminant sources, releases, environmental transport, and biological uptake.

"contaminant of potential concern" [COPC] means any chemical substance or physical agent that has been determined to pose an actual or potential risk to human health. For the purposes of this document the term 'chemical' also includes particulate matter.

"country foods" means all foods sourced outside of commercial food systems, also referred to as environmental livelihoods. This includes any food that is trapped, fished, hunted, harvested, or grown for subsistence or medicinal purposes outside of the commercial food chain.

"dose" or dosage, is often expressed on a per-unit body weight basis, yielding units such as mg/kg bw/d expressed as averages over some time period (e.g., a lifetime).

"dose-response" means the relationship between the dose of a chemical administered or received and the magnitude of an adverse health effect in exposed populations.

"environmental media" includes soil, sediment, surface water, groundwater, air, vapour, animals, and plants.

"exposure control" refers to the actions taken to prevent completion of exposure pathways, such as physical barriers or changes to the environment.

"exposure pathway" means the physical pathway through one or more environmental media by which a released contaminant is conveyed to a human receptor.

"exposure route" means the physiological means through which a chemical enters the body. Within this document it refers to ingestion, inhalation, or dermal uptake.

"exposure scenario" means a set of facts, assumptions, and inferences about how exposure takes place that aid the exposure assessor in evaluating, estimating, or quantifying exposures.

"fate and transport modelling" refers to mathematical or computer modelling used to predict how compounds will behave in the environment over space and time due to chemical, physical, and biological influences.

"fenceline" means the extent of the project area within which access to members of the general public is physically restricted.

"food-chain modelling" means the quantitative estimation of the dose of contaminant received due to bioaccumulation (including bioconcentration and biomagnification) by each member of a food chain.

"GBA+" refers to Gender Based Analysis Plus, and examines the impact of programs, initiatives and policies on different groups of women, men and people of different gender identities. The 'plus' indicates that the analysis also takes account of the multiple other identity factors that define a person, including race, ethnic origin, religion, age and intellectual or physical disabilities.

"half-life" means the period it takes the concentration of a substance to be reduced by half by transformation in a medium.

"hazard index" [HI] means the sum of hazard quotients for any substances over all exposure pathways that affect the same target organ or organ system or have similar toxicological endpoints, and are assumed to have additive toxicity.

"hazard quotient" [HQ] is the form of risk estimate computed for threshold-response chemicals, also known as the exposure ratio. Derived by dividing the estimated environmental exposure rate (mg/kg bw/d) by a TRV (mg/kg bw/d).

"health authority" refers to the five regional health authorities in B.C. which govern, plan, and deliver health-care services within their geographic areas; and the First Nations Health Authority, which is responsible for planning, management, service delivery, and funding of health programs in partnership with First Nations communities in B.C.

"health impact assessment" [HIA] refers to the assessment of a broad range of potential impacts to the health of individuals and populations including social, economic, cultural, and biophysical determinants of health. A human health risk assessment is typically a sub-component (or appendix) of a much larger health impact assessment.

"human health risk assessment" [HHRA] refers to a standardized approach for assessing the potential human health risks from exposure to environmental contaminants.

"human receptor" refers to a hypothetical person intended to represent a reasonably maximally exposed individual that may be exposed to a substance or be impacted by project activities. The term 'human receptor' is used rather than human, or person, to signify the fact that the HHRA is only assessing hypothetical risks and is not predicting expected health-outcomes for actual people.

"incremental lifetime cancer risk" [ILCR] means the increase in lifetime cancer risk above the normal risks associated with background exposures.

"Indigenous groups and peoples" include any Indigenous, First Nations, or Métis Chartered Communities with traditional, ancestral, or other ties to land in the Study Area.

"indoor air" include the atmosphere inside a human made enclosure that is not open to the external weather.

"maximum point of impingement" [MPOI] is represented as the location outside the project fenceline with the greatest predicted COPC concentrations in environmental media.

"measurable increase" means a predicted change in concentration equal or greater than the lowest laboratory analytical detection limit (the method detection limit) available for a COPC in a specific environmental medium as available through an accredited environmental laboratory (or food-grade laboratory for country foods) within B.C., or as established by the current version of the *British Columbia Environmental Laboratory Manual* (ENV, 2020b).

"microenvironments" means any well-defined and characterized surroundings within the Study Area that can be treated as homogeneous with regards to the concentrations of a chemical or other agent.

"non-threshold-response contaminant" means a contaminant that is believed to have the potential to elicit a toxic effect at any level of exposure greater than zero.

"octanol-water partition coefficient" [K_{ow}] means the ratio of the concentration of a substance in an octanol phase to the concentration of the substance in the water phase of an octanol-water mixture.

"precautionary principle" asserts that the burden of proof for potentially harmful actions by industry or government rests on the assurance of safety and that when there are threats of serious damage, scientific uncertainty must be resolved in favor of prevention.

"potentiation" refers to when a substance that does not normally have a toxic effect makes another contaminant more toxic.

"probabilistic risk assessment" means the use of a mathematical model based on probability distribution functions as opposed to fixed point estimates to characterize exposure and quantify risk and hazard in a risk assessment.

"project" means the proposed project, event, or activity requiring a human health risk assessment.

"proponent" refers to the legal entity that owns the project. For example, a proponent could be a city, a private company, or crown corporation.

"reference concentration" [RfC] see "tolerable concentration".

"reference dose" [RfD] see "tolerable daily intake".

"release" in the context of this guidance document, means any release, discharge, emission, mobilization, or modification of a substance by a project or its associated supporting operations through leaks, fugitive emissions, or emergency releases, either intentionally or as reasonably expected.

"remediation" means action to eliminate, limit, correct, counteract, mitigate, or remove any contaminant or the adverse effects on the environment or human health of any contaminant.

"reversible" refers to any temporary adverse health effect which is completely mitigated after the cause is removed.

"risk" is the likelihood or probability that toxic effects associated with a chemical may be produced in populations of individuals under actual conditions of exposure.

"risk assessment" refers to quantitative human health risk assessment, and is the process of scientifically estimating the nature, probability, and significance of adverse health effects in humans from exposure to chemicals or other contaminants in the present or in future.

"risk assessor" refers to the qualified individual conducting the HHRA (i.e., gathers data, does HHRA calculations, writes the HHRA report) or who reviews the HHRA. It is expected that the risk assessor has appropriate education, experience, or knowledge. It is recommended that the risk assessor is registered with a professional association or is a registered professional whose profession is regulated by a regulatory body named in the *Professional Governance Act*.

"risk management" means the reduction or elimination of ongoing risks through ongoing and direct control over sources, exposure pathways, or human receptors.

"risk mitigation" means the prevention of risk through the elimination of sources or changes to project design (also known as risk control).

"risk-specific concentration" [RsC] is the exposure concentration for a non-threshold compound associated with a specified level of risk (e.g., 1 in 100,000 incremental average lifetime cancer risk).

"risk-specific dose" [RsD] means the TRV determined for chemicals assumed to act as genotoxic non-threshold carcinogens. A RsD is a function of carcinogenic potency (slope factor) and a defined risk level (e.g., 1 in 100,000).

"slope factor" [SF] means a measurement of carcinogenic potency. The slope of the low-dose region of the dose-response model is used for the estimation of risk following exposure to a carcinogen.

"site-specific risk-based concentration" is the concentration of a substance in an environmental medium predicted to result in exposure equivalent to (a) for a carcinogenic substance, a calculated human incremental lifetime cancer risk of one in 100,000, and (b) for a non-carcinogenic substance, a hazard index of one.

"stakeholders" are all people, institutions, or entities that have an interest in the design, implementation, and sustainability of the project or which may be either positively or negatively impacted by it.

"Study Area" means the spatial boundaries of the HHRA including all areas of supporting assessments that directly contribute to the potential for biophysical changes in environmental media (e.g., air quality and water quality).

"summary statistics" includes the following information describing a dataset: number of data points; limits or detection; number of non-detectable results; minimum; maximum; measure of central tendency (median and/or mean as appropriate); 95% UCLM; and a measure of dispersion (such as standard deviation).

"synergistic toxicity" means that the combined effects of two or more contaminants are significantly greater than the sum of the effects of the individual contaminants.

"threshold-response contaminant" means that a contaminant chemical that elicits a toxic effect only at or above some threshold of exposure and manifests toxicity via a threshold-response mechanism.

"tolerable concentration" [TC] means an estimate of the maximum concentration to which the human population (including sensitive subgroups) could be exposed on a continual basis without an appreciable risk of adverse health effects.

"tolerable daily intake" [TDI] means the estimated amount of a substance to which humans (including sensitive subgroups) can be exposed to over a defined period of one day without risk of adverse health effects.

"toxicity" means the production of any type of damage, permanent or impermanent, to the structure or functioning of any part of the body.

"toxicological reference value" [TRV] means the maximum estimate of exposure to a substance which would not elicit an unacceptable adverse toxicological effect in a human receptor.

"unit risk" [UR] means the amount of risk predicted per unit concentration (e.g., risk per mg/m^3 in air) for a non-threshold substance to which a human receptor is exposed on a continual basis. The unit risk multiplied by the amortized exposure concentration is the estimated risk.

"vulnerable human receptor" refers to individuals with a greater inherent risk of experiencing adverse health effects from exposure to COPCs due to increased sensitivity or susceptibility. Increased sensitivity means that health effects may occur at lower doses than in the general population. Susceptibility refers to behaviours, environmental conditions or any other condition that results in a higher rate of exposure than the general population.

"worker-resident" refers to any individuals who are exposed occupationally within the project fenceline, and reside within the Study Area. This includes individuals housed in work camps, as well as individuals who live in residential areas.

ACRONYMS

ADAF	age-dependent adjustment factor
atm-m^3/mol	atmospheric metre cubed per mol
ATSDR	Agency for Toxic Substances and Disease Registry (United States)
B.C.	British Columbia
CalEPA	California Environmental Protection Agency
CAS	Chemical Abstracts Service
CCME	Canadian Council of Ministers of the Environment
CEAA	Canadian Environmental Assessment Agency
COPC	contaminant of potential concern
CSM	conceptual site model
CSR	Contaminated Sites Regulation
DAD	Discharge Abstract Database
DQRA	detailed quantitative risk assessment
EA	environmental assessment
EAO	Environmental Assessment Office
EDI	estimated daily intake
ENV	British Columbia Ministry of Environment & Climate Change Strategy
ET	exposure term
FNHA	First Nations Health Authority
g/mol	grams per mol
GCDWQ	Guidelines for Canadian Drinking Water Quality
HHRA	human health risk assessment
HI	hazard index
HIA	health impact assessment
HQ	hazard quotient
IARC	International Agency for Research on Cancer
ILCR	incremental lifetime cancer risk
INCHEM	International Program on Chemical Safety
IRIS	Integrated Risk Information System
ITER	International Toxicity Estimates for Risk
K_{ow}	octanol water partition coefficient
L/min	litre per minute
LADD	lifetime average daily dose
m/s	metre per second
mg/kg bw/d	milligram per kilogram of body weight per day
mg/L	milligram per litre
mg/m^3	milligram per cubic metre
ministry, the	Ministry of Health
mm Hg	millimetre mercury
MPOI	maximum point of impingement

MSP	Medical Services Plan
OCAP	ownership, control, access, and possession
PAH	polycyclic aromatic hydrocarbon
$PM_{2.5}$	particulate matter less than 2.5 microns in diameter
PM_{10}	particulate matter less than 10 microns in diameter
RAF	relative absorption factor
RAGS	risk assessment guidance for superfund
RAIS	Risk Assessment Information System
RfC	reference concentration
RfD	reference dose
RIVM	Netherlands National Institute of Public Health and the Environment
RMDI	recommended maximum daily intake
RsC	risk-specific concentration
RsD	risk-specific dose
SF	slope factor
TC	tolerable concentration
TDI	tolerable daily intake
TK	traditional knowledge
TRV	toxicological reference value
UCLM	upper confidence level of the mean
µg	microgram
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples
UR	unit risk
US EPA	United States Environmental Protection Agency
VC	valued component
WHO	World Health Organization

1. INTRODUCTION

1.1 Purpose of guidance document

This technical guidance provides a standardized approach to assessing the potential human health risks from exposure to environmental contaminants related to proposed projects, events, or activities (projects) in British Columbia (B.C.). This standardized approach is herein referred to as 'prospective human health risk assessment' (HHRA). The guidance can support reviews of HHRAs conducted for regulatory approval processes such as environmental assessments (EAs) and permitting, or other purposes such as government or community-led assessments. With this guidance, the Ministry of Health (the ministry) provides greater clarity and transparency for risk assessors, industry (proponents), and the public on recommended best practices for prospective HHRAs.

This guidance does not replace or supersede regulatory requirements or related policy under the *B.C. Environmental Assessment Act* (2018), the *B.C. Environmental Management Act* (2003), or requirements set out by other decision-making processes and authorities. For cases where there are differences in the available guidance, the regulatory decision-maker's discretion takes precedence (e.g., permitting guidance, EA guidance).

Note that this guidance is not intended as a substitute for the sound judgment of qualified and experienced risk assessment professionals. It is recognized that the guidance may not be applicable or practical for all HHRAs and that depending on the conditions of the project, location or local priorities, it may be justified to apply methods or assumptions that differ from this document. However, the use of alternative methods or assumptions should be clearly documented and supported with sound rationale including references and implications for the HHRA findings where relevant. The ministry can be consulted to receive early feedback on any aspect of an HHRA (e.g., Problem Formulation; chemicals and receptors to consider).

This guidance document will be updated periodically. Comments and suggestions on the guidance document can be submitted to the Ministry of Health, Health Protection Branch.

1.2 Background and context

HHRA is a scientific process that estimates the potential toxicological human health risks from exposure to chemical contaminants in environmental media. An HHRA determines if contaminant(s) with potential health effects are present, if human receptor(s) are present, and if there are exposure pathways from the contaminant(s) to the human receptor(s), which could result in risks to health. The results of an HHRA are often used by decision-makers and others to communicate, manage, and plan for potential risks to the population.

HHRA has been recognized internationally for many years by Health Canada, the United States Environmental Protection Agency (US EPA), the World Health Organization (WHO), and other regulatory agencies (Alberta Health, 2019). In Canada, the Canadian Council of Ministers of the Environment (CCME), Health Canada, and various provincial agencies apply HHRA methods to develop environmental quality criteria for air, soil, food, and drinking water.

The ministry and health authorities regularly apply HHRA methods to identify, assess, and respond to potential public health hazards and prioritize policy needs in B.C.

1.3 Scope of guidance document

This document provides technical guidance on HHRAs conducted for proposed projects that may result in the release (see section 2.3), disturbance, or mobilization of substances to the environment which pose a potential risk to human health. Proposed projects may include, but are not limited to, activities which require: EAs, permit applications, or government or community-led assessments. The following are beyond the scope of this guidance:

- HHRAs conducted under B.C.'s Contaminated Sites Regulation (CSR);
- assessments supporting an emergency response;
- assessments of existing contamination; and,
- assessments of impacts to human health from biological (e.g., pathogenic microorganisms), radiological (see Health Canada, 2016b), or physical hazards such as noise (see Health Canada, 2017b), vibration, or light.

The B.C. CSR standards are intended for application at contaminated sites (not prospective projects) and allowing contaminant concentrations to increase up to CSR values is not an acceptable risk management strategy.

While this HHRA guidance does not cover impacts to human health from the biological, radiological, or physical hazards listed above, assessment of these aspects is also typically required for EAs. Reference to these assessments should be provided in the HHRA. An exception to this is the assessment of parameters that have aesthetic or operational criteria (e.g., the Canadian Drinking Water Quality Guideline for chloride is aesthetic). Aesthetic and operational criteria can help determine if the water can be considered drinkable, and these parameters may also have indirect health endpoints and/or water treatment implications (Health Canada, 2019b). Thus, a qualitative assessment of parameters with aesthetic or operational criteria should be presented in the HHRA, as this is typically not included in water quality effects assessments within an EA. The results can then be used by health authorities and water suppliers to determine the quality of source water and level of treatment required.

HHRA is a component of Health Impact Assessment (HIA), which is not addressed in this guidance. HIA involves evaluating a broad range of potential impacts to the health of individuals and populations including social, economic, cultural, and biophysical determinants of health. Aspects of HIA are addressed in other required components of an EA, such as the social, economic, and culture/heritage effects assessments. The B.C. Environmental Assessment Office (EAO) provides guidance for these effects assessments.

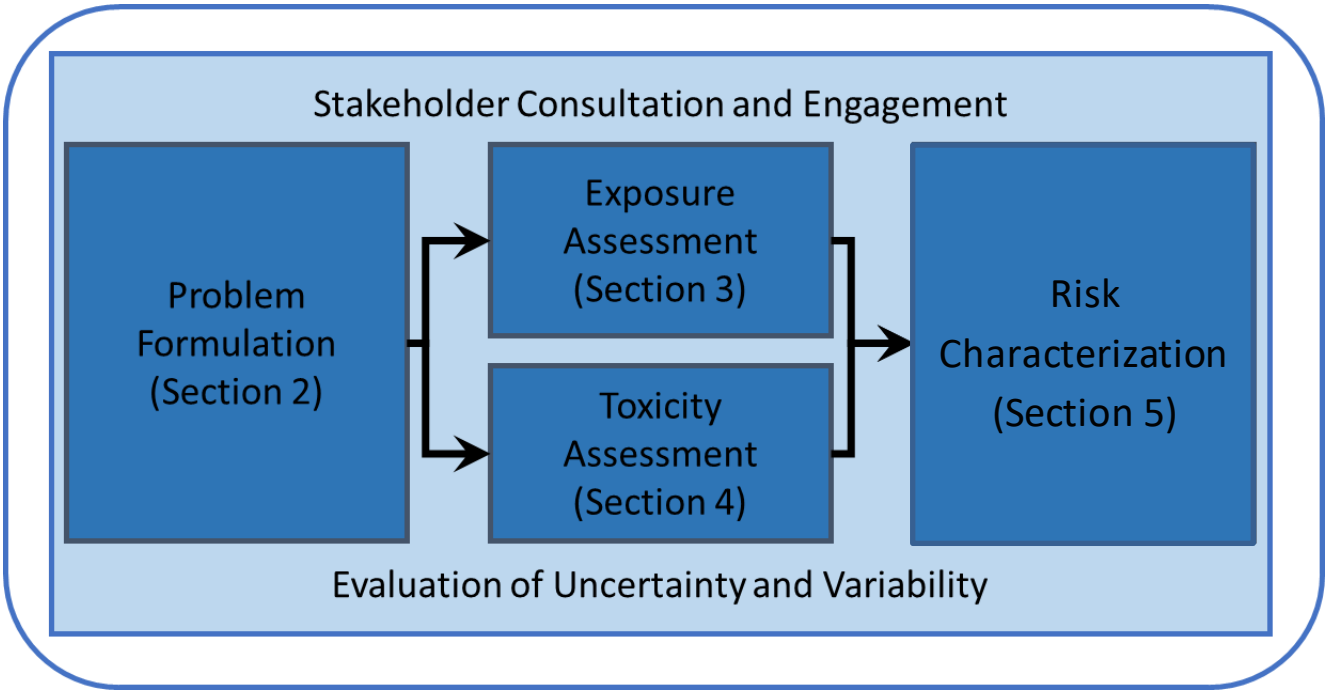
When determinants of health other than chemical exposure are assessed, HHRA should be conducted with the intent of being integrated into HIA. An HHRA is often a sub-component (or appendix) of a much larger HIA. It is recommended that HIA be conducted in accordance with any policies or guidance provided by Health Canada, or provincial agencies such as the B.C. EAO.

1.4 Overview of human health risk assessment framework

All HHRAs should follow the risk assessment framework recognized and used by regulators and industry internationally, as shown in figure 1. The key stages in this framework are:

- **Problem Formulation:** At this stage, the contaminants of potential concern (COPCs), exposure pathways, and human receptors that may be affected are identified. The level of detail required for the HHRA is then determined, followed by development of the conceptual site model (CSM);
- **Exposure Assessment:** The next stage in the HHRA involves estimating the dose or concentration of COPCs to which human receptors (hypothetical person or life stage with predefined physical and biological characteristics) may be exposed;
- **Toxicity Assessment:** This stage, which is conducted concurrently with the Exposure Assessment, involves identifying the potential health effects of each COPC and published toxicological reference values (TRVs) recommended by regulatory agencies;
- **Risk Characterization:** The final stage of the HHRA brings together the results of the Exposure and Toxicity Assessments to estimate potential risks to human health;
- **Evaluation of Uncertainty and Variability:** During all stages, uncertainty and variability are considered, and both need to be acknowledged when interpreting the results of Risk Characterization; and,
- **Risk Communication:** This stage provides the necessary context for the numerical results so that the HHRA can be interpreted. Communication between the proponent, regulator, and potentially affected stakeholders is ongoing throughout the HHRA process.

Figure 1: Risk assessment framework



The HHRA process is not linear and may include multiple iterations, returning to earlier stages of the process in more detail. Use of preliminary or less detailed screening assessments (see section 1.4.5) is an option for smaller or inherently low-risk projects.

1.4.1 When to conduct an HHRA

There are circumstances where an HHRA is a regulatory requirement. However, there may be circumstances outside a regulatory regime that would warrant the completion of an HHRA. It is recommended that an HHRA be completed under the following conditions:

- proposed activities may result in environmental conditions where chemical concentrations exceed guidelines or standards for the protection of human health, or chemicals released by an activity could be reasonably expected to be present in multiple environmental media;
- proposed activities are predicted to contribute contaminants to the environment;
- proposed activities are in an area that is already experiencing environmental pressures from other current or approved projects;
- proposed activities involve several contaminant sources, exposure pathways, and human receptors; or,
- there are concerns from the public, health agencies, stakeholders, or regulators that proposed activities may impact human health.

For HHRAs conducted outside of the EA process, it is important to consider and describe the following:

- the purpose of the HHRA (e.g., to address community concerns);
- decisions to be made based on the HHRA results;

- legal/regulatory context for the HHRA;
- how the HHRA was funded;
- how local communities were engaged; and,
- consideration of other health endpoints outside of the HHRA (e.g., social, economic, cultural/heritage determinants of health) and where those assessments are located.

1.4.2 Engagement of other parties

An HHRA should follow best practices for engagement and planning (British Columbia Ministry of Health, 2018) including with Indigenous groups and peoples, as it serves to address the concerns of all potentially affected parties. Further, in November 2019, the provincial government passed the *Declaration on the Rights of Indigenous Peoples Act* (2019a), to align B.C.'s laws with the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). The new legislation respects the human rights of Indigenous peoples and introduces a framework that guides how work done together is accomplished in a transparent and predictable manner.

It is strongly encouraged that engagement with stakeholders, Indigenous groups and peoples, and community members takes place as early in the process as possible as this step merits significant consideration. The important of engagement with other parties should not be underestimated as the HHRA will only be as useful as the initial scoping defines. Topics for engagement and planning may include the following:

- defining the scope of the HHRA;
- clarifying the purpose of the HHRA and the decision-making process;
- determining communication methods and timelines;
- establishing methods for identification and screening of exposure pathways, COPCs, and human receptors (including identification of vulnerable groups);
- determining appropriate human receptor characteristics as well as exposure assumptions;
- coordinating data collection and sampling plan methodology;
- selecting Risk Characterization methods, including defining the levels of acceptable risk based on scientific evidence and dose-response data; and,
- developing plans for community involvement and communication.

Early and meaningful community engagement can lead to increased acceptance of the assessment findings.

CONSIDERATIONS FOR ENVIRONMENTAL ASSESSMENT

For EAs, engagement of public, stakeholder, and Indigenous groups and peoples should be completed in accordance with the EAO's guidance materials and procedural requirements, which would apply to any HHRA conducted as part of an EA. The EAO's guidance documents outline the requirements and recommendations for project proponents to ensure clarity and consistency in the implementation of the *Environmental Assessment Act* (2018). The EAO's guidance and materials are available online at: https://www2.gov.bc.ca/gov/content/environment/natural-resource-stewardship/environmental-assessments/guidance-documents/2018-act-guidance-materials

Traditional knowledge should be obtained and used in accordance with the EAO's guidance materials and procedural requirements, and other provincial guidance. The EAO's Indigenous Nation guidance is available online at: https://www2.gov.bc.ca/gov/content/environment/natural-resource-stewardship/environmental-assessments/guidance-documents/indigenous-nation-guidance-material

The EAO also has specific guidance on Indigenous Knowledge, available online at: https://www2.gov.bc.ca/assets/gov/environment/natural-resource-stewardship/environmental-assessments/guidance-documents/2018-act/guide_to_indigenous_knowledge_in_eas_v1_-_april_2020.pdf

1.4.3 Qualifications of risk assessors

Proper application of this HHRA guidance requires substantial expertise and professional judgment. Conducting an HHRA requires interpretation of information from multiple disciplines, then application of this information in a specialized manner. HHRAs are typically completed by a team of subject matter experts with oversight by a qualified individual, whose area of practice includes risk assessment. A qualified individual has the relevant education, experience, or knowledge, which may include Indigenous and local knowledge (EAO, 2020a).

It is recommended that HHRAs are conducted by a qualified individual who is a registered professional and whose profession is regulated by a regulatory body named in the *Professional Governance Act*. Currently, there are five professional regulatory bodies named in the *Professional Governance Act*: Association of BC Forest Professionals; Applied Science Technologists and Technicians of BC; BC Institute of Agrologists; College of Applied Biology; and Association of Professional Engineers and Geoscientists of BC, known as Engineers and Geoscientists of BC. Professional associations that are not regulated under the *Professional Governance Act* do not have the same responsibilities as professional regulatory bodies (e.g., may not have obligations to maintain ethical or legal duties to protect the public interest).

Hiring registered professionals for a proposed project has the advantage of ensuring that the highest professional, technical, and ethical standards are applied to protect the public interest. Information on professional governance of registered professionals in B.C. is provided at https://professionalgovernancebc.ca/about/professional-governance/.

The following guidelines may assist in obtaining a quality HHRA.

- The lead risk assessor, or the key risk assessors of a project, provides a signed registered professional or accredited practitioner statement in the report which includes the following assertions:
    - the lead risk assessor has a minimum of 10 years of demonstrable professional experience conducting HHRAs or an equivalent combination of education, training, and experience;
    - the lead risk assessor takes responsibility for the HHRA and its findings;
    - information on which the HHRA is based (such as supporting assessments or data produced by other disciplines) is appropriate for application in an HHRA context;

- appropriate registered professional(s) or accredited practitioner(s) should provide professional statements asserting they have the necessary experience to provide such data and the information is adequately characterized;
- the HHRA has been completed in accordance with current general standards of professional practice and any guidance provided by the ministry; and,
- the information provided is true and accurate based on current knowledge as of the date completed.

It is recommended that the HHRA be developed and reviewed in collaboration with other disciplines which contributed inputs to the HHRA to ensure that analysis and interpretation of the input data was valid and appropriately applied.

1.4.4 Linkages to other scientific disciplines

HHRAs require information from other scientific disciplines and stakeholder engagement to use as inputs. In turn, the HHRA may inform other assessments, including HIA.

HHRA reports completed as a component of an EA must include key information used as inputs in the HHRA, and reference the applicable chapter and section of the EA so that reviewers can easily locate the complete data set and applied methodology. For HHRAs completed independent of an EA it is required that they exist as a complete stand-alone document. Linkages to other reports or data sources must be clear and any external supporting material is easily accessible to reviewers. Key pieces of information and inputs should be summarized and referenced (to the specific chapter and section) with enough context provided that the original source does not need to be consulted and the HHRA results can be reproduced. The nature of any shared information should be clearly presented within the HHRA document, indicating where the following was completed:

- determination or calculation of input/output values;
- quality control and quality assurance checks; and,
- analysis and interpretation of data.

Changes to the proposed project or supporting information may require revising the HHRA.

1.4.5 Level of detail

The level of detail for an HHRA will vary depending on the nature of the decision being made, the regulatory context, and the outcome of the Problem Formulation. A more detailed HHRA will have larger data requirements, which allows for a more refined assessment of potential risks; however, all levels of HHRA should provide the same level of health protection. While additional detail can give the appearance of greater accuracy, any additional detail should reflect the information gaps and inherent uncertainties in the HHRA process without overstating the accuracy of the results. The required level of detail of an HHRA is driven by the following factors:

- type, magnitude, and duration of potential impacts from the project;
- number of COPCs and their physical-chemical/toxicological properties;
- availability of environmental data and level of reliance on predictive modelling;

- magnitude of predicted COPC concentrations;
- availability of community-specific data;
- proximity to human populations and land use; and,
- information and communication needs of stakeholders.

A simplified or screening-level risk assessment using only worst-case assumptions or qualitative assertions may be sufficient to demonstrate that human health risks are negligible. For example, providing evidence that there are no operable exposure pathways and therefore no means of exposure could be used to demonstrate negligible human health risks. Increasing in complexity, use of worst-case predicted COPC concentrations, receptor characteristics, and toxicity assumptions could be sufficient to demonstrate either a lack of human health risk, or identify COPCs that require more detailed assessment.

Worst-case and qualitative assessments are often not sufficient for larger or higher-risk projects such as those requiring an EA. In these cases, qualitative or simplified HHRAs with generic and overly conservative assumptions should only be undertaken as a preliminary step to remove low-risk elements from further consideration by demonstrating that the applied qualitative or quantitative methods are protective of all the human receptors defined in the Problem Formulation. However, if there are multiple potentially operative exposure pathways (see section 3.7.2), interactions between chemicals, or the methods used are not protective of all potential exposure scenarios, then a more detailed HHRA is required.

After an initial assessment based on worst-case scenarios the HHRA can undergo incremental refinement introducing additional detail as required for any COPCs or exposure scenarios where health risks are predicted or there is concern from the community, stakeholders, Indigenous groups and peoples, or government agencies. This allows for effort and resources to be efficiently targeted at hazards posing the greatest potential risk. A minimum level of detail for HHRAs is not required and will not be defined in this document; however, in any case where an HHRA predicts potential health effects, the following information should be provided:

- the nature of the potential adverse health effect(s);
- the relevant conditions (location, frequency, meteorological conditions, operational conditions, receptor behaviours, project phase, etc.) under which potential health effects are predicted;
- the groups or locations that could be affected under both present and future scenarios;
- the contribution to overall risk from each exposure pathway;
- the controls, mitigation measures, or monitoring programs that can be implemented to prevent or address the potential effects; and,
- the residual impacts to human health (if any) with the implementation of these mitigation measures.

If risks are predicted using simplified or screening-level risk assessment methodology, further detailed assessment is strongly recommended. Relying on the conservative nature of applied assumptions or

assuming risk is overestimated is not an acceptable means to demonstrate that a project does not pose risks to human health.

CAUTION

Care should be taken when interpreting predicted risks calculated with methods having different levels of detail. As the level of detail in the HHRA increases, there is an associated decrease in conservatism as uncertainties are reduced. Comparisons between predicted levels of risk with different levels of assessment detail are not appropriate.

Use of more detailed HHRA methods such as probabilistic risk assessment should be consistent with Health Canada (2010c) guidance.

1.5 Using this guidance

As mentioned, this guidance provides a standardized approach to conducting HHRAs in the B.C context. Each section of the guidance represents a key component of the HHRA process. A list of required elements of an HHRA is provided in Appendix A: Prospective Human Health Risk Assessment Review Checklist (review checklist). In cases where required elements of the guidance are not applicable for an HHRA, explicit justification should be provided for their exclusion. Failure to include any of the listed requirements will be considered a deficiency in the HHRA. It is recommended that any HHRA be presented using the same sections (as applicable) and order as written in this document. Large tables and supporting information should be presented as appendices rather than in the main text.

The review checklist in Appendix A will assist risk assessors to ensure that all required elements have been considered in the HHRA. The intent of the checklist is only to identify elements of the HHRA which may require further technical review; inclusion of all the elements on the Review Checklist is not necessarily sufficient for an HHRA to be considered complete. HHRAs which are found to be incomplete or which contain major errors that could substantively change the conclusions of the risk assessment should be returned to the proponent for resubmission.

The review checklist is not intended to replace internal reviews for quality control by the risk assessor, or ongoing collaboration. The submitted HHRA should include a completed version of the checklist, with references to sections, page, numbers, and paragraphs where the applicable information has been presented to facilitate review and potentially reduce the number of information requests.

ENVIRONMENTAL ASSESSMENT

When consulting BC EAO guidance referenced in this document, the most current version should be consulted. Current versions are available at:
https://www2.gov.bc.ca/gov/content/environment/natural-resource-stewardship/environmental-assessments/guidance-documents/2018-act-guidance-materials

1.6 Alternative methods

There is no one-size-fits-all approach to HHRA and situations can arise where recommendations in this guidance cannot be realistically or practically followed, or where alternative methods may be more appropriate. Examples of alterative methods could include:

- application of novel or site-specific fate and transport models;
- alteration of human receptor characteristics or behaviour patterns;
- use probabilistic risk assessment or more detailed statistical analysis;
- comparison to epidemiological or population health studies; and
- any other risk assessment technique not discussed in this guidance.

While deviation from the methods recommended in this guidance will warrant further scrutiny by health reviewers, other approaches can be proposed by risk assessors to replace or enhance any part of this guidance. However, use of alternative methods based solely on professional judgement or familiarity, or their adoption in other jurisdictions, is not considered sufficient as this causes significant confusion and delays during the review process and potential inconsistencies in decision-making. If alternative methods are proposed, it is strongly recommended that:

- the alternative method be introduced to the health reviewers as early in the process as possible, to determine acceptability;
- the need for an alternative method be clearly outlined (e.g., data availability, unique study area conditions, applicability of recommended methods to the proposed activity, etc.), along with the advantages and disadvantages of using the alternative method;
- a discussion of the assumptions and limitations of the alternative method, and how these differ from the recommended methods be included. This discussion must also establish that the assumptions and limitations of the alternative method are consistent with the rest of the HHRA; and
- justification be provided to explain how the alternative method provides an equivalent level of protection to existing and potential human receptors as the recommended method. This could include a discussion on the conservativeness of alternative methods' assumptions, the scientific basis of the alternative method, or case studies where the alternative method was successfully utilized.

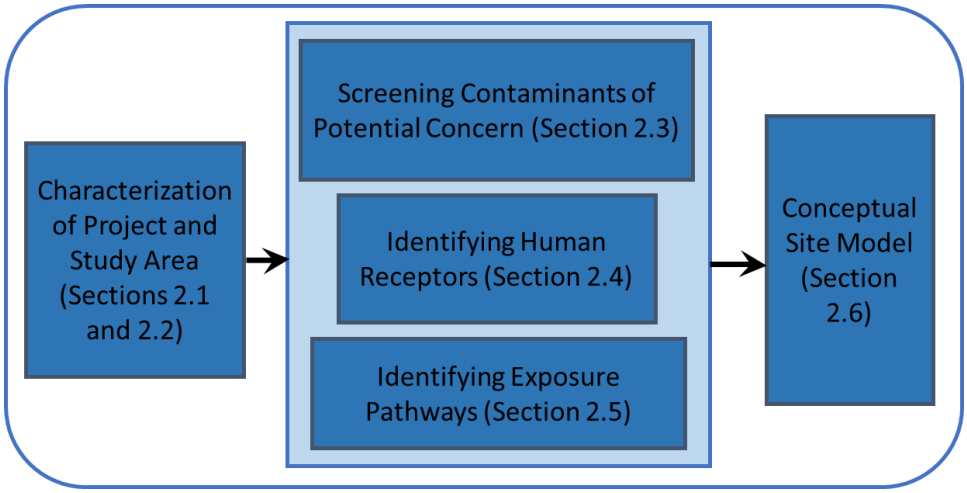
2. PROBLEM FORMULATION

The Problem Formulation stage determines the required scope and detail of the HHRA. These determinations are based on the nature of the proposed project, event, or activity and the characteristics of the surrounding Study Area. The Problem Formulation focuses the HHRA to ensure that the correct issues are being addressed, and determines what information is required to answer the identified problems and concerns. Once finalized, the Problem Formulation should be able to identify all approaches, methods, and data needed to complete the HHRA. This is vital to ensuring the HHRA is suitable for its intended purpose and will meet the requirements of the regulatory and health agencies, as well as the concerns of stakeholders. After characterizing the proposed project and Study Area, the overall objectives of the Problem Formulation are to:

- identify COPCs;
- identify current and potential human receptors;
- identify exposure pathways through which COPCs may reach human receptors; and,
- use the above information to develop a CSM.

These overall objectives are summarized below in figure 2.

Figure 2: Problem Formulation overview



Where possible, consensus should be sought on the Problem Formulation from the risk assessor, stakeholders, and affected groups, including Indigenous groups and peoples as part of a planning and scoping stage. While it is not necessary that consensus is achieved on the Problem Formulation before continuing with the HHRA, it is strongly recommended that there is agreement on key elements before continuing, to prevent future delays and substantive information requests. At this stage, consideration should be given to filling critical data gaps and/or modifying the project to eliminate major sources of potential risk before proceeding further.

PLANNING AND SCOPING

The scope of the HHRA and the procedures and methods for conducting the assessment should be established as early as possible. For HHRAs conducted to support an EA, the overall scope, procedures

and methods are determined in a collaborative process following EAO guidance. For HHRAs conducted for purposes other than EA, similar scoping and planning methods are recommended, scaled as appropriate based on the nature of the proposed project and decisions to be made.

2.1 Characterization of the proposed project

The initial step in the HHRA process is determining the project-related sources of potential health risks. The resulting potential health risks should be listed, including clarification of those that will be addressed through the HHRA and those which may be addressed through other assessment methods, such as an HIA. The following information should be provided by the HHRA:

- the location and spatial footprint of the project, with geographic coordinates and accompanying figures or diagrams;
- a list of project and project-related infrastructure;
- sources of potential health risk and their general location;
- changes to the surrounding environment, including but not limited to, building of roads or transmission lines, limitations on public access, or land disturbances; and,
- the timescale for each phase of the project.

All phases of the project require evaluation, including: construction, operation, decommissioning, and closure/remediation. Assessing the largest releases of COPCs between each project phase as a combined worst-case scenario is an option; however, if risks are predicted this can make development of mitigation and/or management strategies more difficult, and it may be necessary to distinguish between project phases and assess them separately for key COPCs. In the EA process, baseline conditions can differ from existing conditions, please see EAO (2020c) for more information.

REMINDER

Completion of an HHRA requires information on the project design. Any changes to the design could require revisions to the Problem Formulation. Key areas of influence, such as sources of contaminant release or control, should be identified so that any proposed changes to project design can be linked to requirements to update specific elements of the HHRA (see section 1.4.5).

2.2 Characterization of HHRA Study Area

The HHRA report must include a description of the Study Area and provide information to identify relevant human receptors, exposure pathways, and potential health effects of the project.

Study Area refers to the spatial boundaries of the HHRA, including all areas of supporting assessments that directly contribute to the potential for biophysical changes in environmental media (e.g., air quality and water quality). The Study Area should be sufficiently large to capture the spatial extent of project releases (e.g., chemical fate and transport) in all relevant environmental media. If exposure pathways are not operable for certain environmental media, then the Study Area can be adjusted to reflect the applicable spatial boundaries (e.g., if there are no project-related releases to groundwater, then the Study Area for the HHRA would not include the spatial boundaries for the groundwater assessment). The Study Area does not include the spatial area within the project fenceline where access to the

general public is restricted; however, if worker camps are present within the fenceline then those locations must still be assessed (see section 2.4.2).

Temporal boundaries should also be established based on the proposed duration of the project, starting from the construction phase and continuing until decommissioning and reclamation. Temporal boundaries should consider any infrastructure or COPCs remaining in place that can pose ongoing health risks. The assessment must also consider the full temporal scale of potential project-related effects, that may extend past the project and remain after closure/decommissioning, on current and future generations.

It is not necessary to include a detailed characterization of the Study Area in the HHRA if it is provided in another document; however, all relevant information needed to evaluate the HHRA must be summarized within. The original content should be included as an appendix if possible or cross-referenced to a specific chapter and section of the EA if necessary. A discussion on how input from the public, stakeholders, regulators, Indigenous groups and peoples, and other interested parties was incorporated into the characterization of the Study Area must also be included.

Information on the Study Area should represent the current conditions and existing environmental impacts or exposure, especially if there has been ongoing industrial development or changes to the environment, and should consider natural or anthropogenic trends reasonably expected to occur during the lifetime of the project. All sources of data, including Indigenous Traditional Knowledge (TK), and the methods of data collection should be documented.

If there is limited information available and collection of data from the Study Area is not feasible, proxy data originating from a nearby area may be appropriate. Rationale justifying the use of literature sources, databases, or environmental monitoring data should be clearly described and explain how the information is representative of the Study Area.

The overall quality and reliability of the data used in the Study Area characterization should also be discussed (see section 3.1.1), including any data gaps, uncertainties, or use of proxy data. Data sources may include:

- information collected from field studies;
- information collected from stakeholder engagement;
- published reports from government or regulatory sources;
- reports from previous assessments or regional studies conducted in the Study Area; and,
- any other peer-reviewed literature.

2.2.1 Physical description of the Study Area

The physical description of the Study Area should provide information on the following characteristics and their variability within the Study Area:

- regional geology, local geology, and topography;
- soil types and characteristics;

- surface water bodies present, and their distance from the project;
- hydrogeological conditions including shallow groundwater depth, flow direction, hydraulic conductivity, and hydraulic gradient if groundwater-based exposure pathways are applicable;
- climate and meteorology (i.e., atmospheric phenomena and weather) within the Study Area; and,
- presence of terrestrial and aquatic plant and wildlife species.

Project activities may affect physical characteristics of the Study Area through the release of COPCs, earthworks and compaction of soil or sediment, diversion of water bodies, loss of organic material, erosion, or disruption of agriculture and other land use. These changes may cause direct or indirect health effects in the population and this information should be provided in the assessment.

Physical characteristics of environmental media in the Study Area, or climatic, physiographic, and/or hydrogeological features that could create contaminant pathways linking human receptors with contaminants should also be discussed.

If possible, potential changes to the physical characteristics of the Study Area should also be discussed and predicted changes which could affect future land use or human activity (see section 2.2.3) should be briefly addressed.

2.2.2 Chemical description of the Study Area

Baseline concentrations of chemicals in the environment identified in the chemical inventory should be evaluated with field sampling programs. Other parameters which may not directly pose health risks, such as salinity, hardness, pH of environmental media, or meteorology but could influence the fate and transport of chemicals in the environment may also need to be included. Sampling results can be provided as summaries, but the full results, along with discussions of sample collection, number and location of samples, laboratory analysis and detection limits, and quality control documentation should be presented. For HHRAs completed as part of an EA, full sampling results can be provided via references to the specific chapter or section of the EA, otherwise, this information should be included either in an appendix or within the body of the HHRA. If full results are not provided, summary information should still include all inputs into models, calculations, and/or COPC screening decisions.

LABORATORY ANALYSIS METHODS

Caution should be taken when selecting laboratory analytical methods. Limits of detection should be low enough to detect the lowest concentration that could pose a risk to human health. Limits of detection should also be lower than any relevant health- or risk-based environmental quality guidelines. Failure to choose appropriate limits of detection will result in a significant source of uncertainty and may require additional sampling of environmental media.

The chemical description should include all relevant environmental media. Summary statistics should also be provided (see section 3.6).

For common air contaminants, the application of statistical percentiles to the data may be required for consistency and comparison to air quality criteria. For example, the 2025 Canadian Ambient Air Quality Standard (CAAQS) for 1-hour sulphur dioxide (SO_2) is 170 µg/m^3, which is calculated as the three-year average of the annual 99th percentile of the SO_2 daily maximum 1-hour average concentrations (CCME, 2017).

CAUTION

Comparison to environmental quality guidelines can be used at this stage, but only to establish if baseline concentrations are elevated naturally and/or from previous anthropogenic disturbances (see section 2.3). Comparison to environmental quality guidelines should not be used to assess potential risks to human health unless they are appropriate COPC screening criteria for use in HHRA (see section 2.3). section 3.8.1 describes the use of air quality criteria for inhalation exposure only. Application of individual environmental quality objectives does not sufficiently address the potential for multimedia exposure, chemical mixtures, or additional exposure pathways which may be relevant for prospective HHRAs.

The chemical description provides the foundation of the HHRA and should be as complete as possible. Chemicals can be excluded from the baseline concentration survey or from consideration in specific media if it can be reasonably expected that there are no natural or anthropogenic sources which would result in their presence; however, specific justification for any exclusion should be provided. Modelling of baseline concentrations should only be undertaken when collection of data from the Study Area is deemed to be not practical or feasible; for example, using food-chain modelling to predict tissue concentrations in large mammals. Supporting rationale and validation of the predicted concentrations should be provided when collected data are not available.

The chemical description should include consideration of anthropogenic sources and historical contamination as it is not intended to represent the pristine natural environment. If locations within the Study Area are expected or are shown to have significantly different baseline concentrations for any reason, these locations should be evaluated as separate microenvironments (see section 3.7.3). Care should be taken to ensure that collected data are relevant to human exposure and does not include locations physically inaccessible to human receptors or from which contaminants could not be transported; however, this does not apply to assessment of country foods or wildlife (see section 3.5.4).

CAUTION

While existing sources of exposure to contaminants should not be overstated to minimize the estimated contribution of the project's impacts, if baseline conditions are not properly established in the chemical description, then any elevated concentrations detected after the project begins could be attributed to the project.

Requirements for sampling programs are discussed in more detail in section 3.5.

2.2.3 Human activity in the Study Area

A discussion of the historical, current, and potential future land uses and associated human activities should be included in the Study Area characterization. The following elements should be included:

- general description of all land uses within the Study Area and potential future changes to these land uses, including official community or development plans, Indigenous groups and peoples land use plans, presence within the agricultural land reserve, and existence of provincial or federal parks;
- description of all communities including Indigenous groups and peoples, First Nations reserves and other traditional territories within the Study Area and their proximity to the project;
- description of the available population health information (see section 3.3.2) for the identified communities and the presence of any vulnerable populations;
- identification of any individual residences (permanent and temporary), recreational areas, or culturally significant locations within the Study Area;
- identification of any current and historical sources of contamination including residential, commercial, agricultural, or industrial activity;
- presence of structures or features that may influence human activity patterns, including preferential use areas or permanent restrictions on accessibility to the general public (including trespassing);
- discussion of expected human activities within each land use, based on reasonably expected and preferential uses and consultations with stakeholders;
- discussion on country food consumption and agricultural activity (including backyard and community gardens) in the Study Area;
- specific discussion on traditional uses such as food collection, trapping, hunting, and fishing, as well as any programs or initiatives promoting traditional practices (see section 2.5.1); and,
- identification of drinking water sources and description of project watershed.

Identification of these elements should primarily be based on input from residents and stakeholders, public records, or zoning/planning documents, in accordance with requirements of the applicable regulator.

If worker-residents are present, additional characterization of the project workforce may be required (see section 3.3).

Engagement with stakeholders and Indigenous groups and peoples should take place as early as possible to obtain information on community-specific activities and land use in the area of the proposed project. Appropriate protection of this community-specific information should be ensured. While community-specific data from the area is preferred (e.g., community-specific country food consumption rates), it must be available and appropriate. Appropriateness of community data can be evaluated using the analysis presented in section 4.0 of the Alberta Health (2018) document *Inventory and Analysis of*

Exposure Factors for Alberta. The EAO also provides guidance on engagement and the incorporation of Indigenous Knowledge into EAs.

Clear methodology should be presented showing how data was collected, used, and the implications of any high or low values compared to generic exposure factors. If there is a high degree of uncertainty in community-specific data, the use of more generic factors for exposure model inputs should be considered. Self-reported data might not be reliable or standard within a community, and caution should be taken before applying information of this nature across an area. All information obtained in engagement with stakeholders and Indigenous groups and peoples should be summarized. It should be clear where and how this information was used in completion of the HHRA.

2.2.4 Cumulative effects in the Study Area

HHRAs must consider cumulative effects, as defined in paragraph 22(1)(a) of the federal *Impact Assessment Act* (2019), from the project in combination with effects of other physical activities that have been or will be carried out. Consideration of other sources of COPCs should be included as part of the Study Area characterization. This includes COPCs from existing projects, any activities that overlap with the effects of the proposed project, as well as any activities which have received regulatory approval (see section 3.2.4). Assessment of cumulative effects for HHRAs completed as part of an EA should be undertaken in accordance with guidance from the B.C. EAO (2017, 2020b) and federal cumulative effects guidance in *Assessing Cumulative Environmental Effects* (CEAA, 2018) under *IAAC* (2019) and should consider work under the B.C. Cumulative Effects Framework (EAO, 2017). For projects being assessed outside of the EA framework, the scope of the cumulative effects assessment should be based on requirements outlined in legislation or by the decision-maker; however, following the B.C. Cumulative Effects Framework is recommended.

If a detailed list of other projects and activities is included in another section of the application or technical assessment report, such as the air quality assessment, that information can be briefly summarized and clearly cross-referenced in the Problem Formulation. Each activity should be described in adequate detail to allow potential environmental effects to be characterized for later assessment. Key pieces of information include:

- location, size, and spatial distribution of components;
- components and supporting infrastructure;
- expected life or period of activity, and phasing involved;
- variations in seasonal operation;
- frequency of use for intermittent activities;
- transportation routes and mode of transport;
- processes used for industrial activity;
- emissions, discharges, and wastes that are likely to be released;
- approvals received and maximum allowable rates of release of COPCs; and,
- duration of any in-place or planned follow-up program.

Where a scenario of future development is being considered, data surrogates for key pieces of information may be established by referencing typical development characteristics. The appropriate regulatory or permitting agency may need to be consulted when using data surrogates. Additional guidance on assessment of cumulative effects is available from the Impact Assessment Agency of Canada (CEAA, 2018).

2.3 Screening Contaminants of Potential Concern (COPCs)

The COPC screening process includes two determinations:

- whether the chemical requires further evaluation in the HHRA; and,
- if the chemical is reasonably expected to be present in multiple environmental media (section 2.3.1).

All chemicals that may be released by project activities must be listed. For the purposes of this document, 'releases' are defined as any chemical released, discharged, emitted, mobilized, or modified by the project or any associated operations in the surrounding environment such as through leaks, spills, and fugitive emissions either intentionally or as reasonably expected. This includes pre-existing natural or anthropogenic chemicals that could be disturbed or mobilized in the environment due to project activities. Associated operations include, but are not limited to, power generation, waste management, and increased vehicle and road use that would not occur without the project. Generation of the chemical inventory will rely on the facility design, but other activities associated with the project including mobile source emissions also need to be included. Identifying every chemical released may not be possible; in such cases, alternatives such as a list of complex chemical mixtures may be acceptable.

The chemical inventory should include chemicals directly associated with the project and any chemicals generated by degradation or interactions within the environment. This could include reactions such as the formation of ozone or secondary particulate matter (PM) from nitrogen oxides. For the purposes of this document, PM is to be considered a chemical contaminant. Generic chemical inventories based on similar projects may be used as a starting point (see Health Canada, 2012, table A2; Health Canada, 2016a; and Appendix A of US EPA, 2005); however, the chemical inventory should be consistent with the proposed activities and be based on the project design specifications. Any changes to the project design or proposed processes will require a re-evaluation of the chemical inventory.

To facilitate risk management activities, for each chemical in the inventory, the source of its release to the environment should be specified.

A major objective of the Problem Formulation is to identify any chemicals that may be elevated in environmental media as a result of project activities in the Study Area. The process of determining whether to include a chemical as a COPC for further evaluation in the HHRA is a conservative first step that will be refined throughout the HHRA process. All chemicals identified in the chemical inventory as well as any naturally occurring chemicals or historical contaminants that may be mobilized during project activities must be included in the initial screening of COPCs. Following that, COPCs can then be removed from requiring further assessment through the multiple processes described below.

Justification must be provided for the removal of any chemical from the inventory from further evaluation.

CAUTION

Relying solely on baseline concentrations is not sufficient or appropriate for identifying or screening COPCs or for the eventual characterization of risks.

If measured baseline chemical concentrations are unavailable (see section 2.2), scientifically defensible rationale should be provided along with a qualitative discussion of the potential health risks. If measured baseline concentrations are unreliable, the causative or associated uncertainty should be clearly described, along with how such sources of uncertainty will be addressed. Chemicals cannot be screened out based on concerns regarding uncertainty; this would be considered a critical data gap in the Problem Formulation. If there is uncertainty as to whether a chemical is expected to approach or exceed recommended exposure limits for human health, it should be selected for inclusion.

The process for identification of appropriate COPC screening criteria for use in HHRA is described by Health Canada (see section 7.1.2 and Appendix C in Health Canada, 2019a). Appropriate COPC screening criteria for use in an HHRA are:

- solely health- or risk-based, and not consider factors such as achievability;
- scientifically defensible;
- based on current toxicological information;
- protective of all relevant exposure pathways and human receptors;
- address any concerns related to multimedia exposure and bioaccumulation potential; and,
- acceptable to the governing regulatory agencies (Health Canada, 2010c).

If COPC screening criteria do not meet all of these requirements, then risks to health must be fully characterized for each COPC. Provincial or federal environmental quality guidelines intended for contaminated sites, commercial food consumption, or individual exposure pathways that do not meet all of these criteria cannot be applied to existing or predicted chemical concentrations for screening COPCs except for the specific cases outlined in section 3.8.1.

It is possible that under certain conditions COPC concentrations less than the applicable CSR standard or other environmental quality guideline will result in exceedances of target levels. Several factors could contribute to this, such as: CSR standards not considering all relevant exposure pathways and biomagnification, additional exposure to more sensitive human receptors, or use of more recent TRVs. As such, comparison of predicted COPC concentrations against the CSR standards cannot be used to demonstrate that project risks are acceptable without specific consideration of the requirements above.

If measured or predicted maximum concentrations of any chemical exceeds the appropriate COPC screening criteria, the chemical should be retained in the HHRA. If measured or predicted maximum concentrations of any chemical is lower than the appropriate COPC screening criteria (defined above) for all applicable environmental media, the chemical may be excluded from further consideration. However, this does not apply to chemicals of special concern described in section 2.3.1 (e.g.,

bioaccumulative chemicals such as methylmercury). Exclusion of chemicals at any stage in the HHRA should be clearly documented.

If a chemical does not have an appropriate COPC screening criteria it should be included in the HHRA as a COPC. Chemicals without appropriate COPC screening criteria require further evaluation in the HHRA as COPCs, unless at least one of the following conditions for removing them from the HHRA are met:

- an initial evaluation of toxicity indicates the chemical is innocuous and does not pose any risk to human health (Health Canada, 2010c, section 3.4.2.4) based on the following conditions:
    - it is not a known or probable human carcinogen; and,
    - a Canadian regulatory review has indicated that human health-based guidelines are not required for the COPC due to low toxicity; or,
    - it is a naturally occurring chemical with no evidence of human toxicity.
- the project design has been changed to remove this chemical from use or to prevent its release or dispersion in the environment;
- the COPC cannot be assessed directly and will instead be assessed using a surrogate chemical or chemical group with similar physical parameters and toxicity information;
- fate and transport modelling (section 3.1.2) or results from other supporting reports indicate no measurable increase in predicted COPC concentrations at any location or environmental media, or in exposure to an identified human receptor.

MEASURABLE INCREASE

A measurable increase is defined as a predicted increase from baseline concentrations equal or greater than the lowest laboratory analytical detection limit available for that specific COPC and media available through an accredited environmental laboratory (or food-grade laboratory for country foods) within B.C. or established by the current version of the *British Columbia Environmental Laboratory Manual* (ENV, 2020b) due to project activities. Note that confirmatory sampling may be required to confirm this assertion, and that the values defined for measurable increase can vary between COPCs, even within the same chemical group.

Once an initial list of COPCs has been identified from the chemical inventory, as well as any naturally occurring chemicals or historical contaminants that may be mobilized during project activities, the properties of each COPC should be provided including:

- name and chemical abstracts service (CAS) registration number;
- chemical class (organic or inorganic);
- molecular weight;
- soil and water partitioning coefficients;
- octanol water partitioning coefficient;
- Henry's law constant;
- solubility; and,
- volatility.

2.3.1 Multimedia assessment

Multimedia assessments evaluate how multiple exposure pathways to a COPC contribute to health risks. Thus, a COPC identified in one environmental medium (e.g., copper in water) should be evaluated in all other environmental media (e.g., copper in air, soil, and sediment) to determine the potential risk from total exposure.

Physical-chemical properties of several chemicals are available in ENV Protocol 13 for Contaminated Sites, in Appendix A, tables A-1 through A-4 (ENV, 2017b), or can be obtained from Health Canada. The physical-chemical properties can be used to determine which chemicals should be included in a multimedia HHRA. Chemicals which meet any of the following criteria must be assessed using a multimedia approach (described in section 3.7.2), in accordance with the Persistence and Bioaccumulation Regulations under the *Canadian Environmental Protection Act* (1999):

- persistent – includes all inorganic and any organic chemicals with expected degradation half-lives greater than 2 days in air, 182 days in soil or water, or 365 days in sediment;
- bioaccumulative potential – includes any organic chemicals with a bioaccumulation factor greater than 5,000, a logK_{ow} (octanol water partition coefficient) value equal to or greater than 4.5, or any chemical which is known or suspected to bioaccumulate, bioconcentrate, or biomagnify;
- low volatility – includes any chemical with a molecular weight greater than 200 g/mol, Henry's Law constant less than 1.0×10^{-5} atm-m^3/mol, or vapour pressure less than 0.001 mm Hg (millimeter mercury); or,
- the chemical will be released directly to multiple environmental media.

A chemical which meets any of the multimedia criteria above must be assessed as a COPC in all potential environmental media and cannot be excluded from any individual media. (see section 3.7.2). Section 3.8 provides additional information on assessing exposure for individual environmental media (e.g., air contaminants that are only present in air).

Bioaccumulation factors are a preferred metric as they take all uptake pathways into account; however, it is recognized that problems exist with many published bioaccumulation factors for chemicals. For example, bioaccumulation factors often lack consideration of physiological or toxicokinetic mechanisms for substances that are essential at low concentrations or that mimic those essential substances. To account for this, multiples lines of evidence should be applied when identifying the bioaccumulative potential of COPCs.

2.3.2 Refining the list of COPCs

While the purpose of the initial COPC screening process is to identify all COPCs, the COPC list can be further refined for feasibility purposes in cases where hundreds of contaminants are released by the proposed project.

2.3.2.1 Use of surrogate chemicals

If a COPC cannot be assessed directly (e.g., due to lack of chemical-specific information) it may require assessment using a surrogate chemical or chemical group with similar chemical structures and modes of toxicity (see section 4.2.1). A surrogate chemical is a chemical with a similar structure that has toxicity information available. The most conservative published TRV for any potential surrogate is applied to the individual COPC or group of COPCs. A group of COPCs can be assessed using a single surrogate chemical by combining releases of all COPCs in the group into an overall exposure concentration.

2.3.2.2 Toxic-potency screening

Consistent with guidance from Alberta Health (2019), a second option for COPCs that cannot be assessed directly is toxic-potency screening to remove COPCs that are not expected to significantly contribute to overall risks. Toxic-potency screening cannot be undertaken at the Problem Formulation stage, as it requires information from the Exposure and Toxicity Assessments. Toxic-potency screening cannot screen out any COPC which requires assessment in multiple media.

TOXIC-POTENCY SCREENING

Toxic-potency screening is accomplished by establishing a risk factor for each contaminant, calculated as follows:

$$R_i = \sum_i (C_i) \times (T_i)$$

where:

- R_i = risk factor for chemical i
- C_i = maximum predicted concentration of chemical i
- T_i = toxicity value for chemical i (either as slope factor or 1/Risk-specific Dose)
- i = contaminants included in chemical inventory

If acute, subchronic, or chronic TRVs are available for a chemical, then the most conservative TRV and endpoint must be selected. Chemicals without TRVs cannot be screened with this procedure and must be included as COPCs, for more information see section 4.2.1. No averaging or statistical manipulation of maximum concentrations should be undertaken at this stage.

Chemicals contributing less than 1% of the total risk factor do not have to be considered further; however, if a chemical contributes more than 1% of the total risk factor, it is considered to potentially contribute significantly to risks and must be included. It should be made clear in the HHRA that this method is only for reducing the number of contaminants carried through in the HHRA and should not be presented as a quantitative statement on risks to human receptors. Additional details on toxicity-based screening are available in section 5.9.5 of US EPA (1989 and updates) *Risk Assessment Guidance for Superfund Part A: Human Health Evaluation Manual*.

Should a contaminant contribute ≥ 50% of the total toxic potency, this contaminant should be considered a COPC and then removed from the screening process to allow for the remaining

contaminants in that category to be re-screened. This method can only be used once and is not repeated.

2.4 Identifying human receptors

Human receptor is a term used to designate persons who may be exposed to COPCs. Human receptors are intended to represent a hypothetical individual, or individual's life stage, with predefined physical and biological characteristics representative of a reasonably maximally exposed person. A hypothetical maximally exposed person is used to ensure that risks are not underpredicted, and is assumed to have any of the following characteristics:

- physically present within the Study Area location with the highest predicted concentrations of COPCs or within an established human receptor location (see section 3.3.3);
- has a diet representing the highest expected, or preferred, rate of country food consumption of the Study Area population;
- is consuming the foods/tissues with highest predicted COPC concentrations;
- participates in cultural or spiritual practices that may result in increased exposure to COPCs;
- has a lifestyle and level of health representative of any vulnerable populations within the Study Area; and,
- undertakes all relevant domestic, agricultural, or recreational activities associated with identified land uses.

2.4.1 Selecting locations

Human receptor identification involves determining the location and characteristics of human receptors that may be exposed to COPCs in the Study Area using a combination of publicly available data and information from communications with stakeholders and Indigenous groups and peoples. Human receptor locations should be presented on figures or maps of the Study Area. The following areas must be included as human receptor locations:

- the maximum point of impingement (MPOI) (see section 3.3.3);
- permanent cities, town, communities, or individual residences;
- temporary general use camps or work camps constructed for the project or any other project;
- drinking water sources;
- recreational or other temporary or seasonal use areas;
- traditional food or medicine collection, trapping, hunting, or fishing areas; and,
- any area accessible to the general public (including trespassing).

Additional human receptor locations should be included as necessary based on the potential presence of sensitive human receptors, such as hospitals, schools, hunting/fishing/harvesting areas; and areas of stakeholder interest, cultural importance, or preferred use. Early collaboration between the air quality modelling team and the HHRA team is important to ensure all appropriate human receptors are included in the air quality dispersion modelling.

For all assessed human receptor locations, the geographic coordinates and distance from the project boundary should be described along with the characteristics of the applicable human receptors. Areas used for traditional purposed should not be identified or published on maps without permission from the Indigenous groups and peoples identified in the HHRA.

2.4.2 Selecting receptors

Human receptors are selected and evaluated based on either biological (e.g., increased chemical sensitivity, sex, gender), behavioural (e.g., increased consumption rates), lifestyle (e.g., smoking), or other factors (e.g., socio-economic) that could result in higher or more frequent exposures, adverse responses at lower doses, or more severe health effects relative to the general population. The hypothetical human receptor evaluated in an HHRA would be assumed to have any and all of these vulnerable characteristics. In the case of contradictory vulnerabilities, for example considerations based on specific gender or age groups, the risk assessor would have the option to use multiple receptors to address these different scenarios. Vulnerable human receptor populations can include, but are not limited to:

- consumers of country foods;
- infants consuming breastmilk or re-constituted formula from the drinking water source, toddlers, children, pregnant women, and the elderly (e.g., day cares, schools, hospitals, nursing homes);
- individuals with existing medical conditions;
- occupationally exposed individuals/workers at work camps; and,
- individuals with higher baseline exposures based on lifestyle or other factors.

Stakeholders and local authorities may need to be consulted to identify vulnerable human receptor populations and their locations. Selected human receptors should be protective of any and all vulnerable populations in the Study Area.

WORK CAMPS

Workers are protected by occupational health and safety regulations only while working; however, in most cases it should be assumed that workers can live and use the Study Area similarly to any other human receptors, which are protected by the *Public Health Act*. Work camps where worker-residents may be present must be included as separate human receptor locations, even if they are present within the project fenceline or are otherwise inaccessible (see section 3.3.3).

For areas where there are currently no permanent human receptors (e.g., if the MPOI is in a remote or uninhabited area), the potential for human receptors must still be evaluated. This could include consideration of transient human receptors using the area for traditional or recreational activities, or potential human receptors based on planned or reasonably foreseeable future changes to land use. It is recommended that land use information is gathered from nearby municipalities, communities, and regional districts. Selection of human receptors in these circumstances is discussed in section 3.3.3 and should include consideration of stakeholder inputs and TK. Significant justification is required to conclude that there are no potential human receptors in the Study Area, as this would terminate the

HHRA process. If no foreseeable future changes to land use are anticipated, information should be provided on how this was determined, considering the timeline of the proposed project.

At this stage of the assessment, all potential human receptor groups and their locations should be identified. Refinement of human receptor groups can be completed at the Exposure Assessment stage (section 3.3). Once all potential human receptor locations have been identified, a general description of the human receptors expected to be present in those locations should be provided, focusing on sensitive or vulnerable populations.

2.5 Identifying exposure pathways

An exposure pathway refers to the physical movement of a COPC from the emission source through environmental media to a human receptor. An exposure route is how the COPC enters a human receptor's body through ingestion, inhalation, or dermal absorption.

Identifying exposure pathways requires an understanding of the physical, chemical, and biological properties of the COPCs, properties of the environmental media, and behaviour of the human receptors. Exposure pathways are identified as complete, potential, or incomplete. Complete and potential exposure pathways are evaluated for all COPCs and human receptors. A complete exposure pathway evaluation includes identifying:

- source(s) of COPCs;
- mechanism(s) of COPC release to the environment;
- transportation of COPCs to a human receptor; and,
- potential exposure route(s) (dermal contact, inhalation, or ingestion).

All the above elements must be present for the exposure pathway to be complete; however, changes in land use or human receptor behaviour over time may result in changes to the status of exposure pathways. Pathways which could become complete in the future should be identified as potential. The purpose of evaluating potential exposure pathways is to establish if the project will limit development or uses of land that could reasonably be expected in the future and determine what mitigation and management measures will be needed.

The following is a non-exhaustive list of the three exposure routes and potential exposure pathways:

- inhalation:
  - of gases and vapours (outdoor and indoor); and,
  - of particulate (indoor and outdoor dust).
- dermal absorption:
  - of soil;
  - of water; and,
  - of sediment.
- ingestion:
  - of soil incidentally;
  - of water (drinking water and incidentally during recreation);

- of sediment incidentally; and,
- of food.

All complete exposure pathways must be assessed and carried forward in the HHRA. Incomplete pathways do not need to be carried forward, but rationale for their exclusion must be provided including references to site-specific evidence. Exposure pathways cannot be excluded on the basis of the project contribution being insignificant, unless conservative predictions indicate releases will not result in a measurable increase in COPC concentration as defined in section 2.3.

Potential exposure pathways may be evaluated using a hypothetical future use scenario, separately from the currently complete exposure pathways, with the understanding that this is not representative of exposure to current human receptors and only represents potential future risks. Any cases where it is assumed that reasonably expected or desired behaviours, as identified through stakeholder engagement, will be limited by the project or not explicitly considered in the HHRA should be clearly stated with justification. Any potential pathway not assessed must include a statement indicating that risks were not calculated, followed by full documentation of the rationale by which the pathway was determined to be incomplete.

At this stage it is often beneficial to identify potential management options which could change the status of an exposure pathway from operative to incomplete. Any permanently implemented mitigation measures, such as changes to project engineering or design, can be incorporated into risk estimates (section 7.4); however, risk estimates should be completed without management or exposure control measures that require ongoing actions by the proponent or restrictions on stakeholders. Pathways which have been rendered incomplete with risk management measures should still be included for assessment, but results can be presented with and without the proposed mitigation. The effectiveness of the proposed risk management can be discussed as part of the Risk Communication (see section 7.4).

The decision to include a currently inoperable exposure pathway as a potential exposure pathway will require some degree of professional judgment and stakeholder input. Specific considerations for the country foods and water ingestion pathways are included in sections 2.51 and 2.5.2, respectively.

2.5.1 Country foods (environmental livelihoods)

The term "country foods" (a.k.a. "environmental livelihoods") refers to all foods sourced outside of commercial food systems, that are trapped, fished, hunted, harvested, or grown for subsistence or medicinal purposes from the Study Area. The identification of country foods consumption in the Study Area should occur through engagement with stakeholders and Indigenous groups and peoples and use TK wherever possible. Country foods include:

- aquatic and terrestrial fauna fished, trapped, hunted, and/or harvested for consumption;
- aquatic and terrestrial produce harvested from naturally occurring sources (e.g., seaweeds, berries, seeds, leaves, roots, and lichen);
- plant tissues ingested for medicinal or other uses;
- produce grown in gardens, and/or home orchards; and,

- aquatic and terrestrial fauna and by-products produced for consumption.

Country food ingestion must be included if any stakeholder or Indigenous groups and peoples within the Study Area either currently consume country foods or indicate the preference to consume country foods in the past, present, or future. Exclusion of a country food from assessment should be justified with appropriate technical or scientific data.

Once the likelihood for consumption is established, the country food exposure pathway is assessed as complete, potential, or incomplete. Transient individuals from outside the Study Area, such as sport fisherman or recreational hunters may also be exposed to country foods. While this possibility should be acknowledged in the HHRA, it does not have to be quantitatively assessed if a more conservative exposure scenario for human receptors residing within the Study Area is included.

Certain COPCs associated with the proposed project or that are naturally occurring may also be present in foods in the market (retail or commercial) food system. Information on the assessment of market foods is presented in section 3.5.4.

2.5.2 Drinking water

Impacts to potential sources of drinking water must be evaluated regardless of whether they are currently being used for domestic purposes. Surface water is considered to be a potential future drinking water source if baseline water quality meets the ENV Source Drinking Water Quality Guidelines (ENV, 2020a) or could meet these guidelines with a reasonably achievable level of treatment, and can provide a sufficient supply to support domestic activities. Surface water from ephemeral or temporarily constructed lakes or ponds is not considered a potential source of drinking water and does not have to be considered; however, any surface water used as drinking water as part of traditional land use must be considered and should be assumed to be ingested with no treatment.

Groundwater is considered to be a potential future source if it is a mapped aquifer and has been determined by the province of B.C. to be so, or if it meets al of the requirements described in Protocol 21 – Water Use Determination (ENV, 2017c):

- is comprised of a saturated geological unit with a minimum yield of 1.3 L/s, or a saturated unconsolidated geological unit with a bulk hydraulic conductivity equal or greater than $1x10^{-6}$;
- has a naturally occurring concentration of total dissolved solids less than 4,000 mg/L; and,
- is not located within 500 m or marine or estuarine foreshore.

Testing aquifers for these requirements should be completed in accordance with ENV (2017c).

Assessment of potable water must not be limited to ingestion as there is potential for exposure through dermal contact via bathing/showering (US EPA, 2007), inhalation of volatile COPCs during bathing/showering, and usage of water on produce intended for human consumption (US EPA, 2005). Due to the large amount of uncertainty in predicting exposure through these additional pathways, it is expected that any potentially operative pathways which cannot be reasonably quantitatively assessed be formally acknowledged with a qualitative discussion of potential exposure. If a quantitative

assessment is considered warranted by the risk assessor, appropriate methodology will be determined on a case-by-case basis.

2.6 Conceptual site model (CSM)

The conceptual site model (CSM) brings together all the elements of the Problem Formulation and sets the scope for the HHRA. The purpose of the CSM is to demonstrate the presence of a causal chain from the source of COPCs to a human receptor exposure point. The CSM informs and establishes the data requirements for the completion of the subsequent sections of the HHRA. The risk assessor should provide scientific rationale for the CSM with minimal reliance on professional judgment alone. The CSM must include the following components:

- list of COPCs (see section 2.3);
- location of project and other relevant COPC sources and their release mechanisms;
- COPC fate and transport mechanisms and migration pathways, including biota and food web relationships;
- complete and potentially complete exposure pathways to human receptors; and,
- identified human receptor groups.

Linkages between sources, exposure pathways, and human receptors should be clear. All potentially affected environmental media should be represented in the CSM, even if they are not part of a complete exposure pathway. Barriers or exposure control measures preventing the completion of potential and incomplete exposure pathways should also be included in the CSM. Exposure control measures should be clearly bounded. If there are spatial or temporal limits on the exposure control measures or the measures require active maintenance by the proponent, they should be considered risk mitigation and should be assessed separately (see section 7.4).

The preferred formats for presenting a visual CSM are as a flow chart or in a pictorial format, as demonstrated in figures 3 and 4. For additional examples, please see figures 3.8 and 3.9 in Health Canada (2010c) *Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA$_{CHEM}$)*. Visual representation of the CSM should be accompanied by a narrative description providing a summary or references to the key data used to support the CSM, the general fate and transport assumptions, and any scientific rationale used to support professional judgments. Separate CSMs may be necessary for different project phases (e.g., baseline, construction, operation, and decommissioning), and for different human receptor groups or microenvironments.

A well-developed CSM can be a useful tool for communication and evaluation of risk management and mitigation options. The CSM should be developed in consultation with stakeholders and Indigenous groups and peoples to ensure that the CSM adequately captures all potential health risks and community concerns, and it should be clearly stated how this input was incorporated. It is strongly recommended that engagement occurs before starting the Exposure Assessment, and for EA projects that the CSM be provided during Early Engagement and Process Planning. Failure to do so could result in delays and higher costs to the proponent if additional work or data collection is required.

Figure 3: Example of conceptual site model in flow chart format

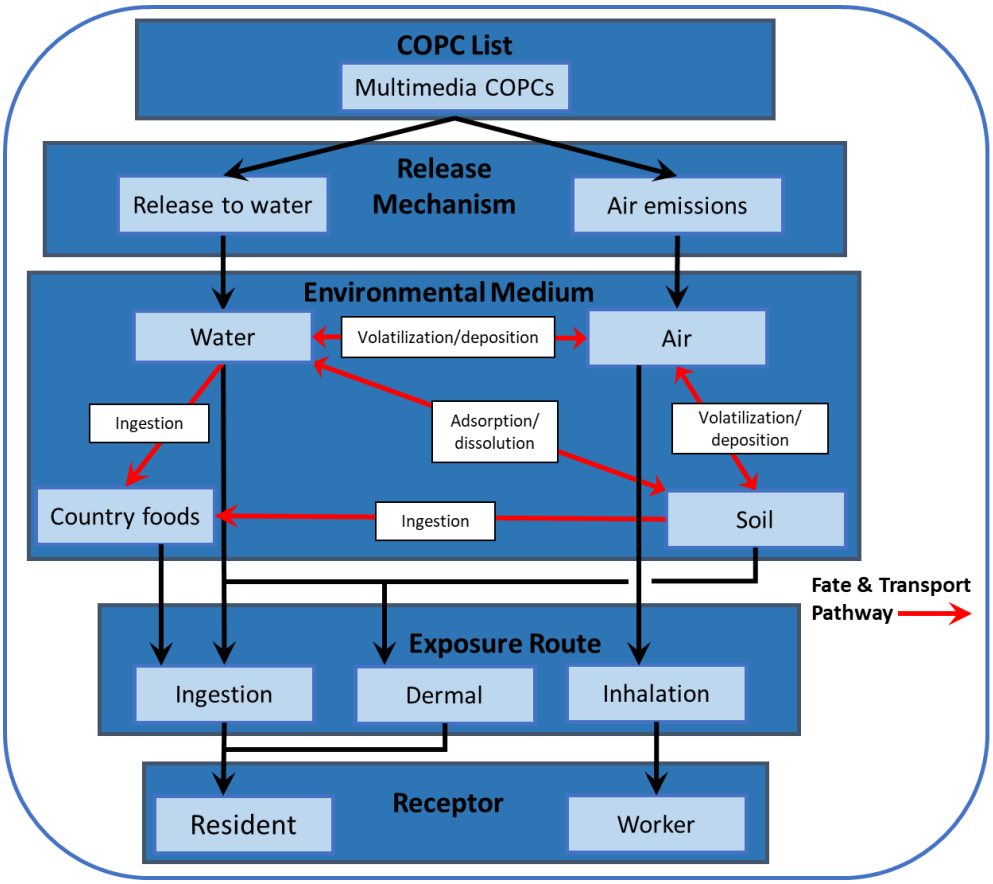
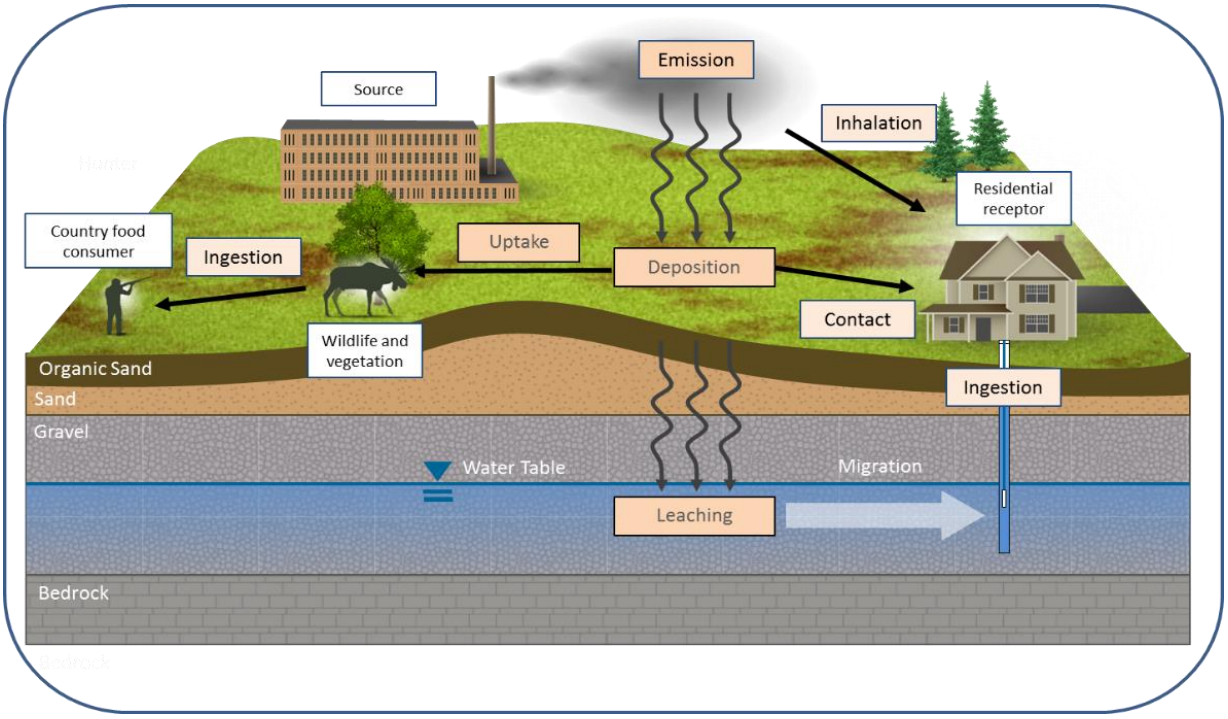


Figure 4: Example of conceptual site model in pictorial format



Created with Health Canada's CSM Builder Tool (eSolutionsGroup Ltd., 2015).

2.7 Scope of the HHRA

The CSM identifies the most significant COPCs, exposure pathways, and human receptor locations, which helps determine the scope of the HHRA, and helps ensure the HHRA is focused on critical issues. Further effort is required to identify relevant health endpoints, and finalize the spatial and temporal boundaries of the Study Area. The scope of the HHRA depends on:

- the number of identified exposure pathways;
- the availability of data and/or feasibility of data collection to assess the identified exposure pathways;
- diversity in land uses, baseline conditions, and human receptor groups;
- the need for precision/statistical power; and,
- the amount of fate and transport modelling required.

The HHRA should focus on COPCs, human receptors, and exposure pathways with the greatest potential risk to human health. While a precautionary approach is advised, quantitative assessment of all COPCs, receptors, and exposure pathways can over complicate the HHRA (see section 1.4.6). At this stage, the removal of high risk or uncertain elements through mitigation or project design changes should be considered.

TIERED APPROACH TO HHRA

A tiered approach is recommended for projects with complex CSMs or large numbers of COPCs. Applying overly conservative assumptions for receptor characteristics, exposure scenarios, and toxicity can

greatly simplify an HHRA and identify COPCs or exposure pathways which are unlikely to pose a risk to human health. A conservative assessment ensures the HHRA is focused on key exposure pathways and/or COPCs (see section 1.4.5), which allows for a more optimal allocation of resources.

Note that risk assessment is an iterative process and the scope may need to be revisited as an assessment proceeds. This could involve reducing the scope as COPCs, exposure pathways, or human receptors are eliminated, or increasing the scope if additional detail is needed to refine estimates when risks are predicted.

2.8 Data requirements for HHRA

The Problem Formulation should provide sufficient detail to identify what information is required to complete the HHRA. At this stage, the risk assessor reviews feedback from Indigenous groups and peoples, stakeholder engagement, and existing physical and chemical data from the Study Area to identify any data gaps.

All sources of data, including TK, and the methods of data collection should be documented. Any data requests that were not fulfilled should also be documented to provide full transparency and context for the Evaluation of Uncertainty and Variability (section 6.0).

Required information may be collected before or after completion of the Problem Formulation. However, even if information has already been collected for other purposes or assessments, it is recommended that the risk assessor determine if the available information is sufficient to complete the HHRA as defined by the CSM. This evaluation should consider:

- the statistical power of the existing data set;
- if the data set is representative of current conditions of the Study Area, and variability between the relevant receptor locations; and,
- the uncertainty which will remain if no additional data is collected and how that will affect the decision-making process.

To ensure that appropriate information is used for the HHRA, the most recent data (compiled within five years of conducting the HHRA), should be applied representing as close as possible, current conditions in the Study Area, and where relevant, locations preferentially used by human receptors. If data are missing, additional data should be collected.

If recent data from the Study Area is not available, the closest published data from a similar area can be applied; however, data from outside the Study Area should be applied with conservative assumptions and understanding of the limitations and uncertainties involved. If additional data collection is necessary based on the CSM, an analysis plan describing the methods for data collection and analysis, and interpretation required to complete the HHRA should be developed. This work may need to be coordinated with other regulatory or permitting agencies. With respect to data collection, the plan should include:

- a summary of currently available data, including data from peer-reviewed literature;

- a summary of key data gaps and limitations on the available data;
- a clear description of the rationale for the data collection methods, including sample size calculations, rationale for sample locations, and an assessment of variability;
- an explicit statement of how this data plan will capture variability of the Study Area; and,
- how collection of data will improve the HHRA.

Data requirements for baseline COPC concentration, Study Area characteristics, and fate and transport modelling are identified during the development of the CSM and data review. As information is often incomplete, the use of simplifying assumptions, extrapolations, or surrogate data from other locations or populations may be necessary. Potential requirements for modelling are outlined by CCME (2016) in the *Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment*, table 2-2, but will depend on the specific nature of the proposed project.

The collection of additional site-specific data on existing conditions can help reduce the need for conservative assumptions, and it may reduce uncertainty in predicting future conditions. If additional data collection activities cannot eliminate critical data gaps, a confirmatory monitoring program should be developed (see section 7.3).

It is best practice that the collection of data from Indigenous groups and peoples use OCAP® (ownership, control, access, and possession) principles and ethical standards for health data collection (First Nations Information Governance Centre, 2015). Any information obtained from Indigenous groups and peoples for the purposes of completing the HHRA will be considered the property of that group unless otherwise agreed upon, to be stored, used, and shared only with their consent.

3. EXPOSURE ASSESSMENT

Exposure Assessment involves estimating the dose of all COPCs for the exposure pathways and human receptors identified during the Problem Formulation stage. The dose is the quantity of each chemical received by human receptors, commonly expressed as units of mass of COPC per unit of body weight per unit of time (e.g., mg/kg bw/d). Exposure can also be evaluated using exposure concentrations if concentration-based values are being used to express toxicity (see section 4.2).

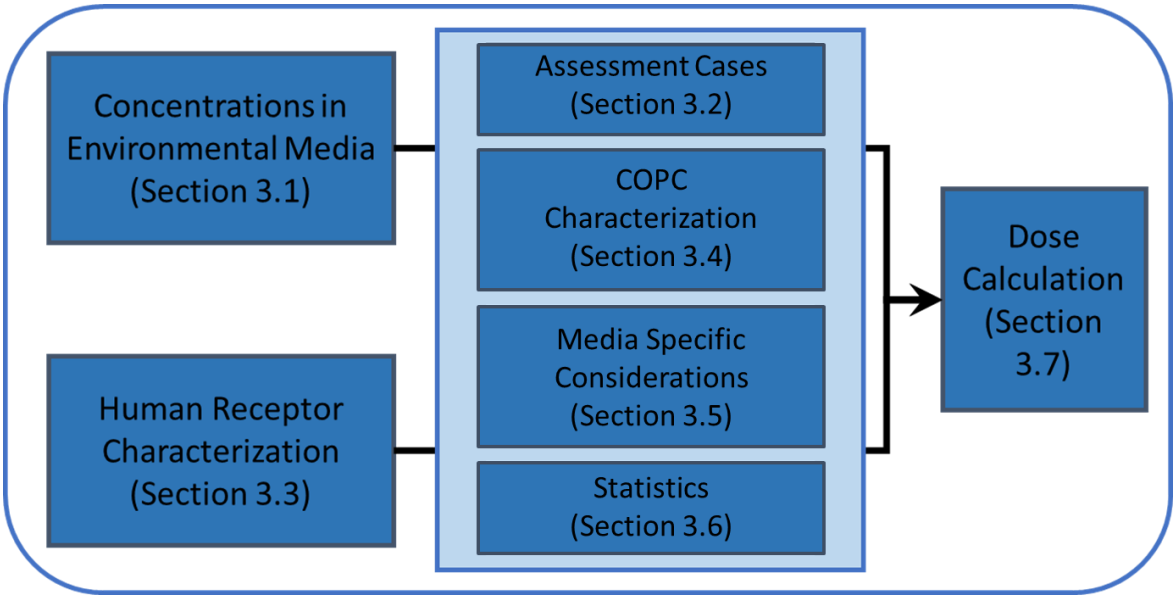
Dose estimation involves the determination of COPC concentration and human receptor intake rates for each relevant exposure medium, with the combination of concentration and intake rate yielding the estimated dose. This calculation also must consider the duration, timing, frequency, and consistency of exposure. The following steps are included in the Exposure Assessment and are outlined in figure 5:

- estimation of COPC concentrations in environmental media;
- characterization of human receptors, land use, and exposure scenarios;
- assessment of bioavailability; and,
- calculation of exposure doses.

Exposure doses must be calculated for each COPC and for each assessment case (section 3.2). If a COPC is included in the multimedia assessment, then exposure doses must be calculated for all complete and potentially complete pathways through which exposure to a COPC could occur, regardless of the

expected contribution from the project. This calculation should not account for principle risk controls, exposure controls, or risk management measures taken outside the project footprint; however, these adjustments can be considered when interpreting risks. The Exposure Assessment should include any modelling results, assumptions, formulae, calculations, measured data, and must include a worked example calculation. For each input used in the dose calculation, it should be stated whether the value has been modelled or measured and indicate the associated level of uncertainty.

Figure 5: Exposure Assessment overview



The Exposure Assessment and Toxicity Assessment are interdependent and should be conducted concurrently. The toxicological characteristics of COPCs affect the exposure periods to be considered, and the Toxicity Assessment may identify particularly sensitive human receptors that must be considered in the Exposure Assessment. The exposure dose, when combined with the results of the Toxicity Assessment, allows the calculation of predicted risks.

3.1 COPC concentrations in environmental media

Adequate characterization or estimation of COPC concentrations in environmental exposure media is a critical component of the HHRA. Baseline data collection is required for all COPCs identified during screening. For any COPCs included in the multimedia assessment, baseline concentrations from all potential exposure media is required.

COPC concentrations are typically represented by point estimates and should be presented with consistent units of measurements throughout the HHRA. The point estimates may be based on statistics, but it is recommended that the maximum measured or predicted concentration initially be employed. Use of other values may be permitted if sufficient justification is provided to demonstrate that the applied concentrations are protective of all human receptors and a reasonably maximally exposed individual (see section 2.4). For common air contaminants, the application of statistical percentiles to the data may be required for consistency and comparison to air quality criteria (see section 2.2.2).

Concentrations of COPCs can be estimated using two general approaches:

- direct measurement through sampling of environmental media; and/or,
- fate and transport modelling.

It should be stated if the data represents field measured or modelled concentrations, along with an indication of confidence in the applied value.

CAUTION

If a COPC has multiple chemical forms (such as inorganic or organic metal speciation) with different behaviour or toxicities (see section 4.2), then justification must be provided for the applied distribution or ratio of these forms in the environment. Laboratory analysis of field samples or monitoring data should be used if possible and are recommended to validate any applied literature values. If no determination of the ratio of different forms can be adequately justified, it should be assumed that the COPC is present as a combination of the most toxic and persistent forms. However, this does not apply to common air contaminants, due to the complexity of formations and interactions with the environment.

3.1.1 Sampling environmental media

In prospective HHRAs, future COPC concentrations in environmental media are typically predicted using fate and transport modelling; however, for the Base case (section 3.2.1) measurements of existing concentrations should be obtained whenever feasible. The measured baseline COPC concentrations should be directly incorporated into the predicted concentrations of the other assessment cases. The need for baseline sampling will depend on the nature of the COPCs being released and their potential to be present in other environmental media. Use of existing baseline data from the Study Area, such as from air or water quality monitoring networks, is encouraged provided it is current and validated for quality. In general, targeted data collection is considered more reliable, transparent, and efficient than applying modelled values.

When measured concentrations are used to establish Base case conditions, the quantity of data required to adequately characterize a given medium for the Study Area must be determined. This includes consideration of both spatial and temporal variability within the Study Area and potential for a COPC to be present. Spatial definition is particularly important for the application of any microenvironment analysis (see section 3.7.3), as risks can be under-predicted if generalized conditions are averaged over the entire Study Area. Temporal definition of the Study Area is needed to address changes in chemical concentrations over time so that long-term and future risks can be characterized, if required.

Sampling considerations will vary on a case-by-case basis and any appropriate sampling methodologies recommended in provincial or federal guidance documents can be used if sufficient scientific justification is provided. Characteristics of the site and local land use will determine the most appropriate sampling protocols. Locations of frequent and/or continuous human receptor use should be reflected.

Sampling methodologies intended for ecological risk assessments are typically concerned with the long-term survival and well-being of populations of organisms and may not be appropriate for HHRAs which are concerned specifically with the protection of vulnerable individuals.

The following sampling principles are recommended:

- detection limits should allow for accurate calculation of exposure doses near the TRV (e.g., be sufficiently low that exposure to concentrations at the limit of quantification will not result in predicted risks);
- before calculation of the 95% UCLM or other representative values, it must be ensured that the data meet all underlying assumptions of the applied statistical method;
- all data sets should be large enough to ensure that there is sufficient statistical power to make meaningful comparisons (e.g., between two potentially different parts of the Study Area or when follow-up monitoring is expected to be needed):
    - determining a sample size to meet the needs of the HHRA depends on establishing the minimum required detectable difference, the acceptable Type I error probability (defined by the ministry for HHRA as 0.05), the acceptable Type II error probability (defined by the ministry for HHRA as 0.1), and the inherent variability in the data set. Formulae will vary depending on the distribution of data and calculation of an appropriate sample size should be completed by an experienced statistician.
- summary statistics should only be applied to single populations where a distribution has been identified, microenvironments with different conditions must be evaluated differently (see section 3.7.3); and,
- sampling should be representative and protective of all human receptor locations included in the HHRA.

As baseline concentrations are intended to represent current levels of exposure, they should match the actual media, locations, and durations (for air quality data) that represent human exposure to the COPCs (see section 2.2.2). Regional data can be used in combination with data from the Study Area, but Study Area data must be available for comparison to ensure its validity.

The use of composite samples is strongly discouraged, as composite samples are not able to identify maximum chemical concentrations or characterize spatial distributions. However, there are cases where using averaged concentrations may be necessary or appropriate, such as in conditions where there is high natural variability of a COPC in media in a small spatial range, insufficient mass of country food tissue samples for laboratory analysis, or to achieve more realistic estimate of average chronic exposure appropriate for refining exposure estimates.

Considerations for sampling specific environment media are discussed in section 3.5. Baseline information collected should meet requirements outlined in:

- section 2 of *Technical Guidance 1: Environmental Management Act Applications - Terms of Reference Environmental Impact Assessment Technical Assessment Report* (ENV, 2014);

- *B.C. Field Sampling Manual for Continuous Monitoring and the Collection of Air, Air-Emission, Water, Wastewater, Soil, Sediment, and Biological Samples* (ENV, 2013b);
- *Technical Guidance 6: Water and Air Baseline Monitoring Guidance Document for Mine Proponents and Operators* (ENV, 2016); and,
- if tissue samples are to be collected then baseline studies should develop a tissue residue database as outlined in section 2.8.3 of *Technical Guidance 1: Environmental Management Act Applications - Terms of Reference Environmental Impact Assessment and Technical Assessment Report* (ENV, 2014).

REMINDER

All collected data should be validated through a documented quality control process. A complete discussion of quality control procedures to support risk assessment is provided in section 3.0 of CCME (2016). A description of the quality control process used in the HHRA should be provided.

Analytical results used in the HHRA should be provided in full and made available to all stakeholders once laboratory and any internal quality control checks have been completed.

3.1.2 Fate and transport modelling

Fate and transport modelling is used to estimate COPC concentrations in exposure media which cannot be measured or to predict future conditions. Consideration of the fate and persistence of COPCs is important, especially if there is potential for human exposure to COPCs via multiple media.

Data from fate and transport models should be supplemented by data from the Study Area and subsequent data collection may be required to address data gaps. Early identification of key data requirements (see section 3.1) is encouraged to ensure data collection is directed toward providing relevant information for the HHRA. In cases where fate and transport models are utilized, validation of the predicted concentrations through a monitoring program should be considered.

For any modelling completed within the HHRA by risk assessors, the report should document all assumptions, model inputs, and data sets used to obtain modelling predictions, provide a rationale for their selection, and discuss the associated uncertainties.

For any modelling completed outside of the HHRA by other professionals to generate inputs for the HHRA, clear references to the chapter and section of these reports where these inputs were generated should be provided. There should also be confirmation that the models are appropriate for use in an HHRA and were completed by a qualified professional in that field (see section 1.4.3). Models should be consistent with existing B.C. guidance. For example, air dispersion models should be completed in accordance with the *British Columbia Air Quality Dispersion Modelling Guideline* (ENV, 2015) and a dispersion modelling plan approved by ENV.

3.1.2.1 Model selection

Models chosen must be scientifically defensible and appropriate for the scenario being modelled. Modelling should be transparent and reproducible, providing sufficient detail to validate the model

predictions, if required. The selection of model input parameters needs to be supported by references to appropriate sources.

Numerous fate and transport models are available. Model selection should account for applicability and relevance to the transport media and processes, defensibility and regulatory acceptance of the models, and availability of appropriate data. Fate and transport models are generally classified as one of the following types:

- **simple dilution**, where an initial concentration is adjusted with a dilution factor;
- **equilibrium**, where a distribution between media is predicted based on partitioning or fugacity parameters;
- **dispersion**, which calculates a reduction in atmospheric concentrations dependent on properties of the emission source (e.g., stack height, stack diameter, exit velocity, temperature), and assumes the COPC's horizontal and vertical distribution has a Gaussian distribution (ENV, 2015);
- **transport**, where concentrations change over a distance, and may also include representations of degradation and absorption; and,
- **other** models prepared by qualified professionals as needed.

Specific fate and transport models are not explicitly recommended, as models should be selected based on the applicability to Study Area conditions and project needs. However, models are recommended if they have been used for development of the B.C. CSR (1996) and are recommended in B.C. CSR technical guidance, if they have been adopted by the CCME, or if they have been used by Health Canada for HHRAs in support of contaminated site or EA purposes, provided all model assumptions are shown to be valid for the project and Study Area. Fate and transport or exposure models recommended or developed by the US EPA are also generally acceptable. Although there are no restrictions on what models can be applied, models from other regulatory jurisdictions, academic studies, or proprietary models should be used with caution as they may not be applicable to B.C.

The HHRA should provide a rationale for the selection of model and model inputs and discuss the associated uncertainties. Risk assessors must clearly demonstrate that the model they are proposing is applicable to the circumstance in which it will be used. Use of proprietary models will require documentation of basic principles and should include all mathematical expressions and assumptions used. The HHRA must identify the model limitations, uncertainties, sources of error, and relative accuracy of the presented results. It is recommended that statistical confidence limits or other quantitative measurements of uncertainty also be provided.

3.1.2.2 Input requirements

All input data used in fate and transport modelling should be included in the HHRA report or referenced in an appendix. For each model input value from a literature or regulatory source, whether site-specific or generic, justification for its selection and applicability should be provided.

3.1.2.3 Transformation and degradation of COPCs

Future concentrations of COPCs in the Study Area may be affected by environmental fate or chemical processes. For example, concentrations of organic chemicals may decrease over time through processes such as dispersion, degradation, volatilization, or biotransformation. Degradation and transformation rates can be applied to fate and transport modelling; however, rates for any given COPC can vary considerably depending on environmental conditions. Evaluation of applicable degradation or transformation should be undertaken with considerable caution and an appropriate level of conservatism.

The HHRA should identify if any degradation or transformation by-products of COPCs may also be toxic. While the HHRA would ideally estimate the future concentrations of any toxic by-products, it is recognized that this can be extremely complex. Unless these analyses are built into existing fate and transport models (such as in some air dispersion models), evaluation of toxic by-products may have to be limited to qualitative statements. If degradation or transformation of COPCs is expected to significantly change predicted exposure concentrations or result in toxic by-products, follow-up monitoring may be needed to verify HHRA predictions.

3.2 Assessment cases

The following assessment cases should be evaluated in the HHRA to characterize the project's potential impact on the environment and human health throughout the Study Area defined in section 2.2, and contribution to COPC exposure. These assessment cases may not apply to projects outside of EA or permitting processes.

For situations where a proposed project's Study Area encompasses a regulated contaminated site, it is recommended that all applicable provincial and federal guidance and requirements for contaminated sites are implemented.

3.2.1 Base case

The Base case establishes the current conditions that exist in the environment, either from naturally occurring conditions, or impacts from existing industrial facilities and other emission-related activities (e.g., motor vehicle emissions). The Base case should use collected field data or results from existing monitoring programs to provide a clear description of the current environmental conditions in the Study Area (see sections 2.2 and 3.1).

While consideration of other existing projects is required, potential impacts from future (unapproved) projects (section 2.2.4) in the Study Area should not be included in the Base case. As proposed projects are not yet operative or guaranteed to be approved and developed, the potential impacts from them cannot be assumed to be inevitable. The inclusion of future projects in the assessment are addressed in the Planned Development case (section 3.2.4).

3.2.2 Project Only case

The Project Only case includes effects only from the proposed project and does not include baseline. It is recommended that this case is assessed for all COPCs; however, depending on the project, assessment

of the Project Only case may not be necessary. For EA projects, discussion with the health reviewer is recommended to determine in advance which assessment cases are expected.

Characterization of exposure and risks for the Project Only case provides context on the potential impacts of the project and contribution to the existing level of exposure in the population. For threshold COPCs with a defined level of exposure that is considered safe, the HHRA must determine whether total exposure from all potential and proposed sources remains below that threshold.

For non-threshold carcinogenic COPCs, where target risk levels are based on incremental lifetime cancer risks from exposure to COPCs with a linear dose-response (see section 5.1.2), evaluation of effects from the project alone (Project Only case) is considered appropriate. While the Project Only case is often the most relevant to regulators, the Base case and Application case also assist in decision-making and understanding potential impacts to human health.

3.2.3 Application case

The Application case is the addition of the Base case with the predicted effects from the Project Only case. This case is used to determine where control or mitigation measures may be necessary to reduce potential health effects, and is a representation of the future environmental conditions that are expected if the project is approved.

3.2.4 Planned Development case

The Planned Development case, or Cumulative Effects case, describes conditions that would exist if the project, and any other planned projects were operating. The types of planned projects that should be considered and the applicable legislation are described in section 2.2.4.

Assessment of cumulative effects for the Planned Development Case relies on data from other projects that may not be operational or otherwise releasing COPCs during completion of the HHRA. For approved projects which are not yet operational, quantitative assessment of cumulative effects is only required for COPCs released through air emissions, based on equipment or process rates or as described in the application or permits for those facilities. While the same assumptions should be applied in the evaluation of approved projects and the proposed project, applying maximum allowable emission rates to approved projects in the Planned Development case may artificially inflate emission conditions. Therefore, actual or expected emission rates should be applied instead. Exposure calculations cannot be taken directly from another project application or permit and must be re-assessed to ensure consistency with the current HHRA. Evaluation of other potential COPC releases from such projects can be done qualitatively.

For prospective HHRAs completed within the EA framework, results of the Planned Development case of the HHRA may be presented as part of the overall Cumulative Effects Assessment.

For HHRAs completed outside of the EA framework, the requirements of the Planned Development case should be established with the regulator. The Planned Development case is intended to represent a cumulative effects assessment, discussed in section 2.2.4.

3.3 Human receptor characterization

The human receptor groups relevant to the HHRA are identified during the Problem Formulation stage. The Exposure Assessment characterizes these human receptors in sufficient detail to establish intake rates of all relevant environmental media. As exposure and risks may not be evenly distributed throughout the Study Area with some populations or areas being disproportionately affected, all populations within the Study Area must be considered.

The physical and behavioural human receptor characteristics applied in the HHRA must be appropriate for the exposed population and depend on the exposure pathways evaluated. Applied human receptor characteristics are not intended to be a realistic representation of an actual individual or a population average but should be protective of all individuals.

The rate at which human receptors contact environmental media affects the amount of exposure, as does the frequency of contact, and the duration of each contact event (if applicable for the exposure route). The amount of exposure depends on: a) rate at which human receptors contact environmental media; b) the frequency of contact; and c) the duration of each contact event (if applicable for the exposure route).

CAUTION

Use of absolute worst-case assumptions may result in a hypothetical human receptor that is not plausible. While this can be useful as an initial evaluation that is further refined, use of a reasonably maximally exposed human receptor (see section 2.4), representing the maximum dose reasonably expected to occur, is recommended.

Relevant human receptor characteristics may include, but are not necessarily limited to:

- body weight;
- soil/sediment/dust ingestion rate;
- air inhalation rate;
- water ingestion rate;
- exposed skin surface area;
- soil loading to exposed skin;
- food ingestion rates; and,
- frequency and duration of exposure events.

Surveys can be used to obtain human exposure characteristics from the community or population of interest, where possible. If community specific data cannot be obtained, exposure characteristics from Health Canada (2012) should be prioritized. If necessary, additional sources of human receptor characteristics can be consulted, including the *Canadian Exposure Factors Handbook* (Richardson & Stantec Consulting Ltd., 2013), the *Inventory and Analysis of Exposure Factors for Alberta* (Alberta Health, 2018), the US EPA (2011) *Exposure Factors Handbook*, and US EPA (1989 and updates) *Risk Assessment Guidance for Superfund* (RAGS). Preference should be given to current Canadian sources of

information recommended by Health Canada, and the validity of the selected values justified in the HHRA report.

As the demographics, behaviour, and general physical characteristics of the general population can change over time or can be specific to the Study Area in question, the recommended exposure parameters may not necessarily be appropriate. However, adoption of human receptor characteristics from multiple sources should consider that there may be inconsistencies in methodology or assumptions between sources and this practice not recommended. Use of published literature may be used if data refer to similar populations with similar behaviour and exposure patterns. However, it is strongly recommended that information on community-specific consumption patterns and preferences is included (see section 3.5.4 for more information on food ingestion rates), as food ingestion is typically a major source of exposure to COPCs and uncertainty in intake rates can greatly affect the risk estimates.

Health Canada (2012) identifies five age groups with an assumed total life span of 80 years into which the physical characteristics of the human population should be classified for most risk assessments:

- infant (0 to 6 months inclusively);
- toddler (7 months to 4 years inclusively);
- child (5 years to 11 years inclusively);
- teen (12 years to 19 years inclusively); and,
- adult (greater than or equal to 20 years).

The Exposure Assessment must be completed for all applicable age groups. Not all age groups may need to be considered in every exposure scenario; however, if access to the Study Area is not restricted, then all age groups should be included. If infant exposure is possible, the HHRA should consider potential exposure through ingestion of either breast milk or re-constituted formula from the drinking water source. The exposure route with the higher dose (either breast milk or formula) should be evaluated, which may vary across individual COPCs. Assessment of exposure to infants through breastmilk can utilize data and models from the Canadian Human Milk Survey (Health Canada, 2014), the US EPA Exposure Factors Handbook Chapter 15 (US EPA, 2011, and updates), and section 2.7 of the Child-Specific Exposure Scenario Examples (US EPA, 2014). Adult receptors should include pregnant women, in order to be protective of prenatal exposure to infants.

For HHRAs that include a work camp and worker-resident human receptor, adult human receptor characteristics under a residential land use scenario should be assumed. The exposure for worker-resident receptors should persist for the entire duration of the camp's operation (see section 3.3.4) but inapplicable exposure pathways, such as produce grown in gardens, should be removed.

3.3.1 Assessment of multiple and vulnerable human receptor groups

Exposure to chemicals in environmental media is highly dependent on the physical and behavioural characteristics of the exposed human receptors and varies among individuals and age groups. The HHRA can include the general population, but population subgroups that may be more vulnerable should also be considered. Subgroups may be more vulnerable because of sensitivity to contaminants or because of

higher rates of exposure. Subgroups should be addressed during the Toxicity Assessment (see section 4.4.2).

Identifying a critical, most vulnerable human receptor or human receptor group is not a requirement at this stage. Due to the complexity in evaluating exposure from multiple pathways simultaneously, it may not be clear which human receptors will have the highest predicted risks. Hence all human receptor groups with different exposure patterns should be evaluated. Evaluation of multiple human receptor groups can be accomplished in two ways:

- defining and evaluating all the applicable human receptor groups based on their individual exposure patterns and characteristics; and/or,
- ensuring that the most sensitive individual characteristics between all the human receptor groups are applied to a hypothetical combined human receptor(s) (e.g., applying the highest consumption rates or exposure terms between multiple human receptors).

For each human receptor group, the following information should also be provided:

- behavioural and consumption characteristics with respect to country foods (considering local knowledge and/or TK when possible);
- increased vulnerability based on sex, age, or other biological factors;
- location of expected exposure and distance from project boundaries;
- common activities and use patterns in the Study Area; and,
- use of water resources in the Study Area.

3.3.2 Population health

Although the HHRA risk estimates relate to individual risks, consideration can also be given to potential population-level impacts, which depend on the characteristics and composition of the community. While a population health assessment is generally beyond the scope of an HHRA, but the use of existing population health information can provide context for the HHRA. It is recognized that this information may be found in different sections of the EA, such as the social and economic effects assessments. Any such analysis should be developed by, or done in consultation with, a professional with expertise in population health and epidemiology to ensure accuracy in analysis and interpretation of population health data.

A general community profile can be compared to the general population of B.C., including the prevalence and/or distribution of factors that may influence the sensitivity or susceptibility of the population or sub-populations. This general community profile can inform various stages of the HHRA, including identification of vulnerable human receptor groups, development of risk communication tools, characterization of the extent or magnitude of project impacts at the population level, interpretation of the HHRA results, and residual effects assessment (see section 7.1). Although the type and availability of information may vary across communities, some key variables for consideration include:

- demographics (e.g., population size, density, distribution, age, culture);

- socioeconomic factors (e.g., income, education, employment);
- access to health services;
- personal health practices (e.g., alcohol, drug or tobacco use, nutrition, physical activity);
- common behaviours and activities (e.g., recreational, traditional, or other land uses); and,
- health status and chronic disease (e.g., sensitive individuals or predisposing physiological or medical conditions).

Data or information on these community indicators can be found through various sources but it is recommended that the risk assessor first consult the following community profiles, which apply consistent methodology in terms of data source, analysis, and interpretation:

- B.C. Community Health Profiles (Provincial Health Services Authority) (http://communityhealth.phsa.ca/HealthProfiles#panel-nha);
- Local Health Area Profiles (https://connect.health.gov.bc.ca/lha);
- My Health My Community profiles (Vancouver Coastal Health and Fraser Health) (https://www.myhealthmycommunity.org/); and,
- Community Profile (Northern Health) (https://chip.northernhealth.ca/CommunityHealthInformationPortal/NorthernTopics/CommunityProfiles.aspx).

The relevant health authority should be consulted on how to apply the community information in the above sources as they may use different methodologies. If there is no established profile available for the community, the profile of a similar nearby community can be used as a proxy if the community is comparable with respect to location, demographics, health status, and other key indicators. Regional data may be appropriate in some cases. For Indigenous groups and peoples, the community health director or the First Nations Health Authority (FNHA) surveillance team should be consulted directly. Other publicly available publications that draw on government or health authority data sources can also be consulted, such as:

- Census of Population (Statistics Canada);
- Canadian Community Health Survey (Statistics Canada);
- B.C. Stats;
- Vital Statistics;
- Medical Service Plan (MSP) data (Ministry of Health);
- Discharge Abstract Database (DAD) (Ministry of Health);
- Chronic Disease Registries (Ministry of Health);
- B.C. Cancer Registry (B.C. Cancer Agency); and,
- First Nations Regional Health Surveys (FNHA).

Other published sources may include:

- government studies and publications;
- review of literature on local population;

- review of scientific literature on similar populations (i.e., similar geographic and climatic area, cultural background, exposure to similar projects); and,
- studies and publications by community-based organizations, such as community health and wellness plans.

If published sources are not available for key factors, data or information may be sought through direct engagement with local health authorities, governments, Indigenous groups and peoples, community organizations, or residents. The risk assessor should consult community-based or local knowledge to verify the information, particularly when using sources based on large geographic areas that may not be representative of the community level.

3.3.2.1 Land use in the Study Area

The land use in the Study Area (see section 2.2) will determine what activities could be undertaken, the potential exposure scenarios, and inform input parameters of the applied exposure models at each human receptor location (see section 2.4.1). Though evaluated by the risk assessor, potential land uses should always be confirmed through engagement with stakeholders and Indigenous groups and peoples. Default land use categories have been defined by ENV for contaminated sites; however, land uses specific to the Study Area should be considered and additional land use categories may require definition.

REMINDER

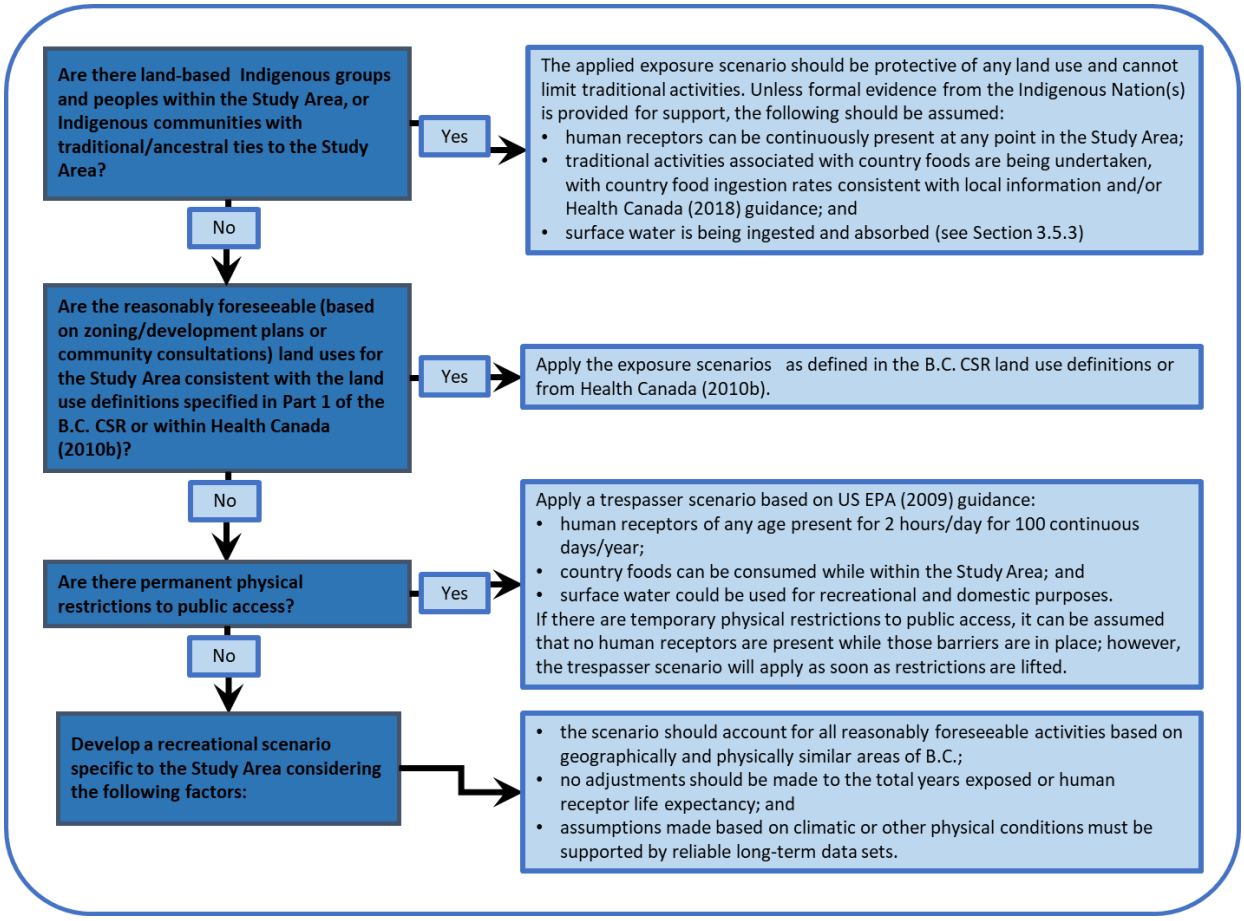
Land use determination must incorporate community values for current and desired future uses, and at this stage of the HHRA should not impose any restrictions as to the extent or nature of potential interactions with land in the Study Area.

While the presence of a project can change the perception and potentially the behaviours of individuals within the Study Area, the risk assessment should be carried out under the assumption that current and desired future uses will not change. The following information should be considered when establishing current and potential future land uses of the Study Area:

- activity patterns of the potential human receptors, including transient human receptors;
- use of natural resources, including traditional food consumption, agriculture, food crops, and fisheries;
- local zoning, bylaws, and land use plans;
- domestic, agricultural, and recreational water sources;
- seasonal variation in land use; and,
- accessibility to the general public (including trespassing).

If information from communities or other stakeholders cannot be obtained and land use cannot be determined, residential land use should be assumed for the purposes of exposure modelling. Any departure from this assumption requires justification. The decision tree in figure 6 can also be used to establish an appropriate land use for the Study Area. Exposure scenarios defined by Health Canada (2010c) are recommended; however, exposure scenarios from the BC CSR or developed based on stakeholder input can be applied if necessary.

Figure 6: Land use decision tree



3.3.3 Multimedia MPOI considerations

As exposure estimates are generally based on point-of-exposure estimates at discrete locations, the selection of human receptor locations (see requirements outlined in section 2.4.1) is a critical element in the Exposure Assessment.

In a multimedia assessment, the MPOI may not be at the same location in difference environmental media. In these cases, the MPOI can either be represented as a hypothetical composite location using the maximum predicted concentrations from all media (simple, conservative approach) or assessed at each location where a maximum predicted concentration was predicted for an individual media (complex, realistic approach).

3.3.4 Exposure duration and amortization

The following three different exposure lengths, consistent with the Health Canada (2010c) approach to defining exposure duration, are recommended for the classification of exposure duration:

- acute exposure less than 14 days;
- subchronic exposure between 14 to 90 days; and,

- chronic exposure greater than 90 days.

Exposure for more than 90 days but less than the major part of a lifetime is not truly chronic; however, for the purposes of HHRA it will be considered chronic exposure.

Typically, a dose of a COPC is presented as an average dose over a day and accounts for the overall duration of exposure and the pattern(s) of exposure in the scenarios selected for the site. Exposure should be determined for a time period relevant to both the anticipated activities and possible adverse health outcomes (see section 4.4). The HHRA must address health risks associated with both short- and long-term exposure, as is appropriate to the various exposure pathways and the characteristics of the human receptors. Considerations for using less-than-lifetime exposure are outlined in section 4.4.1.

Exposure is normally amortized (averaged) over a total exposure period when evaluating chronic exposures. Amortization uses an exposure term (ET), representing the time exposed divided by the total exposure period, which is applied to exposure calculations. The ET could include the hours per day, days per week, and weeks per year a human receptor is exposed. In some cases, daily exposure is based on events per day, irrespective of duration. In these cases, the number of hours per day exposed would not be considered in the ET (e.g., ingestion or dermal contact with soil and ingestion of water is typically expressed as events/day). Exposure amortization must meet the following conditions:

- amortization should only occur over the period of actual exposure;
- the total exposure period must not be greater than the exposure time frame specified for the applied TRV;
- potential short duration toxicity should be considered separately; and,
- exposure through country foods must allow for stockpiling of food through seasons and ongoing exposure after leaving the Study Area.

If these conditions are not met, there is potential for underestimating chronic health risks.

Threshold COPCs should not be amortized over periods of more than seven days unless suitable rationale can be provided. Amortization over longer periods of time will require proportionally more justification.

Exposure amortization is not always appropriate for chronic exposures. Assignment of the total exposure period, and whether to proceed with amortization, should be based on the exposure conditions, the expected mechanism, and site of toxicity. Exposures should not be amortized if:

- human receptor activity patterns result in intermittent or repeated acute or subchronic exposures;
- the applied TRV is intended for shorter durations than the intended amortization period;
- the toxicity endpoint is solely dependent on the maximum COPC concentration and not the exposure duration (e.g., developmental neurotoxicity);
- the toxicity endpoint is based on exposure during a specific life stage (amortization should only be over that life stage); or,

- an acute toxicity endpoint is based on the point of contact with the body, such as skin or respiratory irritation.

3.3.4.1 Less than lifetime exposures

A tiered approach is recommended for assessing exposure to threshold COPCs for acute and subchronic exposure durations (short durations). Exposure doses can be compared to TRVs for similar or longer durations but cannot be compared to TRVs derived for shorter durations than the exposure period of interest. The following options are available for short duration exposure:

- direct comparison of the maximum expected continuous short duration dose with no averaging or amortization to a chronic TRV;
- direct comparison of the maximum expected continuous short duration dose with no averaging or amortization to a short-term TRV based on an equal or greater duration; and,
- comparison of an amortized or averaged short duration dose to a TRV equal to or longer than the entire amortization period.

These options represent tiers of increasing complexity while becoming more realistic. The appropriate option should be based on the information available and can proceed from the initial tier as a screening approach, to a more complex evaluation for specific COPCs as necessary. If there are separate health endpoints for acute and chronic exposure, then both acute and chronic exposure durations should be considered. If exposure averaging is applied, it will need to be evaluated on a COPC-specific basis, and the HHRA should indicate if toxicity is driven by COPC concentration, time integrated exposure, or both.

TRVs intended for acute exposure may not consider repeated intermittent exposure, such as seasonal country food consumption or weekend use of recreational areas. This can be an issue if COPCs accumulate in the body. Intermittent exposure can be assessed by comparing the time between intermittent exposures and the expected rate of COPC metabolism or removal from the body. Dose averaging cannot be used if the time between intermittent exposures is less than the time needed for complete COPC removal from the body or the toxic effect persists between exposures. Either a TRV based on intermittent exposure or a longer duration TRV covering the entire exposure period and which assumes constant exposure must be applied.

Within the context of this guidance document, 'complete removal' from the body is considered to occur after a period of five whole-body elimination half-lives have elapsed. This is approximately equivalent to 97% removal, assuming elimination mechanisms are not saturated.

3.3.5 Occupational human receptors

Occupational receptors must be included in HHRAs if they have the potential to be exposed both occupationally and non-occupationally. Occupational receptors may be assessed separately with specific conditions applied for mitigation or exposure control; however, all sources of exposure must be considered in the HHRA. Worker safety and worker exposure during occupational activities does not have to be directly assessed in an HHRA as is the responsibility of WorkSafeBC under the *Workers Compensation Act* (2019b) and the Occupational Health and Safety Regulation (1997). For on-duty

mining project workers, safety and exposures are captured under the Ministry of Energy, Mines and Low Carbon Innovation's jurisdiction and the *Health, Safety and Reclamation Code for Mines in British Columbia* (British Columbia Ministry of Energy and Mines, 2017). This is recognized as an existing element of uncertainty in HHRA, as assessing occupational exposure of receptors living in the Study Area may not be possible or feasible in most cases.

As mentioned in section 3.3, work camps housing worker-residents must be assessed as human receptors in the HHRA during off-work hours if the work camp is within the Study Area. Workforce-specific exposure characteristics, such as number of employees, work shift duration, time-off, location of any on-site or worker-specific accommodation, and any other relevant characteristic that could influence predicted worker-resident exposure should also be presented. Special consideration should be given to Indigenous workers, who may have different exposures and may also consume country foods.

CAUTION

If workers will be residing in camps within the project fenceline, then concentrations within the fenceline and the exposure of worker-resident receptors must be evaluated. Regardless of the work camp location, exposure to worker-resident receptors should be evaluated with a residential exposure scenario adapted as applicable based on the proposed operating and permitted conditions of the work camp. Only time spent off-duty requires assessment for worker-residents; however, uncertainties related to the potential for both on and off-duty exposure should be addressed (see section 6).

3.4 COPC characterization

Concentrations of COPCs in exposure media (except air) should be characterized with an upper range estimate of the data. Maximum concentrations are generally the most applicable; however, 95% UCLM concentrations can be applied if sufficient data are available (see section 3.6). It should be noted that any methods chosen for use in the development of an exposure point concentration should be driven by the quality and quantity of data available. Concentrations of COPCs in air should be assessed using statistics consistent with the applicable: a) health-based ambient air quality criteria (see section 3.8.1); b) averaging period for the applied TRV(s); and c) dispersion modelling methods, as recommended in *Guidelines for Air Quality Dispersion Modelling in British Columbia* (ENV, 2015).

If COPC concentrations are expected to vary significantly over time due to project operations, naturally occurring activities, human activities, or climate change, then consideration of changes to COPC concentrations and resulting exposure over time should also be addressed.

3.5 Media-specific considerations for establishing Base case conditions

Sampling as part of baseline characterization or a monitoring program should be consistent with ENV guidance on environmental characterization and section 3.1.1. Detailed guidance on development and implementation of sampling programs, including program design, statistical methods, sampling methods, and data interpretations are available in ENV (2013b), CCME (2016), and Health Canada (2010d). Whenever possible, samples from multiple media should be co-located to allow for validation of fate and transport modelling (e.g., water and fish tissue samples collected at the same time and place).

3.5.1 Air and dust

The atmosphere is an important pathway for the transport of contaminants to human receptors, who may be exposed to airborne COPCs either directly (through inhalation) or indirectly (through deposition onto land or water). It is expected that both wet and dry deposition be considered appropriately and modelled explicitly in the air quality dispersion model, with results applied to multi-media exposure models. It is not appropriate to estimate wet and dry deposition after the air quality model has been run. These considerations will require close collaboration between the HHRA team and the air quality modelling team at the dispersion modelling plan phase. Air quality modelling should be conducted in accordance with section 3.5 of the *British Columbia Air Quality Dispersion Modelling Guideline* (ENV, 2015).

It is strongly recommended that proponents coordinate requirements (e.g., human receptor locations, averaging periods, list of COPCs) for air quality assessment and HHRA as early in the process as possible. Typically, only outdoor air concentrations are assessed using this methodology; however, consideration of indoor air concentrations may be warranted if indoor conditions may result in higher levels of exposure (increased duration or frequency of exposure, higher predicted concentrations, presence of sensitive receptors) or if sheltering in place is recommended as a mitigation/risk management strategy.

REMINDER

Air quality concentration isopleths of the Study Area should be provided for all COPCs and averaging durations, and all assessed human receptor locations should be shown (see section 3.8.1). It is recommended that isopleths from all assessment cases are provided for context, especially when there are elevated concentrations under Base case conditions.

For permit applications, air quality models are required to show the "permit case", which can produce higher concentrations than the expected operations (i.e., they often allow for increased future capacity or because of the nature of the operations).

Establishing baseline should be in accordance with recommendations of the ENV (2016) *Water and Air Baseline Monitoring Guidance Document for Mine Proponents and Operators*. Baseline air quality concentrations should primarily be based on measured data (section 2.2.2), and not rely on modelled concentrations. Concentrations in air should be reported in consistent units of concentration (e.g., $\mu g/m^3$) and not as emission or release rates (e.g., tonnes/year). Modelled air concentrations must also indicate what averaging period and statistics were used as these variables must be consistent with the applied health-based standards or guidelines.

It is understood that there is significant uncertainty involved in air quality modelling, especially with inorganic COPCs in PM and formation of secondary pollutants (e.g., ozone). Regardless of the inherent technical challenges and uncertainty in assessing these exposure pathways, they cannot be excluded on this basis. As a result of the expected high uncertainty for dust exposure and secondary pollutant formation, it is expected that proponents prioritize reducing levels of PM and nitrogen oxide compounds to as low as reasonably achievable. It is important to track and highlight how uncertainty may impact

final conclusions on risk. This is especially important for emission sources lacking emissions data and when 'poor' quality emission factors are adopted for emission source characterization.

For projects such as mines where dust is a primary source of COPC releases to the environment, use of aerial deposition data to predict COPC-specific deposition rates for the Project Only case and Planned Development case is recommended. Previously collected aerial deposition monitoring data from similar projects (in terms of size, activity, and geographic location), or generic values can also be applied if available. If generic values or data from other projects is applied, provide justification for how it is applicable to the project. General equations to estimate the incremental change in COPC concentrations in soil and vegetation over a specified period of deposition are provided by the US EPA (2005). Other fate and transport models are also available for project-specific releases (e.g., Health Canada, 2010c, 2018a). The models selected for the analysis should be from peer reviewed or regulatory endorsed sources, and they must be fully referenced in the assessment.

For most COPCs, an assumption can be made that concentrations of COPCs in dust or bound to PM are equivalent to concentrations of COPCs in surface soil. This assumption may not be applicable for certain dust sources (e.g., mining activities such as bulldozing, drilling, blasting, conveyors, crushing facilities, use of stockpiles) and additional analysis may be required to predict COPC concentrations in dust from different materials (e.g., ore dust, overburden dust, waste rock dust). COPC concentrations in dust should be predicted following guidance from ENV (2015, 2016). If project activities will lead to measurable increases in indoor air quality (via new emissions or dispersion of existing COPCs), then evaluation of indoor dust and the associated health risks may be required.

3.5.2 Soil

Baseline soil sampling programs should apply COPC concentrations in surface soil that will contribute to incidental exposures (up to 10 cm below ground surface) where direct contact with human receptors is most likely.

Deeper soil concentrations may have to be considered for soils subject to gardening, tilling up to the rooting depth of crops and country foods (typically up to 1.5 m below ground surface), or if project or other anticipated future activities will involve excavation or disturbance of deeper soils creating a potential means of exposure.

When collecting soil samples, ENV (2009) *Technical Guidance 1 on Contaminated Sites - Site Characterization and Confirmation Testing* should be referenced for obtaining *in situ* samples and quality assurance and quality control methodology.

Baseline soil and vegetation sampling should always be completed with co-located soil and vegetation samples when a multimedia HHRA is required. Co-located samples allow for more accurate determination of site-specific bioconcentration factors, compared to the large degree of uncertainty and conservatism needed when applying generic bioconcentration factors. If soil and vegetation samples are not collected for the proposed project, justification should be provided.

Establishing baseline soil concentrations using supplemental reference data is described in ENV (2017a) *Protocol 4 for Contaminated Sites – Determining Background Soil Quality*. Regional background soil metals data are available in ENV (2017e) *Technical Guidance 17 on Contaminated Sites – Background Concentrations in Soil Database*. However, use of existing baseline data from ENV (2017e) or other sources, such as the National Geological Survey of Canada or the B.C. Ministry of Energy, Mines and Low Carbon Innovation, should only be used to supplement data collected from the Study Area. Any reference data from outside the Study Area should be from soils of a similar type, grain size, and geological origin.

Deposition values from air quality modelling results are often used to predict future soil concentrations. Coordinate averaging times, human receptor locations, and general methodology between assessments of air, soil, and human health to ensure consistency across the entire application.

3.5.3 Water

Project activities may affect water quality directly through the release of COPCs into surface or groundwater, or indirectly through deposition and runoff from land. Baseline levels should be established in accordance with recommendation of the ENV (2016) *Water and Air Baseline Monitoring Guidance Document for Mine Proponents and Operators*.

Selection of locations for water sampling should consider which water bodies, and which locations within these water bodies, are primarily used by human receptors. Uses can include drinking water sources (current or potential), recreational activities, agricultural (crops and/or livestock) activities, or fishing. All permanent water bodies or aquifers within the Study Area capable of supporting domestic, recreational, or agricultural uses should be identified. Drinking water suppliers can also be identified or confirmed through the regional health authorities.

Depending on the location and size of the Study Area, comprehensive sampling of all water bodies is not necessarily required; however, at minimum, all registered and unregistered potable water supplies located within the Study Area should be identified and included in the assessment.

REMINDER

Drinking water supplies can be identified through community engagement and existing government resources, including ENV's Groundwater Wells and Aquifers search tool, Water Resources Atlas, iMapBC or the Water Rights Databases (ENV, 2018).

Concentrations of COPCs in water are expected to be highly variable spatially and temporally. It is recommended that individual water bodies be assessed, based on human receptor preference and with a focus on protection of drinking water sources (see section 2.5.2). Justification should be provided as to the comprehensiveness of the sampling plan in determining COPC concentrations representative of exposure to all potential human receptors, and if justification is provided a worst-case water body or water use location can be used to simplify the assessment.

Summary statistics can be used to represent water concentrations (section 3.6) but should only be applied to individual locations and not across multiple water bodies within the Study Area. Applied data

must be protective of human receptors which preferentially use water from specific locations. As concentrations in water are likely to have higher seasonal variability than in soil, water samples should be obtained from each sample location at different times of year, representing low and high-water levels or flow rates. Collection of sediment data is also recommended if country foods in the Study Area may be exposed to COPCs through sediment contact or ingestion.

By default, total metal concentrations in water should be considered. If it can be demonstrated that dissolved metal concentrations are a better representation of exposure or risk, then dissolved concentrations can be applied. Care should be taken to ensure consistency between application of total and dissolved concentrations, and conversion between total and dissolved concentrations is not recommended without substantial supporting evidence. Use of partitioning relationships or fate and transport models to estimate COPC concentrations in water from soil measurements is not recommended unless results are validated with collected field or monitoring data.

Once a COPC has reached a domestic water source, additional means of exposure besides drinking water ingestion should be considered. These could include:

- dermal absorption via bathing/showering;
- inhalation of volatiles during bathing/showering; and,
- use of water on home garden produce and then consumption of this produce.

3.5.4 Country foods

Community-specific dietary information (i.e., what community members consume, how they obtain it, prepare it, and when/how much of various food types are consumed) is critical for completion of an HHRA. Country foods assessment should include the following considerations:

- how do emissions from the project change the quality of the food;
- how will COPC releases from the project affect exposure through country foods; and,
- what is the baseline exposure to COPCs from ingestion of country and market foods?

Unless already covered in another section of the EA, additional considerations could include:

- how does the project change the quantity of the food;
- will the project affect food security of human receptors; and,
- how does the project limit or change the access to subsistence foods?

Exposure to country foods must consider local consumption patterns and apply appropriate exposure durations otherwise the results of the HHRA will not be applicable or relevant to the population. Considerations could include seasonal availability, increased ingestion rates and larger doses during specific times of year, and the appropriateness of averaging exposure over an entire year (see section 3.3.4) based on availability and consumption patterns (e.g., does exposure occur in short bursts during specific times of year). The country foods evaluation should clearly state how the following issues have been addressed:

- increased concentration of COPCs in country foods and preferential consumption of specific tissues;
- differences in how specific species or tissues accumulate COPCs;
- COPC loss or gain due to cooking or preparation methods;
- COPC concentration due to moisture loss during cooking or dehydrating;
- use of washing/peeling factors for vegetation; and,
- use of wet or dry weights for tissue concentration and consumption rates.

HHRA reports should provide referenced data for the consumption frequency of each type of food. Community-specific information (with scientific rationale) should be used to establish country foods consumption rates. If such data cannot be obtained, standard consumption rates for wildlife and fish are available in the *Compendium of Canadian Human Exposure Factors for Risk Assessment* (Richardson, 1997), the *Canadian Exposure Factors Handbook* (Richardson & Stantec Consulting Ltd., 2013), and the *Inventory and Analysis of Exposure Factors for Alberta* (Alberta Health, 2018). Adjustment of default consumption rates without serious consideration of community-specific data is not recommended.

Country food consumption rates based on preferential use of the land should be used to represent unrestricted land use. Health Canada (2018a) recommends obtaining consumption patterns from the specific populations and communities of interest. Consumption rates based on community info or regional studies, such as the *First Nations Food, Nutrition & Environment Study* (Chan et al., 2011) should be used with caution as they may not have been intended for this purpose. Any aggregate consumption data should only consider responses from consumers of traditional food and should not be averaged with responses from non-consumers.

Country food ingestion rates should not be based on current food consumption patterns if there are existing concerns from stakeholders and Indigenous groups and peoples resulting in decreased consumption. Base the consumption rates on the preferential or traditional consumption rates reflecting unrestricted use of the land with the general understanding that consumption of country foods is beneficial to overall community health.

If human receptors are assumed to consume more than just country foods, then overall exposure from food ingestion will have to include consideration of exposure from market foods. In addition, if project activities are predicted to increase COPC concentrations in country foods and those COPCs are known to be present in market foods, then both country and market food should be assessed to ensure risks are properly characterized. Justification for exclusion must be provided if exposure to COPCs through market foods is not included. National exposure estimates have been performed for some chemicals, e.g., through the *Canadian Environmental Protection Act* (1999) Priority Substances List (Government of Canada, 2018). These assessments may be particularly useful for evaluating exposure through pathways such as supermarket food that would not be expected to vary regionally as much as exposure through soil or air. Additional evaluation of baseline exposures through market foods is available through the *Canadian Total Diet Study* (Government of Canada, 2009) and the *Canadian Community Health Measures Survey* (Statistics Canada, 2017), and data should be obtained from the closest recent study.

Publication of any information on Traditional food consumption or practices should not be published without permission from the Indigenous groups and peoples identified in the HHRA.

3.5.4.1 *Selection of country foods to assess*

A quantitative Exposure Assessment is conducted for foods by using the estimated exposure for each COPC in all foods. Food chain modelling may be required to predict baseline COPC concentrations in wildlife, fish, and plant tissue. Selection of country foods (defined in section 2.5.1) should be based on the following information:

- what species of plants, fish/shellfish, and wildlife are present in the Study Area;
- what species are consumed by people in the Study Area;
- which organs/tissues are consumed;
- which species or organs/tissues are expected to be most affected by COPCs; and,
- what areas or locations are preferentially used to obtain country foods?

Although it may not be necessary or feasible to assess all consumed country food species, all consumed country food species should be identified. Surrogate species can be used to represent the expected tissue concentrations in each type of country food. Surrogate species should be selected for the following types of country foods as applicable to country food consumers, covering all relevant sources identified in section 2.5.1:

- above ground portions of terrestrial plants;
- below ground portions of terrestrial plants;
- aquatic plants;
- medicinal plants;
- fish/shellfish or other aquatic wildlife;
- aquatic avian species;
- terrestrial avian species;
- aquatic wildlife;
- terrestrial wildlife (primary consumer); and,
- terrestrial wildlife (secondary and/or tertiary consumer).

If used, surrogate species are intended to represent the expected tissue concentrations for the entire food type for all possible species living in the Study Area and would encompass 100% of that food type's ingestion rate. Surrogates should represent species expected to have the highest tissue concentrations. For example, a single wildlife species with the highest expected tissue concentration of all wildlife species consumed could represent all meat consumption. This can be determined based on literature reviews, the expected ratio of COPC ingestion to body weight, or consideration of other factors such as home range, diet, behaviour, and metabolism. If surrogates known to be present in the Study Area cannot be chosen, conservative substitutions from similar ecosystems can be selected.

Information on community-specific consumption preferences is beneficial and justification on the selection of country foods representing the highest COPC tissue concentrations is required. To increase

the applicability of the assessment, preferentially consumed species should be used if possible. Information on community-specific consumption patterns must also consider differences in consumption patterns over time, such as seasonal availability of foods or periods of high consumption rates.

The selection of surrogates may differ based on the human receptor group (e.g., sport fishers compared to Indigenous groups and peoples), collection method (specific parts of plants or animal organs), and preparation method (e.g., collection of bark for use in medicinal teas compared to vegetables for consumption). Consideration should be given to whether foods are consumed washed or unwashed. It should also be recognized that country foods may be preserved (through freezing, canning, etc.) and consumed throughout the year.

3.5.4.2 *Selection of country foods to sample*

Baseline environmental sampling should be completed whenever possible due to the inherent uncertainty in food-chain modelling. Collection of baseline country food data will require consideration of input from residents of the Study Area and Indigenous groups and peoples. The sampling protocol should be consistent with current Health Canada (2018a) country foods guidance and/or CCME (2016) site characterization guidance. Co-locating samples is strongly recommended to validate food-chain models and provide more realistic estimates of COPC concentrations in country foods.

The risk assessor should consider how country foods are harvested, prepared, and when and how much are consumed, based on engagement with stakeholders and Indigenous groups and peoples. It is important that the consumption rates and patterns applied in the HHRA be representative of a reasonably maximally exposed individual (see section 2.4). Underestimation of consumption or improper amortization of exposure can lead to an underestimation of risk.

Site-specific data must be of sufficient statistical power to enable meaningful and statistically significant comparisons, as well as provide a comparison with monitoring data (see section 7.3).

It is recognized that collection of country food baseline data is resource intensive and challenging, and that collecting a statistically significant data set for large mammals or other difficult to sample species may not be possible. If the consumption of large mammals or other difficult to sample species is expected to be an appreciable source of exposure, the following options are available:

- use a smaller sample size, acknowledging the increased uncertainty in the data set and provide a comparison of the results to food-chain modelling; or,
- rely solely on food-chain modelling, with consideration given to reducing the uncertainty in meat concentrations through further environmental sampling of wildlife diet items such as vegetation prior to the harvesting of the animal itself.

Baseline water, fish and/or shellfish sampling should always be completed when there are chemical emissions from the proposed project to water. If water, sediment, fish and/or shellfish are not collected for the proposed project, justification should be provided.

Additional country food sampling should be completed when: a) elevated risks are predicted that are driven by the consumption of a particular country food; b) if COPCs are already in the environment with the potential for biomagnification; or c) if there are community concerns regarding specific country foods. If collection of tissue samples from the Study Area is not feasible, other studies or local information can be used. Once collected, country foods data should be reviewed and compared against food-chain modelling results to evaluate the best option for exposure calculations.

3.5.4.3 *Modelling country food concentrations*

Modelled and measured concentrations of COPCs in soil, surface water, groundwater, sediment, and vegetation can be used as inputs for subsequent predictions of uptake into vegetation and wildlife used as food sources for human receptors. Uptake factors based on existing literature or calculated based on co-located samples from within the Study Area are both appropriate options, but require a discussion of the uncertainties and limitations of the approach used. Atmospheric deposition and vapour absorption should also be considered directly in the assessment of uptake into foods, particularly for leafy plants and fruit, whether directly consumed by human receptors or consumed by wildlife.

A limited discussion on modelling tissue concentrations and use of uptake models is available from Health Canada (2010d) and the US EPA (2005).

3.6 General considerations for use of statistics

There are several inputs required to complete an Exposure Assessment. While it is recommended that the most conservative input values are applied, this can result in unrealistic estimates of exposure. Statistics may be used to ensure that the Exposure Assessment is based on a reasonably maximally exposed individual (see section 2.4) and avoids unrealistic predictions. Inputs for Exposure Assessment can be divided into four categories:

1. **Environmental concentrations or measured physical characteristics:** the 95% UCLM can be used for chemical concentrations, representing a realistic upper-bound for chronic exposure estimates or any measured inputs for fate and transport models. This requires a data set of sufficient statistical power and should not be applied for estimates of acute exposure (where maximum values should be used).
2. **Behavioural human receptor characteristics (e.g., soil ingestion rate, time spent outdoors, country food consumption rates, etc.):** default values are generally based on upper-bound estimates. If site-specific data are applied it should not represent a restriction on human receptors' behaviour and should represent preferred behaviour or activity patterns, not averages. Use of 95% UCLM values are not recommended and maximum plausible values based on stakeholder input should be applied.
3. **Physical human receptor characteristics (e.g., body weight, inhalation rate, skin surface area, etc.):** recommended values from Health Canada (see section 3.3) should be applied. These values represent arithmetic means of the Canadian population and it is strongly recommended that they are not adjusted statistically.
4. **Physical constants or literature values (e.g., physical properties of COPCs):** the most conservative value based on current scientific understanding should be applied. Statistical manipulation of literature values is not supported.

Use of statistics for environmental media concentrations should be consistent with guidance from CCME (2016) and Health Canada (2010d).

The US EPA's Superfund program has traditionally used 95% UCLM as the concentration term in point estimates of reasonable maximum exposure for contaminated sites HHRA (US EPA, 1989 and updates). The 95% UCLM is considered to be an appropriate statistic for characterizing baseline exposure point concentrations (Health Canada, 2019a). Use of the 95% UCLM should be supported by statistical analysis, with consideration given to data quality, the actual or predicted distribution, and potential for outliers. It is recommended that the same methodology to predict COPC concentrations and to establish an appropriate estimate of reasonable maximum exposure be used.

REMINDER

Proponents are responsible for reporting the *a priori* statistical power of baseline sampling data sets. Sampling programs with insufficient sample size will have low precision and statistical power. Baseline data must be able to predict a significant change with a given degree of confidence, so that any actual changes in the environment during the project life span can be detected by monitoring programs (see section 3.1.1).

It is recommended that the 95% UCLM concentration is only applied when a sufficient sample size is available to represent a high-end estimate of measured baseline COPC concentrations, otherwise the maximum measured values must be applied. If other statistics are used, additional justification on why the applied value is a better representation of a reasonable maximum level of exposure will be required. Regardless, summary statistics should be provided for each measured parameter, including: number of data points; limits or detection; number of non-detectable results; minimum; maximum; measure of central tendency (median and/or mean as appropriate); 95% UCLM; and a measure of dispersion (such as standard deviation). Data outliers should not be discarded from any dataset without providing justification for removal. Combination of multiple data sets from different locations or studies should only be undertaken with caution and should include a discussion on the validity of this approach.

For characterization of Base case exposure with measured values, there must be a clear indication of how samples with COPC concentrations less than laboratory detection limits (non-detects) are being applied and justification should be provided for the selected method. No single method to handle non-detects is specifically required; however, methods which utilize direct substitution of non-detects (for example with a concentration of one-half of the detection limit concentration) are not recommended.

In cases where a COPC has not been detected in any samples, the COPC has no known source of current or historical releases, and if detection limits are consistent with the laboratory requirements outlined in section 2.3, the COPC can be assumed to be absent from the Study Area.

REMINDER

Statistical methods should be described in enough detail to be understood and reproduced. It is recommended that ProUCL, or an alternative peer-reviewed open-source program is used to complete

statistical calculations and select methods to address non-detects. Supporting technical information on ProUCL and selection of statistical methodology is available from the US EPA (2015).

3.6.1 Human receptor characteristics

Human receptor characterization is described in section 3.3; however, for HHRA input parameters related to human receptors (e.g., body weight, inhalation rate) it should be clear if average or more conservative values are applied.

Applied exposure scenarios and exposure factors should be representative of the population in the Study Area and protective of a reasonably maximally exposed individual. Even if not applied directly in the HHRA, community-specific data can be useful in demonstrating that application of generic exposure factors will be protective of all human receptors.

3.7 Dose calculation

The objective of the Exposure Assessment is to calculate an exposure dose. Dose is expressed as a daily intake (mg/kg bw/d), the product of the COPC concentration in the exposure medium and the intake rate of that medium, normalized to body weight. Depending on how a particular chemical acts on biological systems, exposure estimates should be expressed in the form of a dose or as an exposure concentration. Depending on the results of the Problem Formulation, exposure estimates may be required for a few different scenarios and should be calculated for each COPC, exposure pathway, human receptor group, and relevant age group.

Doses are calculated using the following generalized formula:

$$Dose = \frac{C \times IR \times ET \times RAF}{bw}$$

where:

Dose = exposure dose of the COPC (mg/kg bw/d)
C = COPC concentration in environmental medium (as mass of COPC per unit environmental medium)
IR = intake rate or contact rate (as unit of environmental medium per unit time)
ET = exposure term and/or exposure frequency (unitless)
RAF = relative absorption factor (unitless)
bw = body weight (kg)

For measured or modelled parameters, the maximum or 95% UCLM value can be applied (see section 3.6). Calculations may also require additional variables, for example, dermal exposure may also include consideration of the surface area of skin exposed to contaminated media or soil to skin adherence factors. Dose calculations for specific exposure pathways are available in table 4.1 of the Health Canada (2010c) *Guidance on Human Health Detailed Quantitative Risk Assessment of Chemicals*.

Exposure to locally acting chemicals (e.g., irritants) is often more appropriately expressed as a concentration of the chemical in the specific environmental medium that is contacting affected tissues,

and the duration and frequency of exposure. The specific form in which exposure is reported must be consistent with the exposure endpoint determined during the Toxicity Assessment.

If the TRV is based on a threshold or risk-specific concentration, the following formula for an exposure concentration can be applied to calculate an amortized exposure concentration:

$$C_{exp} = C \times ET \times RAF$$

where:

C_{exp} = COPC exposure concentration (as mass of COPC per volume of environmental medium)
C = predicted COPC concentration (as mass of COPC per volume of environmental medium)
ET = exposure term and/or exposure frequency (unitless)
RAF = relative absorption factor (unitless)

Care must be taken to ensure that exposure doses and TRVs are in the same units and both represent either delivered or absorbed doses. Use of a RAF other than 1.0 would require considerable justification and would not be applicable for locally acting substances.

All exposure pathways assessed with the same TRV should be summed to provide the total exposure dose; this will typically include all exposure pathways with the same exposure route. If there are different TRVs for a COPC dependent on the exposure route, then instead of summing exposure, the resulting hazard or risk should be summed instead (see section 5.1.1). If a COPC has different toxicological endpoints for multiple exposure routes than these exposures can be evaluated separately (see section 5.1.3). Exposure doses for different COPCs should not be summed except in cases where mixtures will be evaluated using equivalency factors (see section 4.3.1).

It is recommended, but not required, that threshold COPCs initially be assessed using an unadjusted daily exposure dose with no dose averaging with an exposure term of 1. This dose would be compared to a chronic TRV based on the most sensitive toxicity endpoint and life stage. If health effects are predicted, a more detailed evaluation can be undertaken using shorter term TRVs for similar or longer exposure durations as the exposure scenario of interest. *De novo* short-term TRVs can be derived based on Health Canada (2010c) guidance if necessary. It is preferable to use conservative approaches in preliminary analysis, then refining the assessment if preliminary results suggest unacceptable health risks.

Assessment of non-threshold COPCs should apply lifetime exposure durations, and calculations must be consistent with the considerations on amortization, dose averaging, and life stage adjustment factors described in section 3.3.4.

The complete results of the Exposure Assessment should be presented, either in the HHRA or in a separate appendix, and include the predicted doses for each: COPC, exposure pathway, human receptor, and age group. All baseline data, formulae, and input parameters used in the Exposure

Assessment should be presented along with their source and assumptions. For any calculations, the general equations and completed sample calculations should be provided.

When methods differ significantly from those recommended above, the HHRA should identify the assumptions, methods, and interpretation required by the regulatory agencies and discuss their implications in assessment of potential health risks.

3.7.1 Base case exposure

Many COPCs may be either naturally occurring or related to existing sources. The Base case quantifies sources of exposure not associated with the project using measurements of current conditions in the Study Area and modelled concentrations as necessary (see section 2.2.2). Assessment of Base case exposure should consider all potential COPC exposure pathways from all environmental media, regardless of whether project-related COPCs are expected to contribute to that exposure pathway. If an exposure pathway is determined to be inoperative for a COPC released by the project (e.g., no project-related discharges to freshwater), the Base case should still consider exposure from baseline COPCs for that exposure pathway (e.g., exposure to baseline COPC concentrations in freshwater).

The most common sources of baseline exposure are naturally occurring concentrations of COPCs in soil, air, water, sediment, and country foods. For some COPCs, such as trace elements, market foods may also be a significant source of exposure. Health Canada's *Canadian Total Diet Study* (Government of Canada, 2009) provides estimates of baseline exposure to select COPCs through market foods and is recommended as a source of reliable information on baseline exposure. Due to the complexity consumer product exposure, quantitative evaluation of exposure to COPCs through consumer products is not required.

The calculation of baseline exposure for non-threshold carcinogenic COPCs and evaluation of baseline exposure allows for a more complete discussion on the incremental risks to health associated with the project and overall community health (see section 3.3.2) and is strongly recommended that it be included. Furthermore, as stated in section 3.2.2, decision-makers often request an assessment of baseline exposure for non-threshold carcinogenic COPCs.

3.7.2 Multimedia exposure

Multimedia modelling should use established prediction models obtained from published or other sources that have received peer or regulatory endorsement. The source of all models used in the HHRA must be clearly referenced and rationale for the specific model selected should be provided. The following sources are recommended:

- US EPA (1989 and updates) *Risk Assessment Guidance for Superfund*; and,
- US EPA (2005) *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities*.

The following information on the multimedia assessment must be provided:

- summary of input data;

- referenced source of all fate and transport models and model inputs;
- full description of all fate and transport models including all formulae and equations; and,
- complete sample calculation for all modelled media from project release to predicted hazard/risk.

If a COPC is included in the multimedia assessment, exposure and hazard/risk must be evaluated for all operative or potentially operative exposure pathways regardless of their contribution to overall exposure, and whether hazard/risk exceeds target values for individual pathways.

It is often the case that overall exposure is primarily due to a few key pathways, with the remaining pathways providing only negligible exposure. In these situations, it can be appropriate to only quantify exposure from key pathways; however, a qualitative evaluation should be provided for the remaining pathways to justify why their exposure is negligible.

CAUTION

An exposure pathway would be considered negligible and not require further quantitative evaluation if it would be reasonably expected to represent less than 1% of total exposure, based on predicted COPC concentrations in environmental media and human receptor characteristics. For example, worst-case or screening level calculations could be used to demonstrate that a potentially complex exposure pathway would have a negligible effect on overall risk in an otherwise detailed risk assessment.

Excluding exposure pathways from quantitative evaluation should not be undertaken based on proposed risk management or exposure control assumptions, and it is strongly recommended that the risk assessor consider stakeholder concerns and perceptions before taking this approach.

3.7.3 Microenvironments

Any location within the Study Area where physical, chemical, or biological conditions will alter the expected exposure dose to any human receptor group is considered a microenvironment. Microenvironments can result in higher than expected exposures and may result in under-predicted risks if generalized conditions are averaged over the entire Study Area. Use of specific baseline COPC concentrations (see section 3.6), human receptor characteristics, exposure scenarios, and/or exposure pathways may be needed in different microenvironments. Microenvironment analysis may improve the overall quality and accuracy of the HHRA and should be considered under the following conditions:

- baseline COPC concentrations are not uniformly distributed (see section 3.5); and/or,
- land use or expected human receptor activities are not uniform across the Study Area and have identifiable patterns.

While the use of worst-case conservative assumptions can reduce the requirements for analysis of individual microenvironments, microenvironment analysis can be used to improve the accuracy of the Exposure Assessment and improve risk management decisions.

If usage patterns in microenvironments indicate decreased potential for exposure, care should be taken to ensure that the applied assumptions do not result in exposure control that unnecessarily restricts

potential future land use in the Study Area. Microenvironments should be based on data or inputs from stakeholders on historical and current land use and should not account for decreases from preferred land used scenarios due to project influence.

3.7.4 Bioavailability and absorption

Bioavailability refers to the amount of COPC absorbed and retained in the body relative to the exposure dose. It is assumed that TRVs are derived from an applied exposure dose during toxicity studies and not the absorbed dose, unless explicitly stated. If the TRV did not consider bioavailability (see section 4.2) and was based on the applied exposure dose, then the exposure dose calculations in the HHRA cannot apply a bioavailability factor to that exposure route. Bioaccessibility refers to the fraction of COPC from environmental media that is available for absorption into the body.

Bioavailability adjustments are made in exposure calculations using a relative absorption factor (RAF), also known as a relative bioavailability. The RAF represents the fraction of COPC absorbed by the human receptor relative to the exposure dose. By default, a value of 1.0, representing 100% bioavailability should be applied. A RAF of 1.0 does not imply that 100% of a COPC is absorbed by the body, rather it implies that the environmental exposure is equivalent to the absorption from the toxicity studies used in TRV derivation. Use of absolute bioavailability factors in the Exposure Assessment will likely require additional adjustment to the applied TRV and is not recommended.

Typically, an RAF of 1.0 is assumed but RAF adjustments may be applicable if the toxicity studies were based on a different chemical or physical form(s) of the COPC than that predicted in the Study Area. Absorption of COPCs can be highly variable and affected by COPC properties, the environmental medium, and human receptor characteristics. Bioavailability adjustments should consider these sources of variability and include a discussion of related uncertainties. Health Canada (2017a) recommends that if any bioavailability adjustments are made, they should be accompanied by chemical-specific rationale, noting whether the tests have been validated. In all cases, worked examples should be provided.

Guidance on including oral relative bioavailability and bioaccessibility in HHRAs can be found in Health Canada (2017a) *Supplemental Guidance on Human Health Risk Assessment for Oral Bioavailability of Substances in Soil and Soil-Like Media*. Site-specific evaluation of bioavailability is a resource intensive process and before evaluating bioavailability adjustments, the following factors should be evaluated:

- do the characteristics of relevant environmental media indicate COPCs are substantially less bioavailable than assumed;
- will benefits from bioavailability adjustments outweigh existing uncertainty in the HHRA;
- will the adjustment affect the conclusions of the HHRA and the decision-making process; and,
- are there established and validated methods available for bioavailability adjustment for the relevant COPCs?

Due to the lack of dermal toxicity studies, dermal bioavailability is commonly adjusted in HHRAs. The *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors*, *Version 2.0* (Health Canada, 2010a) recommends relative

dermal absorption factors for several COPCs which can be applied to HHRAs. Any adjustment to bioavailability or absorption should be consistent with current Health Canada guidance, and RAFs recommended by other organizations should only be applied when sufficient justification is provided.

Additional scientific rationale and justification must be provided for all individual COPCs where the RAF for oral or inhalation exposure is adjusted, including cases where site-specific bioavailability has been estimated. Inhalation RAFs should only be adjusted if inhalation toxicity is evaluated using a TRV derived for the oral route, otherwise the inhalation RAF should always be assumed to be 1.0.

3.7.4.1 Dermal contact and permeability

If dermal contact with water is included as an operative exposure pathway, care should be taken to determine if any permeability factors in the exposure calculation already apply a dermal RAF.

3.7.5 Chemicals with multiple forms

For COPCs with multiple forms (such as oxidation states or isomers), it should be assumed that a combination of the most toxic and persistent form is present, unless site-specific evidence is presented.

3.8 Exposure from individual media

If COPCs are only expected to be present in a single media, it may be possible to simplify the HHRA. While certain aspects of the HHRA can be simplified, requirements for risk communication and validation of HHRA predictions with monitoring will still be expected.

3.8.1 Inhalation exposure only

For COPCs that are only expected to be present in air (such as common air contaminants), the HHRA can be simplified to a comparison against appropriate health-based criteria for inhalation exposure (see section 4.2) and a discussion of the predicted change to overall air quality. Air quality criteria often consider other factors than just health (e.g., achievability, historic trends), and it is recognized that population health effects can occur at levels below the CAAQS (Health Canada, 2016a). It is also recognized that there are no available thresholds for health effects from exposure to some COPCs, such as ozone, $PM_{2.5}$, and PM_{10}, as they are considered to be non-threshold substances (Health Canada, 2016a). Thus, if air quality criteria are used for comparison to modelled air quality data, the changes in air quality should be examined and considered for potential changes in risks to human health.

Human health-based screening criteria from B.C., Health Canada, and CCME should be prioritized. Criteria derived by other international, national, or provincial/territorial agencies (e.g., Alberta Ambient Air Quality Objectives and Guidelines; Ontario Ambient Air Quality Criteria) may be used if they are health-based and adjusted appropriately for consistency with the assumptions recommended by this guidance document. Key elements to consider are: averaging times, defined level of acceptable risk, human receptor characteristics, and safety factors used in TRV selection. Regulatory guidelines and objectives may also use assumptions regarding exposure scenarios, human receptor characteristics, absorption ratios, or allocation factors that may not be applicable or consistent with the project's CSM.

The following considerations must be discussed when this approach is used:

- criteria must be solely health-based, scientifically defensible, and up-to-date. A Toxicity Assessment (see section 4.0) is still required and the applied criteria must be protective of the identified toxicity endpoints;
- criteria must be protective of all exposure durations based on the identified exposure scenarios and toxicity endpoints, as short-term exposure may be more important for inhalation-based exposures;
- chemical mixtures must still be assessed (section 4.3);
- cumulative effects must still be assessed;
- the COPC cannot be present in other environmental media;
- air quality must be assessed at the MPOI and all identified human receptor locations (see section 3.3.3);
- increasing concentrations of non-threshold COPCs must still include a residual effects assessment (see section 7.1); and,
- all applied exposure methodology should be consistent with Health Canada (2016a) *Guidance for Evaluating Human Health Impacts in Environmental Assessment – Air Quality*.

Assessment of exposure to COPCs in air may require additional consideration of shorter exposure durations. For acute exposures, the exposure concentration is equal to the predicted COPC concentration in air using a defined averaging time.

For subchronic or chronic exposure, the averaging time for exposure concentrations is often adjusted directly in the air dispersion model. However, if this method was not used or additional averaging times are needed, an amortized exposure concentration can be calculated as follows:

$$C_{exp} = \frac{C_{air} \times ET \times EF \times ED}{AT}$$

where:

C_{exp} = COPC exposure concentration (µg/m^3)
C_{air} = modelled COPC air concentration (µg/m^3)
ET = exposure term (hours/day)
EF = exposure frequency (days/year)
ED = exposure duration (years)
AT = averaging time (years)

The calculated exposure concentration must be consistent with the exposure scenario being evaluated, and toxicity endpoints, and if necessary multiple exposure durations may require assessment (see section 3.3.4).

The discussion of the predicted change to overall air quality should be framed around both the relative and absolute change in predicted air concentrations in relation to health-based air quality criteria. There must be a discussion of the project's overall impact to air quality in the Study Area for all COPCs, regardless of whether predicted concentrations exceed ambient air quality criteria. Changes in air quality should be put into context using potential changes in community health outcomes (section 7.2).

Exceedances of ambient air quality criteria indicate that risk management measures may be required, but concentrations below these criteria may still require additional consideration (see section 4.1.3). As long as the above considerations are made, the following sources are recommended for ambient air quality criteria, in order of preference:

- B.C. Ambient Air Quality Objectives & Standards (Government of British Columbia, 2020);
- Metro Vancouver Ambient Air Quality Objectives (Metro Vancouver, 2020), if the project Study Area is within the Metro Vancouver Regional District;
- Canadian Ambient Air Quality Standards (CCME, 2017);
- US National Ambient Air Quality Standards (US EPA, 2016); and,
- California Office of Environmental Health Hazard Assessment or Ambient Air Quality Standards (California Air Resources Board, 2019).

Additional guidance on completion of HHRA for air quality is available from Health Canada (2016a) as is specific guidance on the evaluation of exposure to coarse PM, diesel exhaust, gasoline exhaust, NO_2, and SO_2 (Health Canada, 2016c, 2016d, 2016e, 2016f, 2017c).

4. TOXICITY ASSESSMENT

The primary objective of the Toxicity Assessment is to weigh the available evidence regarding the potential for a COPC to cause adverse health effects in exposed individuals or populations. The following information should be included in the Toxicity Assessment for each COPC identified as having potential or complete exposure pathways during the Problem Formulation stage:

- determination if the COPC has threshold toxic effects, non-threshold effects, or both;
- identification of the mode of action and potential toxicological health effects associated with the COPCs, differentiated by exposure route;
- selection of a maximum dose or maximum concentration to which a human receptor can be exposed without an appreciable risk of adverse health effects, or identification of the relationship between dose and the severity of adverse health effects based on exposure duration; and,
- evaluation of the suitability and limitations of the available toxicity information.

The Exposure Assessment and Toxicity Assessment are interdependent and these stages of the HHRA should be conducted concurrently. Toxicity Assessment may identify particularly sensitive human receptors that must be considered in the Exposure Assessment. The toxicological characteristics of COPCs can affect which exposure periods must be considered. The exposure dose when combined with the results of the Toxicity Assessment allows the calculation of predicted risks.

4.1 Toxicological reference values (TRVs)

The relationship between the dose and duration of exposure and the increased likelihood of the adverse effects is expressed as a TRV, also known as an exposure limit. TRVs represent the maximum exposure dose that is unlikely to cause an adverse human health effect or an unacceptable increase in incidence of health effects.

As TRVs are often based on animal studies or limited human case studies, it should be stated in the HHRA exactly how risks to human health were determined. Discussion of how uncertainty factors were applied to the results of toxicological studies to account for extrapolation should also be included. For example, TRVs can be derived from a 'lowest observed' or 'no observed' adverse effect level, from animal or human results, based on the general public or sensitive individuals, using acute-term or chronic exposure studies, or could be based on a limited number of evaluated toxicological endpoints.

While TRVs are often considered to represent a safe level of exposure, exceeding the TRV does not necessarily indicate a definite risk to human health. A detailed discussion on TRVs is available from Health Canada (2010c, section 5.5).

4.1.1 Threshold substances

Threshold substances are COPCs for which there exists a level of exposure at which adverse health effects are not expected to occur. The TRVs for threshold substances can either be expressed as a reference concentration (RfC) or reference dose (RfD), to which human receptors can be exposed without an expectation of adverse health effects. RfC are used for air exposures, and RfD are used for exposure to other media via oral and dermal routes. RfCs can also be referred to as tolerable concentrations (TCs), and RfDs can also be referred to as tolerable daily intakes (TDIs).

For contaminants which are also essential trace elements, a tolerable upper intake level should be applied, with the understanding that there is less emphasis on minimizing total exposure as some level of intake is necessary to maintain overall health.

4.1.2 Non-threshold carcinogenic substances

Non-threshold substances pose a potential risk of adverse health effects at any level of exposure. For these substances, the risk of adverse health effect within the exposed population is typically assumed to increase proportionately with increasing exposure in a linear dose-response relationship. However, it should be acknowledged that there is a growing body of evidence suggesting non-linearity in the concentration-response functions for environmental pollutants, particularly at low levels of exposure. A linear-dose response curve should not be assumed without evaluation of the most current toxicity information for each COPC (see section 4.1.4).

The TRV for non-threshold carcinogens is the applied concentration or exposure dose where the lifetime risk of an adverse health effect is considered essentially negligible. If it can be demonstrated that there is a threshold for carcinogenic effects, these COPCs can be assessed similarly to threshold substances using a TDI or TC.

An incremental lifetime cancer risk (ILCR) of 1 in 100,000 ($1x10^{-5}$) is considered essentially negligible, consistent with Health Canada guidance and policy used by ENV to develop risk-based standards for contaminated sites. However, effort should be made to reduce exposure to all non-threshold chemicals to the lowest level reasonably achievable.

The ILCR is defined as the increased lifetime cancer risk due to project activities, disregarding baseline environmental exposures and the baseline incidence of cancer in the general population. For COPCs included in a multimedia assessment, the ILCR is based on the total combined dose from all exposure pathways, which can consider how this exposure is amortized over an individual's life span. A discussion of cancer risk from baseline environmental exposure may be included in the HHRA for context.

The TRVs for carcinogens can either be expressed as a cancer slope factor (ILCR per unit of dose) or unit risk (ILCR per unit of concentration). Cancer slope factors are intended to represent an upper bound estimate of maximum plausible cancer risk (e.g., upper 95% upper bound estimate of the slope) rather than the expected cancer risk (e.g., applying the predicted slope directly). Unit risk values are used for air exposures, and cancer slope factors can be used for exposure to any media. The TRVs for carcinogens can also be expressed as a risk-specific concentration (RsC) or risk-specific dose (RsD). The RsC and RsD values are calculated from the cancer slope factor or unit risk using a target cancer risk. When using RsC or RsD values from other jurisdictions, the applied target cancer risk must be adjusted for consistency with the 1 in 100,000 ($1x10^{-5}$) ILCR target considered essentially negligible in B.C.

Slope factors should be applied according to Health Canada (2010c) guidance in conjunction with composite human receptors. A composite human receptor is assumed to be exposed through all life stages (infant, toddler, child, teen, and adult) in order to account for varying sensitivity of the different life stages. Exposure to a composite human receptor uses straight arithmetical weighting for each life stage based on the fraction of the entire lifetime (80 years) that each life stage group represents, and then sums each stage to determine the lifetime average daily dose (LADD). For mutagenic carcinogens, ILCR can either be calculated by multiplying a slope factor developed for adults with ADAFs for the other life stages (table 1) and the LADD, or by multiplying age-dependent cancer slope factors for each individual life stage with the LADD. Formulae for these calculations are included in section 5.1.2.

4.1.2.1 Less than lifetime exposure to non-threshold COPCs

Assessment of non-threshold carcinogenic COPCs assumes lifetime exposure. Assessment of subchronic or acute exposure to carcinogenic non-threshold COPCs should follow Health Canada (2013) guidance, recognizing that averaging intermittent or less-than-lifetime exposures over a lifetime may underestimate cancer risks.

Exposure averaging for non-threshold carcinogenic COPCs with a mutagenic mode of action (such as polycyclic aromatic hydrocarbons) should use either age-dependent adjustment factors (ADAFs; table 1), age-specific slope factors (SFs), or unit risk (UR) values to account for sensitivity of early life stages. ADAFs do not need to be applied for COPCs with non-mutagenic modes of action, as determined by the supporting studies for the applied TRV.

The applicable exposure duration for non-carcinogenic non-threshold COPCs will depend on the results of the Toxicity Assessment (see section 4.1.3). Dose equations for non-threshold COPCs are shown in section 3.7.

Table 1: Age-dependent adjustment factors for mutagenic carcinogens

Life Stage	Age	Age-Dependent Adjustment Factor (unitless)
Infant	0 - 6 months	10
Toddler	7 months - 4 years	5
Child	5 - 11 years	3
Teen	12 - 19 years	2
Adult	≥20 years	1

From Health Canada (2013).

For additional guidance on evaluating chronic and less than chronic exposures, please refer to Appendix G of Health Canada (2019a).

For other COPCs where ADAFs are considered applicable, guidance from Health Canada should be prioritized. If potency factors from other organizations, such as the WHO or US EPA are available, additional justification should be provided indicating how the proposed approach is consistent, or more conservative, than assumptions and methods recommended by Health Canada.

4.1.3 Non-carcinogenic non-threshold COPCs

Not all non-threshold substances are carcinogens and these terms cannot be used interchangeably (see section 5.1.2). COPCs can potentially exhibit non-threshold toxicity without a cancer-based endpoint, and it is possible that threshold doses for some cancer-related endpoints may be applicable. Regulatory agencies have not established defined levels of acceptable risk for several common non-carcinogenic non-threshold COPCs. The discussion of the significance of predicted health effects and interpretation of the HHRA results is used to determine if project risks are acceptable.

For any chemical which does not have a toxicologically defined acceptable level of exposure, or for which the target ILCR of $1x10^{-5}$ does not apply, any measurable increase in environmental concentrations (as defined in section 2.3) due to the project has the potential for an increase in adverse human health outcomes. This includes, but is not limited to substances such as lead, NO_2, O_3, and $PM_{2.5}$. If there is a predicted measurable increase (as defined in section 2.3) in concentration in any environmental media for non-carcinogenic non-threshold COPCs, Risk Characterization (section 5.1.3) and residual effects assessment (section 7.1) must be completed.

4.1.4 Effect classification

Classification of a COPC as a threshold or non-threshold chemical will normally have been undertaken by the regulatory agency publishing the TRV. Determination if a COPC is a carcinogen should be conducted in accordance with ENV Protocol 30 (ENV, 2017d), which assumes a substance is a carcinogen if it is classified as a known or probable human carcinogen by any of the following organizations:

- Government of B.C.;
- Health Canada;
- US EPA Integrated Risk Information System (IRIS);

- United Nations – WHO; or,
- International Agency for Research on Cancer (IARC).

Any COPCs classified as carcinogenic or non-threshold may have additional toxicity data for non-carcinogenic or threshold endpoints. For any COPCs which have multiple modes of toxic action which require different assessment methodologies (e.g., threshold and non-threshold toxicity endpoints), all endpoints must be evaluated separately.

4.1.5 Non-linear dose-response relationships

Unless otherwise stated, it has been assumed for the purposes of this guidance document that dose-response relationships are linear. This assumption may not be valid in all cases and some COPCs, such as endocrine disruptors, may exhibit increased toxicity at low doses (through non-monotonic or U-shaped dose-response curves), or other non-linear dose-response curves. Due to the limited available toxicological information and lack of consensus on non-linear dose-response curves, at this time non-linear effects must only be considered if a COPC has been established by a Canadian regulatory agency to behave, or potentially behave, in this way. Characterization of risks from these contaminants should either be undertaken by a qualified toxicologist using established peer-reviewed methodology, or following guidance provided by the ministry.

4.2 Selecting TRVs

Health Canada (2010c) and ENV have both specified a hierarchy of preferred sources for TRVs, and consulting published information from the following sources using the following priority is recommended:

- Primary sources - Health Canada TRVs (Health Canada, 2010a, 2018b); US EPA IRIS; or WHO International Program on Chemical Safety (INCHEM); and,
- Secondary sources - Netherlands National Institute of Public Health and the Environment (RIVM); ATSDR; TRVs published by other Canadian provincial/territorial or American state-level government agencies (such as the California Environmental Protection Agency).

It is recommended that TRVs published by the primary sources preferentially be applied, using secondary sources if no primary ones are available. Toxicology is an active area of research and TRVs should be up to date, with the selected TRV should be the one that best reflects current scientific understanding. More recent or relevant TRVs from Health Canada or the WHO can be applied even if US EPA values are available. Consideration should also be made of any recent published studies or publicly available information regarding revisions of recommended TRVs.

All available TRVs from the primary or secondary sources should be presented, and if these sources have different published TRVs, rationale for selecting a TRV must be provided based on the considerations below. While selection of the most conservative TRV from a primary source is straightforward and often protective, the age of the TRV source, methodology used to derive the TRV from toxicity studies, and the consistency of the TRV with the project exposure scenario should also be considered. Use of overly conservative TRVs can result in incorrect prioritization of potential health risks.

The Toxicity Assessment should be supported by the following information for each COPC, and provided for each evaluated exposure duration:

- list of TRVs available from the primary and secondary sources;
- reasoning for selecting the applied TRV;
- age of the applied TRV;
- key studies used to derive the TRV;
- consistency of the selected TRV with Health Canada assumptions (Health Canada, 2010c, section 5.5 and Appendix B);
- consideration of bioavailability in the applied TRVs;
- applicable toxicity endpoint for the established TRV;
- other known toxicity endpoints;
- uncertainty of the selected TRV including limitations in research used to derive the TRV; and,
- uncertainty associated with selecting between multiple TRVs.

TRVs from other published regulatory sources or peer-reviewed scientific literature can be applied if values are not available from the recommended primary or secondary sources. Justification must be provided showing that the applied TRV is consistent with the assumptions and level of protection provided by the recommended sources. TRVs from other jurisdictions may also require adjustments for consistency with Health Canada assumptions. Potential sources for other TRVs are the International Toxicity Estimates for Risk (ITER), Oak Ridge National Laboratory Risk Assessment Information System (RAIS), TOXNET databases, or any other TRVs explicitly recommended by ENV. The following criteria should be used as a basis when selecting a TRV outside of the recommended sources and must be documented in the HHRA:

- there is a comprehensive and contemporary review of toxicity using published studies;
- there is supporting rationale provided for derivation of the TRV from toxicological studies;
- the TRV has undergone scientific peer review; and,
- the TRV is applicable to the applied exposure scenario.

Other factors to consider when selecting a TRV are: dependency on the route of exposure, reversibility of health effects, delayed reactions to exposure, and COPC-specific concerns regarding sensitive human receptor groups.

The risk of adverse health effects may vary depending upon the route of exposure (e.g., inhalation, ingestion, or dermal) as a result of different mechanisms of absorption, metabolism, and elimination. Toxicity through the inhalation and ingestion routes is often considered separately with independent TRVs. If TRVs specific to different exposure routes are available, they should be applied.

Direct application of regulatory guidelines such as ambient air quality objectives or drinking water quality guidelines as TRVs is also possible under certain conditions (see sections 2.3 and 3.8.1); however, it should be ensured that the toxicological basis for the guideline is well understood, documented, and that these limits cannot be used as pollute-up-to levels.

Direct application of occupational exposure limits is not recommended (see section 4.2.1); however, the underlying research or toxicological studies used to derive the occupational limits can be used to support the selection of a TRV.

4.2.1 Alternative TRVs

The absence of a published regulatory TRV is not sufficient for excluding a COPC from further consideration in the HHRA, and the following alternative options are available:

- extrapolation of TRVs between exposure routes using uncertainty factors;
- use of a surrogate chemical with a similar structure that is expected to have a similar mode of toxicity, with the assumption that the most conservative available published TRV for any similar chemical is applicable (see Health Canada, 2010c, Appendix B); or,
- development of *de novo* TRVs based on a critical review of published toxicity studies and Health Canada guidance (see Health Canada, 2010c, Appendix B).

CAUTION

If development of *de novo* TRVs (see section 3.7) is being considered, reviewers should be notified as early in the process as possible. Proponents should be aware that pursuing this option will require significant regulatory review and may necessitate additional review time.

These options should only be undertaken by individuals qualified and experienced in toxicology, and it should be clear if an alternative TRV will be used in the HHRA. Development of *de novo* TRVs should be completed in accordance with Health Canada *Guidance for Development of Toxicological Reference Values (TRVs) for Federal Contaminated Site Risk Assessments, in the Absence of Published Regulatory TRVS* (Health Canada, 2010c, Appendix B).

For COPC(s) where there is evidence of a potential health risk but insufficient information for all of the above options for an alternative TRV, a qualitative discussion on the existing literature should be provided.

4.2.2 Exposure route considerations

In general, use of exposure route-specific TRVs is recommended; however, it is acknowledged that availability of TRVs will be limited in most cases and extrapolation between exposure routes may be necessary. Dermal or inhalation TRVs should not be directly estimated from oral TRVs using bioavailability factors, as toxicity can vary by mode of uptake. Instead, dermal or inhalation exposure should be adjusted relative to oral bioavailability. The overall effect is the same but adjusting the TRV directly implies that the toxicity of that pathway is being directly evaluated. Any extrapolation of this nature should note that COPCs may have different toxicity endpoints based on exposure routes and that this is a major source of uncertainty.

For COPCs where separate TRVs are available for exposure pathways, the exposure dose should be determined separately. If a single TRV is extrapolated to other exposure routes, exposure from all the applicable routes should be summed.

4.3 Chemical mixtures

A chemical mixture is any combination of two or more COPCs, regardless of source, that can influence the risk of chemical toxicity in human receptors. When considering exposure to multiple COPCs, there is potential for interactions between their effects. Possible interactions include:

- additivity (combined effect is equal to the sum of individual effects);
- antagonism (one effect blocks or reduces another);
- synergism (combined effect is greater than the sum of individual effects); and,
- potentiation (a non-toxic chemical increases the effect of a COPC).

All COPCs must be evaluated for potential chemical interactions with each other and with substances reasonably expected to be present in the environment either naturally or from human activity. In some cases, interactions are included in regulatory exposure limits (e.g., carcinogenic PAHs, dioxins/furans); however, interactions between chemical mixtures are not commonly defined in published TRVs. Sources for detailed information on toxic effects from chemical mixtures include Health Canada (2010c), CCME (2010), and ATSDR (2018). Alternatively, studies on health effects from releases of similar chemical mixtures can be provided as supporting evidence. It is recommended that assessment of chemical mixtures utilize the following assumptions, unless it can be specifically demonstrated otherwise:

- all COPCs with the same toxicity endpoint must be assessed as a group (see below);
- all COPCs within a group are assumed to have additive interactions; and,
- COPCs may be represented within multiple groups, with different TRVs for different endpoints, all of which must be assessed.

The following options, listed by increasing complexity, are recommended for determining if COPCs must be assessed as a group:

- **Less complex/more conservative** – all COPCs with similar toxicity endpoints are grouped together (e.g., carcinogenic, acute inhalation toxicity);
- **Moderately complex and conservative** – all COPCs which affect the same organ or organ system are grouped together (e.g., kidneys, cardiovascular system); or,
- **Highly complex/less conservative** – only COPCs which have similar mechanisms of toxicity and/or modes of action, or which have a well understood relationships are grouped together (e.g., inhibit a specific enzyme, inflammation of a specific organ tissue).

Selection of the appropriate option will be based on the COPC-specific information available and the level of toxicological expertise available to the risk assessor. While the options increase in complexity and more accurately reflect the potential for additivity, the more simplistic approaches may be sufficient to demonstrate that target risk levels will not be exceeded. Regardless of the option selected, discussion on the rationale used for grouping COPCs into mixtures must be provided.

If other interactions (antagonism, synergism, or potentiation) are identified, adjustments to predicted risks can be made using professional judgement; however, this will require scientific justification from a professional qualified in toxicological assessment or published sources. Interactions which reduce

toxicity (e.g., antagonistic) should include results with and without subtractive interaction and a discussion of uncertainty.

4.3.1 Additivity

Additivity is the recommended method for assessing the toxicity of chemical mixtures when no information on the nature of chemical interaction is available (Health Canada, 2010c); however, evaluation of the most current toxicity information for the applicable COPCs should be considered before assuming COPCs have additive interactions. Additivity can be assessed using either dose addition or response addition.

Dose addition scales the exposure doses of each COPC in the mixture by their relative potency, modifying the predicted dose for each COPC in the group to an 'equivalent' dose. The overall risk is therefore based on the combined equivalent exposure doses. Dose addition should be used if the COPCs in the mixture have similar mechanisms of toxicity, as it assumes that all COPCs have similar uptake, toxicokinetic, and toxicodynamic processes. Dose addition is usually only relevant for chemicals with similar molecular structures.

Response addition determines risks individually for each COPC in the mixture and then adds the individual risks together. Response addition should be used in cases where COPCs have the same toxicity endpoint but may have different modes of action or independent effects, or if the toxicity endpoint is reproductive toxicity.

Response addition should be applied by default, unless it can be demonstrated that the conditions for dose additivity are met, or if toxicity/potency equivalency factors are available from Health Canada (2012). If COPCs have response-additive toxicity, their individual hazard quotients (HQs) should be added and presented as a hazard index (see section 5.1.1). For COPCs where dose addition is applicable and toxicity or potency equivalence factors are available from a regulatory agency (e.g., PCBs and PAHs), a total equivalent dose can be presented.

Carcinogenic COPCs should be assumed to be additive if they affect the same target organ or if they may cause the same form of cancer.

4.3.2 Toxicity endpoints

Health effects should be classified into the following toxicity endpoint categories based on the nature of the potential health effect:

- organ-specific (with separate additivity for individual organs);
- respiratory;
- cardiovascular;
- neurological and/or behavioural;
- reproductive and/or developmental;
- immunological; and,
- carcinogenic (with separate additivity for individual cancer types).

A qualified toxicologist should be involved in this evaluation, and additional toxicity endpoints may need to be added based on the results of the Toxicity Assessment as the above list is not exhaustive.

4.4 Consistency with Exposure Assessment

The Toxicity Assessment should be conducted in parallel to the Exposure Assessment, and TRVs must be appropriate to the exposure scenario. Details of the applied exposure scenario can affect the selection requirements of TRVs, and the modes of toxicity can affect how exposure doses are calculated. TRVs should be consistent with the expected exposure patterns of the human receptors. While the availability of TRVs may inform what exposure durations can be considered in the Exposure Assessment, the lack of a suitable TRV does not mean a scenario can be excluded from consideration.

The following aspects from the Exposure Assessment must be considered when selecting TRVs:

- is the exposure duration under which the TRV was derived consistent with the applied exposure scenario (e.g., do not apply acute TRVs to chronic exposure scenarios);
- is the TRV protective of sensitive populations (e.g., do not apply occupational health limits to the general population); and,
- is the TRV applicable to the exposure pathway (e.g., do not apply inhalation TRVs to dermal exposure).

If possible, TRVs should be based on similar exposure patterns as the applied exposure scenario. Application of a TRV originally developed for a different exposure duration or exposure pattern can introduce significant uncertainty. Use of exposure amortization (see section 3.3.5) should only be applied if the following information regarding the TRV is available and has been considered:

- mode of action (health effects are driven by concentration, time-integrated exposure dose, or both);
- duration of health effects and their reversibility;
- whole-body elimination half-life of the COPC and any active metabolites; and,
- potential for developmental health effects.

If the above information is not available for the TRV, exposure amortization should not be undertaken. In cases where extrapolation was made between the intended and applied use of TRVs, rationale and justification for the extrapolation must be provided.

4.4.1 Less-than lifetime exposure

For threshold COPCs, the period of contact with environmental media is the relevant duration, and for non-threshold carcinogenic COPCs lifetime exposure is applicable. These classifications are consistent with Health Canada (2010c) guidance, but may not be consistent with other organizations, such as the US EPA. It should be noted that the TRVs recommended by Health Canada (2010a) have primarily been derived and intended for assessment of chronic exposure. TRVs for acute or subchronic exposure durations should be obtained from other regulatory agencies or modified from Health Canada TRVs after evaluating their basis. Consideration of additional acute durations (e.g., 10-minute, 1-hour, 8-hour, 24-hour) may be necessary for evaluation of inhalation exposure to airborne COPCs.

The following must be considered when assessing toxicity for less-than-lifetime exposures:

- acute and subchronic TRVs should be based on a time period that is at least as long as the expected exposure duration, if acute or subchronic TRVs are not available then chronic TRVs can be applied instead;
- if longer duration TRVs are applied then any exposure amortization should not extend beyond the exposure period (e.g., do not average exposure for a week over a year);
- the use of uncertainty-factors to convert from acute or subchronic to chronic TRVs should be evaluated on a COPC-specific basis with documented justification;
- COPCs may have alternate modes of toxicity under acute or subchronic exposure scenarios, such as carcinogens with acute threshold health effects; and,
- an exposure term of 1.0 should automatically be applied for developmental effects.

The following toxicological information is also relevant for less than lifetime exposure:

- reversibility of health effects;
- sensitivity of specific life stages; and,
- whole-body elimination half-life.

It should be ensured that TRVs applied for repeated intermittent short duration exposures are not based on toxicity studies using single-exposure events. For COPCs that accumulate in the body, have long metabolic half-lives, or have long-lasting health effects, the applied TRV should be based on repeated intermittent short-term exposure, or based on chronic exposure using the highest daily exposure rate. However, if health effects can be shown to be reversible or the COPC is completely removed from the body between exposures (as defined in section 3.3.5), then each exposure period may be treated as a separate acute exposure event.

4.4.2 Vulnerable populations

Children, pregnant women, seniors, persons in poor health, and consumers of country foods (Health Canada, 2010c), or other groups may be more vulnerable to health risks associated with exposure to COPCs either through increased exposure or chemical sensitivities. Increased rates of exposure should be incorporated into selection of human receptors and human receptor characteristics to reflect a reasonably maximally exposed individual, including socio-economic conditions. Chemical sensitivities are typically incorporated into published TRVs through uncertainty factors; however, supporting documentation should be reviewed to make sure the applied TRV does consider the sensitive populations expected to be present in the Study Area, and information on the population of concern should be reviewed to determine if there are any special considerations that need to be included.

4.5 Non-toxicological endpoints

COPCs may have aesthetic or operational impacts that are not directly related to adverse health effects but may affect the quality of life and well-being of affected populations. Aside from aesthetic or operational drinking water quality guidelines (ENV, 2020a), the quantitative assessment of these

impacts is often not feasible; however, a qualitative discussion of these impacts and their implications should be included (see section 1.3).

Aesthetic or other non-toxicological impacts which reduce perceived quality of the environment and may impact human health include but are not limited to: undesirable odours in air, and changes to the taste or appearance of water. Other effects, such as noise, light pollution, and loss or impairment of traditional activities should be assessed as part of a social impact assessment and fall outside the scope of a traditional HHRA.

It is recommended that the methodology provided by Health Canada (2017b) be followed for the assessment of noise.

4.6 Indirect health risks

Some chemical releases do not pose direct risks to human health, but increased concentrations in the environment can create health hazards. For example, releases of nutrients like nitrogen or phosphorus to surface water can result in toxic algal blooms. These indirect impacts must still be evaluated but assessment through other disciplines (such as biological or ecological assessment) is generally more appropriate than HHRA. However, when discussing overall health risks from chemical releases and requirements for monitoring, mitigation and/or management of indirect health risks should still be included.

5. RISK CHARACTERIZATION

Risk Characterization involves integrating the results of the Exposure and Toxicity Assessments to provide a numerical estimate of potential health risks. The results of the Risk Characterization are not predictions of health outcomes for individuals, and instead represent whether an established safe or acceptable level of exposure (a target level) has been exceeded for a hypothetical human receptor.

Risk Characterization builds on all the previous stages of the HHRA and it is expected that during the process of completing the HHRA, initial results may necessitate revision or refinement of earlier stages. These iterations may only be necessary for select COPCs, but could be done for any of the following reasons:

- to address significant data gaps and uncertainties;
- to add consideration of risk management or mitigation solutions into the project design or implementation; or,
- to refine the CSM, Exposure or Toxicity Assessment assumptions with more accurate information when unacceptable levels of hazard or risk are predicted.

Exceedances of target levels are normally a trigger to further evaluate a COPC or a chemical mixture, either through a more complex assessment, collection of additional data to reduce uncertainty in baseline or modelling inputs, or use of locally validated data rather than generic assumptions or models. Target levels should not be considered as a strict boundary separating harm and safety. Exceeding target levels for threshold substances based on initial assumptions does not necessarily indicate the potential

for harm, and meeting target levels for non-threshold substances does not necessarily guarantee that exposure is acceptable.

While the incremental change in risk between Base case and the Application case is often the focus of the evaluation of the overall risk to human health, the assessment of the Base case and the Project Only case provides context on the relative risk contribution from each case and helps inform regulatory decision-making.

5.1 Numerical risk estimation

Risk estimates should be calculated for each COPC, over all relevant exposure pathways, for all relevant exposure durations, for all potential human receptors, and at all identified critical human receptor locations. Numerical risk estimation typically separates threshold and non-threshold COPCs as they involve different assumptions.

Complete risk estimation results can produce a significant amount of data. While complete results must be provided, it is expected that only key results will be presented in the main body of the report. It is recommended that a description of the risk assessors' quality assurance or quality control process is included along with worked sample calculations for threshold and non-threshold risk estimates.

Caution
If the HHRA relies on risk controls to remain in place for risk estimates to be valid, these must be documented and presented as part of a risk management plan (see section 7.4).

5.1.1 Threshold COPCs

For threshold COPCs risk estimates are calculated as an HQ, also known as an exposure ratio or a hazard ratio, and are calculated as the ratio of estimated exposure to the TRV:

$$Hazard\ Quotient = \frac{Exposure\ (mg/kg\ bw/d)}{TRV\ (mg/kg\ bw/d)}$$

For exposure through inhalation an HQ can also be calculated as:

$$Hazard\ Quotient = \frac{Amortized\ Air\ Concentration\ (mg/m^3)}{Tolerable\ Air\ Concentration\ (mg/m^3)}$$

(see section 3.3.4 for discussion on exposure amortization).

HQs should be calculated and presented for each COPC by individual exposure routes (dermal, ingestion, and inhalation). For all exposure routes applying the same TRV, the exposure must be summed, resulting in a total hazard index (HI):

$$Hazard\ Index = \sum_i Hazard\ Quotient_i$$

An HI of 1.0 is considered the target level (see section 5.2.5) when baseline exposure (see section 3.2.1) is explicitly considered in the Exposure Assessment and all sources of exposure are evaluated. All predicted HIs greater than 1.0 are considered to represent potential health effects and must have a residual effects assessment if there is contribution of the project to the HI (section 7.1). If a COPC has different TRVs depending on the exposure route, those exposures can be assessed independently against a HI of 1.0. Individual HQs do not need to be compared to a target value and cannot be excluded from the HI calculation. See section 5.2.5 for circumstances when all sources of exposure cannot be assessed.

Exposure or risk should not assume predetermined allocations of exposure between environmental media, typically done using an HQ or HI of 0.2 per exposure media (soil/sediment, surface/groundwater, air, food, consumer products) in HHRA for contaminated sites. The proportion of risk contributed by each media should be identified on an independent basis to inform risk management decisions.

If combined exposure from multiple exposure pathways or exposure routes is calculated, the predicted exposure and HQ for individual exposure pathways or exposure routes should be presented for clarity and to aid in development of risk mitigation or management options. Exposure or risk from multiple pathways must only be summed if they occur simultaneously and for the same human receptor.

CAUTION

Adverse health effects from threshold chemicals can still occur when target levels are exceeded for durations less than a lifetime. Therefore, HIs for threshold COPCs should not be averaged over a lifetime or include any averaging or weighting between life stages or durations of exposure. All age groups must be considered individually and HQs for each age group should be presented. It should be verified that the applied TRV is consistent with the exposure scenario being evaluated.

5.1.2 Non-threshold carcinogenic COPCs

For carcinogenic COPCs, a potential incremental lifetime cancer risk (ILCR) is calculated as the product of estimated exposure (amortized as appropriate) and a cancer slope factor. Non-threshold COPCs with non-cancer endpoints are discussed in section 5.1.3. ILCR is additional to any existing risks from baseline exposure; therefore, inclusion of exposure from the Project Only case for non-threshold carcinogenic COPCs is considered appropriate. Base case and/or Planned Development case ILCRs, however, should be provided as necessary for context (see section 7.1.1), as they inform decision-making, planning, and management that often goes beyond individual projects.

Estimates of non-threshold cancer risk are based on lifetime exposure and therefore can be averaged or weighted across life stages using age-dependent adjustment factors (table 1). The following formula, adopted from Health Canada (2016g) represents a composite lifetime human receptor and is recommended for oral exposure to all non-mutagenic carcinogens:

$$ILCR = \sum_{i} (LADD_i \times SF)$$

where: ILCR = incremental lifetime cancer risk
$LADD_i$ = lifetime average daily dose; dose received during life stage i averaged over a lifetime (mg/kg bw/d)
SF = cancer slope factor $(mg/kg\ bw/d)^{-1}$

And the following for inhalation exposure:

$$ILCR = \sum_i (C_{ai} \times TR_i \times UR)$$

where: ILCR = incremental lifetime cancer risk
C_{ai} = concentration in air during life stage i (mg/m^3)
TR_i = fraction of time exposed (year/80 year)
UR = adult cancer unit risk $(mg/m^3)^{-1}$

The additional application of age-dependent adjustment factors (ADAFs) is required for mutagenic carcinogens:

$$\mathrm{ILCR} = \sum_i (\mathrm{LADD_i} \times \mathrm{SF_i}) \text{ or } \sum_i (\mathrm{LADD_i} \times \mathrm{SF} \times \mathrm{ADAF_i})$$

where: ILCR = incremental lifetime cancer risk
$LADD_i$ = dose received during life stage i averaged over a lifetime (mg/kg bw/d)
SF_i = age-specific slope factor $(mg/kg\ bw/d)^{-1}$
SF = adult cancer slope factor $(mg/kg\ bw/d)^{-1}$
$ADAF_i$ = age-dependent adjustment factors for life stage i (see table 1)

Or as follows for inhalation exposure to mutagenic carcinogens:

$$\mathrm{ILCR} = \sum_i (\mathrm{C_{ai}} \times \mathrm{TR_i} \times \mathrm{UR} \times \mathrm{ADAF_i})$$

where: ILCR = incremental lifetime cancer risk
C_{ai} = concentration in air during life stage i (mg/m^3)
TR_i = fraction of time exposed (year/80 year)
UR = adult cancer unit risk $(mg/m^3)^{-1}$
$ADAF_i$ = age-dependent adjustment factors for life stage i (see table 1)

If the predicted exposure is based on less-than-lifetime exposure, example calculations are provided in section 4.0 of Health Canada (2013) *Interim Guidance on Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites.*

CAUTION

Carcinogenic COPCs may have a toxicological threshold for health effects. Any carcinogenic COPC with a threshold for health effects should be treated as a threshold COPC and assessed based on section 5.1.1.

ILCRs for each exposure route should be summed, unless exposure route-specific SFs or URs have been applied, in which case risks via each exposure route should be evaluated separately. It is recommended that even if exposure from different routes are combined, the predicted exposure and ILCR for individual exposure pathways or exposure routes be presented to aid in development of risk mitigation or management options. Exposure or risk from multiple pathways must only be summed if they occur simultaneously for the same human receptor.

For non-threshold COPCs there is no level of exposure that has zero risk. An ILCR of 1 in 100,000 ($1x10^{-5}$) is considered an essentially negligible level of risk for carcinogenic non-threshold COPCs and the target level. All predicted ILCRs greater than $1x10^{-5}$ must have a residual effects assessment (section 7.1).

CAUTION
Non-threshold risks can be overestimated at low doses. If unacceptable risks are predicted, then further evaluation of the dose-response relationship is available as an option.

5.1.3 Non-threshold non-carcinogenic COPCs

As discussed in section 4.1.3, any chemical which does not have a toxicologically defined acceptable level of exposure (e.g., a threshold below which exposure poses no health risk) and for which the target ILCR of $1x10^{-5}$ does not apply, any measurable increase in environmental concentrations (as defined in section 2.3) due to the project could potentially pose a risk to human health. This increased risk to human health cannot be considered acceptable or negligible without including a discussion on the potential health outcomes in the Risk Characterization section of the HHRA, and completion of a residual effects assessment (section 7.1). The Risk Characterization discussion should describe potential health effects for individuals and communities at the predicted levels of exposure. This could involve a discussion of specific health outcomes (symptoms, morbidity, mortality), their increased prevalence or severity in the population (based on toxicological, clinical, and epidemiological evidence), and a comparison to current conditions. Unlike carcinogens, consideration of sensitive life stages and less-than-lifetime exposure may also be necessary for non-carcinogenic non-threshold COPCs.

Existing standards or objectives, such as ambient air quality objectives, can still be included in this discussion for context, but the focus should be on established toxicological or epidemiological endpoints.

5.1.4 Chemical mixtures

For any COPCs identified in the Toxicity Assessment as having the same target organs, effects, or mechanisms of action, risks should be summed (see details in section 4.3) unless justification for an alternative is provided. Summed numerical risk estimates for threshold COPCs are still compared to a target HI of 1.0 when all sources of exposure are included, and non-threshold carcinogens are still compared to a maximum 1 in 100,000 ($1x10^{-5}$) ILCR.

All COPCs with the same toxicity endpoint (see section 4.3.2) must be included in the mixture, regardless of their individual contribution to overall risk. COPCs which have the potential to contribute to a chemical mixture should not be screened out at earlier stages of the HHRA.

5.1.5 Presentation of numerical results

A summary of HIs and ILCRs that exceed target levels should be presented in the main text, along with results for all non-carcinogenic non-threshold COPCs, as they are assumed to have potential residual effects and require a residual effects assessment. Any COPC where the increase in exposure from the project is greater than 10% of Base case exposure and 20% of the applied TRV also requires a residual effects assessment (see section 7.1.1) and should be included in the key results summary as well.

A complete list of HIs and ILCRs must also be included for all evaluated cases, COPCs, exposure scenarios, age groups, and critical human receptor locations. Ideally HIs and ILCR should also be broken down based on exposure route (using the individual HQs) or exposure pathway for any COPC exceeding target HIs or ILCRs. This is recommended so that the key factors contributing to predicted risks can be easily identified and incorporated into risk communication and management strategies.

Each assessment case (i.e., Base case, Project Only case, Application case, Planned Development case) provides useful information for evaluating changes in risk to human health and the relative risk contribution from each case. This evaluation of overall risk to human health is necessary to understand how the project and baseline conditions could impact human health.

Depending on the complexity of the HHRA, it may not be feasible or clear to present all the numerical risk estimates within the main body of the HHRA. If necessary, complete results can be included separately as an appendix, with the following key results included within the main body of the HHRA:

- the largest predicted HQ or ILCR for the Base, Project Only, Application, and Planned Development cases for all COPCs and COPC mixtures for any location, exposure scenario, or human receptor;
- a summary of all cases where the target HI or maximum ILCR were exceeded; and,
- results for all non-carcinogenic non-threshold COPCs.

It should also be clearly stated what risk management or mitigation measures have been considered in the numerical results. Risk estimates without any approved or planned risk management plan must be presented, unless those risk management measures are built into the project design or required as conditions of project approval. Presentation of separate numerical estimates with and without proposed management/mitigation measures is recommended for clarity.

A completed sample calculation should also be provided, starting from measured or predicted environmental media concentrations and continuing through to a predicted HQ or ILCR value. Calculations should be transparent and reproducible using only information provided in the HHRA report. Estimates of hazard or risk should be presented to a maximum of two significant figures, in order to be consistent with the expected level of certainty in the HHRA process.

PRESENTATION

It is strongly recommended that concentration isopleths of the Study Area for all assessment cases be presented for predicted concentrations of COPCs in air, on a figure which also includes all evaluated human receptor locations. Even though air quality criteria may not be exceeded, several COPCs in air are non-threshold (e.g., $PM_{2.5}$, PM_{10}, NO_2, ozone) and isopleths provide information on the spatial extent of predicted environmental concentrations which could potentially cause negative health effects.

5.2 Special cases

5.2.1 Aesthetic and operational objectives

Many COPCs do not have TRVs based on health outcomes but do have aesthetic objectives based on changes to taste, odour, or appearance of environmental media and operational objectives for interference or impairment of a treatment process/technology or adversely affect infrastructure (Health Canada, 2019b). While a quantitative calculation of health effects from these endpoints may not be possible, it is expected that a qualitative discussion of project impacts on quality of life for the affected human populations and impacts on the water treatment system be included for all COPCs with existing aesthetic and operational objectives. If published regulatory objectives are available for aesthetic and operational endpoints, these should be included for comparison and discussed and recognized that aesthetic and operational objectives may also have indirect health endpoints.

5.2.2 Base case exposure exceeds the TRV

Special attention should be given to any situations where Base case exposure is great enough that health effects are predicted before consideration of the project releases. This situation can arise in areas of heavy industrial development, naturally elevated background levels, or if predicted Base case risks are overestimated due to conservative assumptions. Addressing the health risks from exposure to Base case conditions is not the responsibility of the project proponent or risk assessor; however, any increase in risk due to the project is. When health risks are predicted from Base case exposure any measurable increase in environmental concentrations (as defined in section 2.3) due to the project has the potential for an increase in adverse human health outcomes and will require a residual effects assessment as outlined in section 7.1.

Recognizing that the predicted risks are pre-existing and that the project is contributing to an existing risk, the following options for discussion or more complex analysis are provided as examples:

- what are the causes of the high Base case exposure (specific exposure pathways, previous industrial development vs. natural occurring conditions, community or cultural practices);
- what uncertainty and variability are associated with Base case exposure;
- what uncertainty and variability are associated with the TRV;
- if the COPC is an essential element, what is the ideal exposure range, represented as the difference between the recommended daily intake and the tolerable (toxic) daily intake, compared to the uncertainty in exposure estimates;
- refinements to the Exposure Assessment (such as pathway-specific bioavailability, differentiation of multiple chemical forms, more realistic exposure characteristics);

- additional sampling to refine the Base case and Project Only case exposure estimates, with focus on exposure pathways most likely to be impacted by the project; and,
- presentation of a probabilistic evaluation of Base case exposure, with a discussion of the predicted increase in the proportion of the population with predicted health effects. Applied probabilistic risk assessment methodology should be consistent with recommendations from section 7.0 of Health Canada (2010c) *Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA$_{Chem}$)*.

Risk estimates must still be protective of sensitive individuals and cannot be based solely on the general population. Any assumptions regarding use of statistical values or probability distributions should account for this and still be based on characteristics representative of a reasonable worst-case exposure scenario. Other factors, such as changes to bioaccumulation potential, may also have to be considered on a COPC-specific basis.

If results of the Base case assessment indicate the potential for health effects due to baseline exposure, the risk assessor should directly notify regional health authorities and share their conclusions.

5.2.3 All sources of exposure cannot be assessed

An HI of 1.0 should be applied when assessing all major known sources of potential exposure and when all reasonable pathways of exposure are properly accounted for in the HHRA, including baseline dietary intake. If all major sources cannot be assessed, then justification should be provided for why that assessment is not possible or not necessary. If it is agreed by the proponent, decision-maker and technical reviewers that assessment of a source of exposure is not possible for technical, logistical, or other considerations outside of the control of the proponent, the following options are available:

- assessment using only modelled or predicted data, or data from similar projects;
- application of a target HI of 0.2 for the total exposure from all assessed exposure pathways, along with a qualitative evaluation of why the remaining unassessed pathways are not significant (e.g., total HI with unassessed sources will be less than 1.0);
- development of a target HI based on likelihood and expected magnitude of exposure from the unassessed sources or exposure pathways; and,
- expression of human health risks as the percentage of the TRV that is taken up by the estimated exposure, with discussion of significance and expected health outcomes.

6. EVALUATION OF UNCERTAINTY AND VARIABILITY

A key difference between HHRAs for contaminated sites and prospective HHRA is that prospective HHRAs lack measured data regarding future COPC concentrations and relies on predictive modelling. Prospective HHRAs may also be used for planning and large-scale decision-making purposes that can have effects well beyond the project boundaries. These factors mean that prospective HHRAs require a more detailed consideration of uncertainty and variability compared to HHRAs for contaminated sites.

A discussion of uncertainty and variability is necessary to properly interpret the results of the HHRA. Uncertainty refers to the imperfections and gaps in knowledge, in both individual data inputs and in the

models used in the HHRA. Variability refers to natural variations and differences in the applied parameters and models. The evaluation of uncertainty and variability serves to increase the transparency and credibility of the HHRA, and should include considerations from all stages of the HHRA as well as baseline data collection activities and results from outside information sources. The level of detail in the Evaluation of Uncertainty and Variability should be commensurate with the scope and complexity of the HHRA.

Data or methods with high degrees of uncertainty or variability can still be appropriate if they are clearly explained and documented, allowing the reader to evaluate the choices and trade-offs made by the risk assessor. A discussion of required elements for uncertainty and sensitivity analyses is included in section 6.4.3 of Health Canada (2010c) *Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals*.

The HHRA should clearly discuss the uncertainty and variability of the following information and any additional critical aspects of the project and Study Area:

- project design;
- release of COPCs;
- determining physical, chemical, and ecological characteristics of the Study Area;
- defining characteristics of human receptors and populations in the Study Area;
- application of statistical methods;
- definition of the exposure scenarios, including worker-residents;
- selection and application of fate and transport models, including all inputs and assumptions;
- selection and application of exposure models, including all inputs and assumptions;
- evaluating the toxicity, selection, and interactions between COPCs and the selection of TRVs; and,
- availability and application of TK or other stakeholder inputs.

It is recommended that some form of sensitivity analysis be included in this evaluation. Sensitivity analysis can be either a qualitative or quantitative evaluation to determine what the largest sources of uncertainty are, and should include a discussion of how these uncertainties have affected assumptions and the resulting risk estimates. A quantitative sensitivity analysis is strongly recommended for all aspects of the HHRA where the applied assumptions or methodology differ from the recommended approach in this guidance document.

A sensitivity analysis can increase the level of confidence in the HHRA if it can be shown that changes in highly uncertain or variable parameters only have a minor influence on risk estimates. Conversely, the sensitivity analysis can identify parameters that influence results the most and indicate where additional data collection should be targeted.

The uncertainty in HHRA conclusions must be clearly communicated to avoid misconceptions regarding the accuracy and confidence of the HHRA. This includes the appropriate use of significant figures for numerical risk estimates and a discussion of the limitations of any mathematical models used. A large amount of uncertainty is not necessarily indicative that the HHRA is unacceptable, as less complex

HHRAs may determine there to be minimal risk by using highly conservative (but still uncertain) assumptions that would provide an equivalent level of health protection. However, an overly conservative HHRA may lead to incorrect prioritization of risk management activities or unintended consequences in community behaviour.

Summaries of any internal or peer review processes used to validate the conclusions of the HHRA should also be included here.

7. RISK COMMUNICATION AND MANAGEMENT

Previous elements of the HHRA have derived numerical risk estimates, but the overall focus of the HHRA should be on interpretation and communication of these results and providing relevant context. A common language summary of key results must be provided that is comprehensive, understandable, and relevant to the needs of end-users. Numerical descriptions of risks alone are not considered sufficient to communicate the results of an HHRA, and specific communication strategies will likely be needed for the general public, potentially affected communities, and Indigenous groups and peoples. Risk Communication should also be cognizant of the way stakeholders will perceive predicted risks and what they will consider to be acceptable. It is recognized that this information could be presented within the HHRA itself, or as part of the health effects assessment chapter of the EA.

The following elements should be included as part of Risk Communication:

- confirmation that the concerns raised in the Problem Formulation have been answered;
- context and interpretation for the numerical risk estimates;
- potential adverse effects of the project and what populations are at risk;
- identification of the largest sources of exposure and risk;
- prioritized list of proposed risk management or mitigation strategies to remove or reduce health effects; and,
- discussion of the assumptions made regarding project operation within the HHRA.

A discussion of uncertainty, data gaps, and the limitations of the risk estimates (see section 6.0) is also necessary in order to avoid any misconceptions regarding the accuracy and confidence of the HHRA.

7.1 Residual effects assessment

All COPCs and chemical mixtures with an HI or ILCR greater than target levels and all non-carcinogenic non-threshold COPCs where a measurable increase in COPC concentration was predicted require a residual effects assessment as described below. For HHRAs completed as part of an EA, this can be included in the Effects Assessment chapter of the EA in accordance with EAO (2020b) Effects Assessment Guidance; however, the list of COPCs requiring a residual effects assessment must be provided in the HHRA.

Where predicted risks are less than target levels, a residual effects assessment may still be required (see section 7.1.1). If applicable, corresponding risk mitigation or monitoring measures should also be discussed.

The residual effects assessment must use unambiguous statements and qualitative terminology whenever possible. When a project requires an EA, it should follow EA guidance regarding the characterization of residual effects. All the following criteria, adapted from the B.C. EAO (2020c), must be included. Each criterion must include a discussion of all listed elements:

- *Context* – The current and future sensitivity and resilience of human receptors to changes in exposure caused by the project, considering the cumulative effects of other projects and activities in the Study Area and distribution of existing and potential health effects amongst the population. The following information must be included:
    - epidemiological evidence or baseline community health studies that can provide context on human receptor sensitivity and resilience; and,
    - identification of individuals or populations that could be disproportionally affected.
- *Magnitude* – The predicted increase in health risks due to Project activities and their potential severity. The following information must be included:
    - the change to HI and/or ILCR due to the Project Only and Application cases in numerical terms as both the absolute and relative change in risk from Base case; and,
    - the toxicological endpoints associated with these COPCs.

  While the severity of specific health or clinical outcomes cannot be reliably predicted by HHRA at the individual or population level, comparison of predicted concentrations to health effects observed in epidemiological or other scientific research is recommended where possible.
- *Extent* – The spatial extent of the potential health effects, and their distribution within the population. Inclusion of COPC concentration isopleths or other figures is strongly recommended. The following information must be included:
    - the spatial extent of predicted environmental concentrations which could potentially cause negative health effects;
    - the presence of human receptors and vulnerable populations in that spatial extent; and,
    - current and future activities in that spatial extent.
- *Duration and reversibility* – The duration of potential health effects. Potential health effects are assumed to occur throughout any period where predicted exposure exceeds the applied TRV at an individual human receptor location; effects may develop or persist after exposure ceases. The onset and duration of potential health effects should be based on evidence provided in the Toxicity Assessment. Increased cancer risk greater than target levels and toxicity endpoints based on total lifetime exposure are considered permanent health effects. The following information must be included:
    - whether the potential health effects are permanent or reversible; and,
    - if potential health effects are reversible, the expected duration of these effects, including effects that may persist after exposure has ceased.
- *Frequency* – How often conditions resulting in potential health effects will occur and the operational and environmental conditions under which they are predicted. COPCs included in a multimedia Exposure Assessment are generally assumed to result in continuous exposure. The following information must be included:

  - whether conditions predicted to result in potential health effects are expected to occur continuously or as discrete events;
  - predicted frequency of recurrent environmental conditions that could result in potential health effects;
    - conditions that may reoccur before potential health effects can reverse should be considered continuous; and,
  - other patterns in event frequency (seasonality).
- *Affected populations* – Consideration of potentially affected Indigenous groups and peoples, stakeholders, and the public, as well as any concerns raised by local groups and or other organizations. The following information must be included:
  - concern regarding potential health effects expressed publicly or privately by parties other than the regulatory authority or proponent (these should be specified);
  - potential for the project to disproportionately affect individuals based on gender or other identify factors (based on GBA+);
  - potential for the project to adversely affect the province's ability to meet its responsibilities or commitments on the protection of the environmental and/or human health; and,
  - Indigenous rights and interests in the study area, as well as any commitments and responsibilities to Indigenous groups and peoples.
- *Mitigation* (optional) – Any methods or best practices which have already been adopted to minimize releases or predicted health effects as low as reasonably achievable can also be included for context. The following information may be presented:
  - Mitigation or risk management measures;
  - how proposed mitigation or risk management measures eliminate potential health effects; and,
  - adoption of best available technologies and practices to reduce human exposure as much as possible.

Stating that applied assumptions in the HHRA are conservative is not considered sufficient justification for concluding that human health effects are unlikely or acceptable. Any such statements must be supported by the following:

- the specific parameters or methods considered to be overly conservative;
- a sensitivity analysis showing the range of possible values for these parameters and how they have influenced the results of the HHRA;
- reasoning as to why current overly conservative estimates cannot be refined; and,
- details of the monitoring program proposed to verify this conclusion.

Risks between COPC groups generally cannot be compared to each other due to differences in uncertainty in their calculation, and an absolute determination of significance is not required. Residual effects assessment between COPCs should be discussed in the context of the relative potential change to overall health of the impacted population(s). Any assumptions used in this discussion should be

consistent with the rest of the HHRA and should not rely on inherent assumptions of conservativeness in other elements to explain exceedances of target levels.

RESIDUAL EFFECTS IN ENVIRONMENTAL ASSESSMENT

As part of the EA process, the EAO will reach its own conclusions regarding the residual effects of a project and whether or not these effects are significant. These conclusions are provided in the EAO's Assessment Report for the project (EAO, 2020c).

7.1.1 Additional criteria for identifying residual effects

Where predicted risks are less than target levels, a discussion is still required for threshold COPCs if the increase in exposure from the project is greater than 10% of Base case exposure and 20% of the applied TRV. The intent of this requirement is to ensure that large changes to baseline conditions which may influence future development decisions are captured, and that unnecessary degradation of the environment is avoided. COPCs which only meet the above criteria do not require a complete residual effects assessment, and their effects assessment can be limited to:

- the contribution (relative and absolute) of the project to the overall pollutant load to the Study Area;
- the potential for other sources of exposure;
- resulting limitations on future development or activities; and,
- indication of what strategies have been adopted to minimize releases or human exposure to COPCs from the project.

The following factors should be considered for COPCs meeting the above criteria:

- whether the COPC(s) are common and expected to be associated with other potential future projects;
- whether there is potential for additional development in the area;
- the level of uncertainty;
- whether mitigation measures or best available technologies have been implemented;
- the overall toxic potency of the COPC;
- the project's contribution to overall exposure;
- the overall changes to environmental media and country foods; and,
- whether the project will reduce risks to human receptors from other health hazards.

For non-threshold COPCs, a discussion of the existing baseline rates of cancer or relevant health outcomes in the general population within the Study Area, based on either baseline conditions or available public health data should be included for completeness, if available.

7.2 Public health considerations

In the EA process, public health considerations are typically assessed in social, economic, and culture/heritage effects assessments. However, if available and relevant, baseline population health status (see section 3.3.2), based on available studies or other data sources, should be described and any implications for the HHRA discussed. The discussion of HI, ILCR, and any other risk estimates should be

in the context of the project's impact on the overall health of the community as well as individual human receptors, specifically the valued components of health identified during consultation and development of the Problem Formulation. The discussion of public health implications should include specific reference to effects on any Indigenous communities and vulnerable human receptors within the Study Area.

Potential health effects should be stated as specific outcomes if possible. While determination of a reliable quantitative estimate of public health implications is not possible using the results of the HHRA, potential impacts should be described in terms of specific measurable endpoints; for example, stating 'deterioration of air quality may result in increased hospital visits due to respiratory effects', as opposed to 'deterioration of air quality may adversely affect health'.

LIMITATIONS OF HHRA

While HHRA is a valuable method for estimating the potential or possibility of adverse human health effects, HHRAs are not epidemiological or clinical health studies and do not measure or predict occurrence of disease in the Study Area. Epidemiological studies use data such as rates of mortality, hospital admissions, and emergency room visits to characterize population health risks. In most cases, however, the detection and measurement of actual changes to human health outcomes in the Study Area is not feasible, particularly for small populations or communities where achieving sufficient statistical power can be a challenge.

7.3 Monitoring considerations

Due to the predictive nature of HHRAs, proposed projects will likely require some degree of ongoing or confirmatory monitoring during the various project phases. Monitoring can determine the accuracy of the HHRA predictions, verify assumptions used in the HHRA, assist with implementing or modifying management or mitigation measures, or address public concerns. The extent of monitoring will depend on the degree of uncertainty in HHRA predictions, project activities, predicted COPC concentrations, and predicted levels of hazard and risk. Monitoring programs may be required as conditions of approval or by default through regulation, depending on the nature of the project and the regulatory approval process.

7.4 Risk mitigation and management

Any project-related exceedance of target levels indicates a potential for adverse health effects, and specific recommendations to address the identified health effects must be provided by the proponent. Exceedance of target levels under Base case and potential health effects should also be noted for context.

Information on mitigation and management measures may be located in documents or components of the approval processes outside of the HHRA (e.g., proposed project design, certified project description, or proponent's commitments). However, cross-referencing to this information should be provided along with a description of the ongoing plan for monitoring and maintenance of the risk control measures. The potential for risk mitigation and management measures to fail (e.g., water treatment failures) is typically considered in the assessment of accidents and malfunctions for the project.

Risk mitigation/management should consider the following hierarchy of preferred options:

1. Prevention – high-risk activities are avoided and reasonable alternatives are identified, including changes to the project design or operations.
2. Mitigation – high-risk activities are modified to avoid, prevent, reduce, or offset significant adverse effects.
3. Adaptive management – high-risk activities proceed but additional actions are taken to reduce risks, with modifications made as necessary over time based on actual project impacts determined from monitoring:
    - source control – risk is reduced through actions preventing releases outside of the project fenceline, or limiting operations during high risk periods;
    - exposure control – actions are taken to prevent completion of exposure pathways, such as physical barriers or changes to the environment; and,
    - human receptor restrictions – limitations are imposed on human receptors within specified areas, such as restrictions on access, land use, or allowable activities.
4. Monitoring – high-risk activities proceed as proposed with monitoring to determine the extent of predicted impacts, including action levels to alter or stop operations if measured concentrations indicate unacceptable risks.
5. Remediation – high-risk activities proceed with no controls, and hazards are removed after project decommissioning.

Risk mitigation and/or management actions should be proportionate to the predicted risks (section 7.1) and revised as additional information, technologies, and best practices become available (i.e., adaptive management). Evaluation of which environmental media are the primary sources of risk from all COPCs can be used to identify areas where mitigation and/or management should be focused. When using risk estimates in this way, the differences in uncertainty and conservatism between exposure pathways must also be considered. Actions or recommendations must take into consideration the assumptions made in the Exposure Assessment, as the exposure pathways with higher degrees of uncertainty or inherent conservatism may inherently predict greater risks. If initial results indicate that target levels of risk could be exceeded, then refinement of the Risk Characterization stage through collection of additional data may be an acceptable alternative to implementing risk management measures. Monitoring programs cannot be used as risk management measures, and refinement of predictions or proactive prevention measures should be undertaken during completion of the HHRA.

It is expected that any risk controls will be developed in collaboration with the potentially affected group. ENV (2013a) provides the expectations regarding the type of information that affected parties should receive including allowing potentially affected parties an opportunity to respond.

Where possible, the potential effects of climate change should be considered where long-term risk mitigation and/or management actions are proposed.

EXPOSURE CONTROL

Any proposed risk management action that requires limitation on access or activities within the Study Area, or relies on any other forms of administrative or exposure controls, requires consultation and

acceptance by all potentially affected groups. Any risk management or exposure control applicable to off-duty workers should also be described.

Use of barriers or exposure control needs to be clearly bounded, and the HHRA must clearly demonstrate that risks are acceptable without control beyond this boundary. For example, an HHRA may make assumptions about limitations to the use of land, thus the boundaries where these assumptions remain in place must be clearly delineated. Conclusions and supporting data on the area beyond where the assumptions no longer apply must also be provided. Additionally, information should be provided in the HHRA on how the exposure and risk controls will be monitored in future and how it will be ensured they remain in place.

Risk management plans should be:

- responsive and specific to the predicted health effects;
- technically feasible and culturally acceptable to implement and enforce;
- have specified timing or a schedule of activities;
- assign all responsibilities and outline capacity requirements to meet commitments; and,
- have associated conditions within the project approval.

It is the general expectation that industry best-practices and best available technology be used to reduce health effects and that focus be placed on minimizing impacts to levels as low as reasonably achievable, under the precautionary principle and with the understanding that there are limits to the science and literature available. Adaptive management should rely on monitoring plans collecting data while the project is operational and modified as necessary over time.

Risk Characterization should account for any changes to the project design or chemical release that reduce human health risks (see section 5.1.5). If administrative or exposure control is proposed, then an ongoing plan for monitoring and maintenance of control measures should also be included. It is acknowledged that conditions of the approval or permit are at the discretion of the statutory decision-maker; therefore, clearly identifying the effect of mitigation or management measures within the HHRA will allow decision-makers to make informed decisions about the inclusion of these measures as conditions for the permit or approval.

INCORPORATING MITIGATION

Mitigation measures may be recommended in other components of the approvals processes outside of the HHRA. Mitigation measures typically focus on operational or institutional measures that can be taken to reduce exposure or remove exposure pathways. As part of the sensitivity analysis the HHRA should consider the potential for mitigation measures to fail and the resulting health implications or risks.

8. ACCIDENTS AND MALFUNCTIONS

Accidental releases include any unplanned or uncontrolled release of COPCS to the environment. These are typically low probability events but can potentially have significant consequences for human health. The risk of health effects from releases of COPCs associated with accidents and malfunctions (accidental releases) must be considered. However, if assessment of accidents and malfunctions is already required in other elements of an EA or project approval (e.g., *Environmental Management Act* permit reviews or the B.C. Oil and Gas Commission Drilling and Production Regulation) a reference to those requirements can be presented instead.

Accident and malfunction assessment should be based on worst-case scenarios for risk to public health. Evaluation of accidental releases should be completed independently of expected COPC releases under normal operating conditions.

CAUTION

Accidental releases **do not** include higher rates of emission or release due to planned changes to operating conditions, such as start-up, shutdown, or maintenance activities, which should be assessed directly in the HHRA as acute events.

While there is an expectation that proponents will adopt best practices for design and safety to prevent accidents and malfunctions and mitigate risks, the evaluation of human health risks cannot be limited to the ideal expected operating conditions. It is recommended that the following elements be included in the evaluation of accidental releases, consistent with methodology for 'failure mode and effects analysis':

- identification of potential accidental releases and their causes;
- evaluation of the probability for the identified causes to occur;
- evaluation of the severity of the effects of accidental releases;
- determination of overall significance; and,
- determining risk mitigations and controls.

8.1 Identification of potential accidental releases

It is not expected that all potential accidental release scenarios be evaluated, and the selection of evaluated scenarios should be based on project design, the risk assessors' knowledge and experience, history of similar projects or technologies, severity of potential health effects, and concerns of affected populations. For each evaluated accidental release scenario, the following elements should be discussed:

- element(s) of the project that could fail or are susceptible to accidents;
- conditions or event(s) that would result in failure;
- COPCs that would be released;
- human receptors and locations that would be affected; and,
- the expected duration, extent, and concentrations of COPCs in exposure media.

Only accidental releases resulting in a complete exposure pathway from the point of release to human receptors, consistent with the CSM, need to be evaluated.

8.2 Probability of accidental releases

The HHRA should include a quantitative evaluation and discussion of the probability of all identified accidental release scenarios. Elements of this discussion that may be present in the project description or elsewhere in the EA, permit, or application can be referenced with key points included in the HHRA. Conditions resulting in accidental release can include, but are not limited to, human error, extreme environmental events, or failure of engineered elements. The evaluation of probability can be based on:

- historical data from similar operations or similar expected conditions;
- information published by regulatory agencies or in peer-reviewed journals;
- management practices and technologies adopted to reduce risk; or,
- experience of the risk assessor with similar projects or technologies.

Probabilities should also account for the proposed safety or control measures to be adopted by the project and be expressed as the probability to occur over the lifetime of the project or the applicable project phase.

8.3 Accidental releases assessment

Accidental releases should be evaluated using similar methodology as the residual effects assessment from section 7.1. An additional consideration of detection should also be included, including a discussion of how each means of accidental release and their causes would be detected, and when the detection of a problem would occur.

The overall significance of accidental releases can then be prioritized based on an equal consideration of the severity of potential outcomes and the probability of failure. It should be demonstrated how human health risks associated with unforeseen events or catastrophic failures have been identified, proactively planned for, and controlled to the extent possible, with focus on the highest priority events.

A discussion of how health risks will be addressed should address the safety measures, controls, or best practices adopted to reduce the probability and/or severity of accidental releases. This discussion should also include references to mitigation, communication/notification, or emergency response plans that will be in place to address accidental releases or other emergencies.

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APPENDIX A: PROSPECTIVE HUMAN HEALTH RISK ASSESSMENT REVIEW CHECKLIST

Section	*Content*	*Yes*	*No*	*Notes*
General				
Background	Scope is clearly stated and appropriate for project size and complexity			
	All phases of project are described and included in scope			
	A professional statement of qualifications has been provided for all key individuals involved in completing the HHRA			
	Stakeholders have been consulted throughout the HHRA process			
Structure	Tables and figures are referred to correctly in the text of the report			
	Results are presented in consistent units of measurement			
	Format enables easy cross referencing between report and original data sources			
	Complexity of the assessment is appropriate based on: nature of project, number of COPCs, availability of data, location and sensitivity of human receptors, and level of public concern			
Statistics	Rationale provided for statistical methods used			
Links to other reports	Linkages to other technical reports are identified			
	External supporting material has been provided			
	Data from investigations or other reports are correctly applied and referenced			
Problem Formulation				
General	Questions to be answered by the HHRA are clearly stated			
	Description of all assumptions and uncertainties provided			
Project characterization	Basic information on the project is provided including: location and spatial footprint, sources of potential health impacts, changes to surrounding environment, timescale for each project phase			
	Chemical inventory is provided and includes all chemicals that may be released			
Study Area characterization	Spatial and temporal boundaries of the Study Area are described and shown with maps/figures, inclusive of construction, operations, closure, and decommissioning phases			
	Includes discussion on use of stakeholder information			
	Physical description of the Study Area is provided			
	Chemical description of the Study Area is provided along with original data			
	Current and potential future human activity in the Study Area is described			
	Existing sources of COPCs are described and are included in the baseline assessment			
	Future sources of COPCs are described and are included in the cumulative effects assessment			
	Current and potential future land uses are identified and considered in the CSM			
Data collection	Sampling program methodology and full results are included for qualitative and quantitative information			
	Data sources are appropriate and applicable to Study Area			
	Analytical data summary is provided with: minimum, maximum, median, average, 95% UCLM, and sample size			
	Qualitative data and TK summary is provided			
	All consultation, laboratory, and field data are provided, with observations, laboratory certificates, and quality control/quality assurance checks included			

COPC screening	COPC list is provided along with a description of the screening methodology used and which COPCs require a multimedia assessment			
	Justification is provided for all chemicals from the chemical inventory not included as COPCs			
	Justification is provided for all COPCs not included in the multimedia assessment			
Human receptor identification	All potential human receptor groups are identified in the Study Area with supporting figures or maps			
	Reasonably maximally exposed individual is included as a human receptor			
	Vulnerable populations, human receptors, and locations are identified			
	Justification is provided for any human receptor groups which will not be assessed further			
Exposure pathway identification	All exposure pathways are identified and are categorized as complete, potential, or incomplete for all types of human receptors (e.g., sensitive populations, off-duty workers)			
	Justification is provided for any exposure pathways which will not be assessed further			
	Potential for country foods ingestion specifically considered based on Indigenous land use and rights			
	Potential for drinking water ingestion specifically considered based on presence of potential domestic water sources			
Conceptual site model	CSM with visual and textual representation which completely summarizes land use, contaminant sources, human receptors, critical human receptors, and exposure pathways for current and potential future scenarios			
	CSM is consistent with overall Problem Formulation			
	Data gaps have been identified			
Exposure Assessment				
General	Content of Exposure Assessment is consistent with the Problem Formulation and CSM			
	All assessment cases have been evaluated			
Concentrations in environmental media	Concentrations are provided for COPCs in all relevant environmental media			
	Air concentration isopleth figures included for all COPCs and assessment cases (except Planned Development)			
	Clear how all applied concentrations were obtained			
	Justification is provided for all cases where maximum or 95% UCLM measured/predicted COPC concentrations were not applied in exposure calculations			
	Justification is provided for the averaging periods applied to air concentrations			
	Potential for biomagnification of COPCs has been evaluated			
Fate and transport modelling	Appropriate selection and application of fate and transport models, with a clear description of the models			
	Model assumptions and limitations are described			
	Models are consistent with Study Area conditions and assumptions in the rest of the EA			
	Selection of all model inputs are justified			
	Model equations and sample calculations are provided and reproducible			
	Validation status of models is provided			
	Modelling methodology and full results are included			
Human receptors	Human receptor characteristics for each human receptor group are provided along with rationale for selection			
	All applicable human receptor age groups have been evaluated			
	Human receptor locations are provided along with rationale for selection			
Exposure scenario	All relevant exposure scenarios are assessed			
	All relevant exposure durations are assessed			

	Exposure scenarios are credible and protective of a reasonably maximally exposed individual			
	Applied exposure duration or amortization is consistent with the Toxicity Assessment and applied appropriately with sufficient justification			
Dose calculation	Exposure doses are calculated for each COPC, operative and potential pathway, for each assessment case			
	Formulae are provided and referenced, with a completed sample calculation and all input values are clearly documented			
	Exposures from multiple pathways and/or routes have been summed appropriately			
	Less than chronic exposure doses were calculated appropriately			
	Adjustments to bioavailability are appropriate and justified if 100% bioavailability is not assumed			
	All applicable pathways are included in multimedia assessment			
Toxicity Assessment				
Selection of TRVs	TRVs are provided for all COPCs			
	Toxicity profiles for all COPCs, including classification as threshold or non-threshold substance, and a description of the considered and applied toxicity endpoints are provided			
	Justification is provided for all TRVs and follows recommended hierarchy of sources			
	Justification provided by an individual qualified and experienced in toxicology for TRVs selected from alternate sources			
	Endpoints are clearly identified for all TRVs			
	Selection criteria for TRVs is provided			
	TRVs are provided for all relevant exposure durations and exposure routes			
	All primary sources for TRVs been consulted and a discussion on the limitations of available toxicity information is included			
Mixtures	Approach to chemical mixtures discussed			
	All COPCs with similar endpoints or target organs identified as being a chemical mixture and are evaluated with a clear methodology			
Consistency with Exposure Assessment	Any COPC identified as having acute or subchronic toxicity was assessed with an appropriate duration in the Exposure Assessment			
Other	Vulnerable populations have been considered			
	Aesthetic or non-toxicological endpoints have been considered			
	Justification provided for any bioavailability adjustments made for COPCs			
Risk Characterization				
Risk estimates	Complete results for all assessment cases, human receptor locations, human receptor groups, age groups, COPCs, and exposure durations from the CSM are included			
	Baseline/background exposures are correctly applied			
	Risks from multiple pathways are summed where appropriate			
	Chemical mixtures are properly addressed			
	Any refinement to calculations based on preliminary results is clear, with all changes to assumptions, methodology, and calculations presented			
Results	Common language summary of results provided			

	Exceedances of hazard and risk targets are identified and measurable increase in concentrations of non-threshold non-carcinogenic COPCs are identified			
	Sources of target hazard/risk exceedances are identified			
	Recommendations made for any predicted hazard/risk exceedances			
	Clear statements indicating where risk management or mitigation measures are factored into presented results			
	Conclusion accounts for uncertainties and data gaps			
	Complete sample calculations are provided (one carcinogen and one non-carcinogen)			
Evaluation of Uncertainty and Variability				
Uncertainty discussion	COPC selection			
	Human receptor selection and human receptor characteristics			
	Exposure scenario parameters			
	Exposure pathway selection			
	Fate and transport model(s) selection			
	Fate and transport model(s) inputs			
	Exposure model selection			
	Exposure model inputs			
	TRV and effect endpoint selection			
	Chemical mixtures			
	Risk interpretation			
	Management and mitigation			
	Implications regarding risk assessment conclusions is discussed			
Sensitivity analysis	Exposure pathways, human receptors, and COPCs identified that had greatest impact on results of the HHRA			
Variability discussion	Human receptor characteristics			
	Exposure scenario parameters			
	Fate and transport model(s) inputs			
	Exposure model inputs			
	TRV selection			
	Risk interpretation			
	Management and mitigation			
	Implications regarding risk assessment conclusions is discussed			
Quality	Were independent quality control checks completed			
Risk Communication and Management				
Presentation	All of the issues identified in the Problem Formulation have been addressed			
	Results from the Risk Characterization section are presented in plain language			
	Critical sources of exposure have been identified			
	Implications to population health are discussed			
	Communication plan/schedule clearly outlined for stakeholders and the affected communities			
Residual Effects Assessment	Discussion of effects includes all required elements, is presented in clear language, and uses recommended terminology and structure			

	All cases (COPC, human receptor, exposure scenario) where HQ or ILCR exceeded target levels, or for which there is no target level, have an assessment of residual effects			
	All non-threshold non-carcinogens have a residual effects assessment			
	All threshold COPCs where estimated exposure from the project was >10% of Base case exposure and >20% of the TRV have a residual effects assessment			
Mitigation	Applied mitigation measures and best practices are described			
Management	All risk management measures are described			
	Discussion provided on how risk management measures will reduce predicted risks			
	Risk management measures are specific and actionable			
	Risk management measures address all predicted health risks			
Accidents and Malfunctions				
General	Potential accidents and malfunctions have been identified			
	Probability of accidents and malfunctions is discussed			
	Severity of accidents and malfunctions is discussed			
	Significance of accidents and malfunctions is discussed			
	Risk mitigation measures for accidents and malfunctions are discussed			

Notes:

If a 'yes' response is indicated, the specified content is considered satisfactory.

If a 'no' response is indicated, the specified content requires further clarification or comment, which is referenced in the 'note' column.

Notes should be provided separately indicating the content which requires clarification or any requests for revisions, with references to the section and pages of the most recent HHRA document and any applicable guidance documents.

Additional tools for review are available in Health Canada (2010b).