Guidance for Evaluating
Human Health Impacts
in Environmental Assessment:

HUMAN HEALTH RISK ASSESSMENT

Health Canada Santé Canada

Canada

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To obtain additional information, please contact:

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

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1. ACRONYMS AND UNITS

Acronym	Meaning
BAF	bioaccumulation factor
BCF	bioconcentration factor
CCME	Canadian Council of Ministers of the Environment
COPC	contaminant of potential concern
CSM	conceptual site model
EA	environmental assessment
HHRA	human health risk assessment
HIA	health impact assessment
HQ	hazard quotient
ILCR	incremental lifetime cancer risk
KOW	octanol-water partition coefficient
LSA	local study area
µg	microgram
mg/kg bw/day	milligram per kilogram of body weight per day
mg/m^3	milligram per cubic metre
PAH	polycyclic aromatic hydrocarbon
PCDD	polychlorinated dibenzodioxin
PCDF	polychlorinated dibenzofuran
PHC	petroleum hydrocarbon
RfC	reference concentration
RfD	reference dose
RSA	regional study area
SF	slope factor
TDI	tolerable daily intake
TRV	toxicity reference value
TSP	total suspended particulates
UCLM	upper confidence limit of the mean
UR	unit risk
US EPA	United States Environmental Protection Agency
VOC	volatile organic compound

2. PURPOSE OF THIS DOCUMENT

This document provides general guidance on the need for conducting a human health risk assessment (HHRA) in assessments of major resource and infrastructure projects in Canada. It presents the principles, current practices, and basic information Health Canada looks for when it reviews the environmental impact statement or other reports submitted by project proponents.

It was prepared for the benefit of proponents and their consultants and to support an efficient and transparent project review process. The foundational information described here should be supplemented as appropriate, with additional information relevant to specific projects. As part of its project review, Health Canada may suggest that information not specifically described here be collected in order to help assess the health effects of specific projects.

It describes, in Health Canada's opinion, best practices and approaches to HHRA. Still, as each project and its assessment are unique, not every best practice and approach described here may apply in every case. Human health risk assessments in assessments of proposed projects differ from other HHRAs by their predictive nature and the necessity to characterize potential future effects that may occur as a result of those projects.

Health Canada updates guidance documents periodically and, in the interest of continuous improvement, accepts comments and suggestions at **hc.ead-dee.sc@canada.ca**.

Please verify that you are reading the most recent version available by consulting the publications section of the Government of Canada's website.

3. INTRODUCTION AND CONTEXT

The key objective of Health Canada's environmental assessment program is to help prevent, reduce, and mitigate the potential impacts of project-related exposure to contaminants and other changes to the environment on human health. Health Canada's expertise is made available to assist authorities in assessing the significance of potential project-related environmental effects.

Health Canada provides its expertise in health risks associated with air quality, water quality, radiation, electromagnetic fields, noise, and country foods when it reviews and provides comments on information submitted by proponents in support of proposed projects.

Appendix A provides a glossary of specific terms used throughout.

Appendix B contains a checklist that can be used to record the completion of the main components of an HHRA and to show where this information can be found within an assessment document.

Appendix C provides additional information about screening contaminants of potential concern (COPCs).

Appendix D shows a graphic illustration of a conceptual site model.

Appendix E lists useful equations for estimating exposure and characterizing risk.

Appendix F presents human receptor characteristics.

Appendix G highlights the fundamentals of Health Canada's current approach regarding the evaluation of cancer and non-cancer health risks from exposure to chemicals, where health effects in an assessment are predicted to be related to chronic (or lifetime) and/or less-than-chronic (short-duration) exposures.

Although conducting an HHRA may not always be required for all assessments and is dependent on the potential health effects of a particular proposed project, the results of a well-documented HHRA can provide increased scientific support for the conclusions of an assessment. The findings of an HHRA (particularly a quantitative HHRA) are especially useful for determining the level of potential health effects, and for identifying appropriate mitigation measures and monitoring plans as well as for establishing remediation and/or risk management needs. Section 6.0 determines the level of detail required (e.g., qualitative or quantitative HHRA) to adequately assess health risks for any specific project.

An HHRA is typically conducted when it is anticipated that individuals will be exposed to elevated concentrations of chemicals or other disturbances in the environment associated with a proposed project through one or more exposure pathways (e.g., inhalation, consumption of drinking water or country foods, irradiation). An HHRA can be conducted at various levels of detail, ranging from simple and qualitative to complex and quantitative.

Generally, the complexity of an HHRA will be based on:

- the available amount of information and detail on the COPCs;
- the predicted concentrations of COPCs in the environment;
- the individuals that may be impacted by increased levels of COPCs related to a proposed project; and
- the specifics of the project (such as size, location, and duration of operation).

There is limited scientific guidance available on conducting multi-media HHRAs in the context of assessments, where concentrations of chemicals in various environmental media (e.g., air, water, soil, country foods) are estimated rather than measured as actual contamination has not yet occurred. The purpose of an HHRA in this case is to provide an estimate of the potential risks to human health from all project phases and to respond to government and public concerns related to those projected effects. This guidance document offers general information on assessing exposure to COPCs via multiple routes of exposure. It also provides references to other Health Canada risk assessment guidance documents for additional detail on various aspects of an HHRA.

3.1 ABOUT THIS DOCUMENT

This document is not intended to provide information on health impact assessment (HIA), which is a combination of procedures, methods, and tools by which a policy, program or proposed project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population (World Health Organization 1999). While its main goals may be similar to those of an HHRA (e.g., protecting human health), the HIA usually considers the larger social and economic impacts that a proposed development may have on a population as well as the overall baseline, future socio-economic conditions, and the physical and mental health of a community (e.g., increase of communicable diseases from increased human contact due to a proposed project). In many cases, HHRA may fall under the umbrella of HIA but only looks at health effects from the perspective of environmental exposure. A quantitative HHRA provides an evaluation of health effects on individuals exposed to biophysical stressors, more specifically, to increased levels of chemicals in environmental media associated with various phases of a proposed project (e.g., construction, operation, decommissioning, and post-closure, as applicable).

This document focuses on HHRA associated with chemicals in the environment. General information on the evaluation of radionuclides (e.g., radiation hazards) can be found in the *Guidance for Evaluating Human Health Impacts in Environmental Assessment: Radiological Impacts* (Health Canada 2017a). Occupational exposure to chemicals is typically addressed under provincial or territorial jurisdictions, and Health Canada does not review this information in the context of assessments of projects. Depending upon the nature of the proposed project, the authority conducting the assessment may also want to consider the assessment of noise impacts (specifically sleep disturbance and annoyance) and/or exposure to chemicals on off-duty workers residing in or near the proposed project area. General information on assessing noise impacts related to a proposed project can be found in *Guidance for Evaluating Human Health Impacts in Environmental Assessments: Noise* (Health Canada 2017b).

Several tools and methodologies exist for conducting HHRAs. Direction offered by international, national, and provincial/territorial regulatory agencies regarding the conduct of HHRAs varies. Many provinces and territories also have HHRA protocols and guidelines, which should be consulted depending on the location of the proposed project. Human health risk assessments involve professional judgment and should be carried out by practitioners who possess the appropriate expertise. As projects often present unique situations not specifically addressed by general guidance, alternative or unique approaches used should be sufficiently documented and described to enable technical review, and evaluated for their impact on risk estimates versus the application of identified standard methods.

Health Canada has published several technical guidance documents related to HHRA at contaminated sites, and much of this guidance is also applicable to HHRAs completed as part of the assessment process; however, the main difference between assessments of contaminated sites and future projects is that there is a lack of measured data regarding concentrations of chemicals that may become elevated in the environment as a result of a proposed project. As such, there is a greater reliance on predictive modelling (and the inherent uncertainties associated with modelled numbers) as opposed to measured data. With respect to HHRA methodology for contaminated sites, Health Canada guidance documents related to specific HHRA considerations are available upon request at **www.hc-sc.gc.ca/ewh-semt/contamsite/docs/index-eng.php**.

This document is part of a set of Health Canada guidance documents that provide general information to stakeholders on the requirements for evaluating impacts of proposed projects to human health in an assessment process. Guidance documents on assessing health impacts related to air quality, drinking and recreational water quality, radiation, noise, and country foods can be obtained by sending a request to **hc.ead-dee.sc@canada.ca**.

4. ROLES AND RESPONSIBILITIES WITH RESPECT TO MULTI-MEDIA HUMAN HEALTH RISK ASSESSMENTS IN ASSESSMENTS OF PROJECTS

In Canada, different levels of government play a role in the protection of human health. Health Canada is the federal department responsible for helping Canadians maintain and improve their health. Depending on the proposed project, provincial or territorial health authorities may also play a role in helping to protect human health. The general information contained herein is intended for use in assessments requiring consideration of potential impacts to human health, but is specifically tailored to address Health Canada's role.

4.1 HEALTH CANADA

When Health Canada participates in an assessment, its primary role is to review the documentation submitted by the proponent on the predicted effects of a proposed project that may affect human health through one or more pathways of exposure. This can include information related to the baseline assessment (pre-project) as well as the potential for cumulative effects in an impacted area. Health Canada may consider the following aspects in its review:

- The appropriateness of methodologies used;
- The predicted human health effects and any comparisons to health-based guidelines and standards;
- The identification of any potential human health effects as a result of predicted changes to the environment;
- The conclusions made concerning potential human health effects, including the uncertainties identified in the assessment and the accompanying rationale or justifications;
- The evidence provided to justify the conclusions and the scientific defensibility of the rationale regarding potential effects to human health; and
- The adequacy and duration of monitoring and/or follow-up programs, risk mitigation strategies, and risk management approaches.

Health Canada provides comments to authorities responsible for the assessment and may recommend information to include in the proponent's assessment of potential health effects, based on submitted project-specific documentation. Comments may include identification of data gaps and deficiencies as well as requests for clarification, additional information or rationale. Health Canada expresses an opinion on whether the HHRA was performed according to current practices, is scientifically defensible, and represents a reasonable worst-case scenario for future human health risks. Health Canada does not validate the fate and transport models, and does not verify modelling results that predict future contaminant levels in environmental media.

Health Canada does not make any decisions, or approve or issue licenses, permits or authorizations in relation to the assessment of a proposed project. The authority responsible for the assessment determines whether Health Canada's comments will be used to inform the environmental assessment report.

4.2 PROVINCIAL AND TERRITORIAL GOVERNMENTS

While the information presented in this document may be applied in the context of an assessment authorized under provincial or territorial legislation, a proponent should also consult provincial, territorial, and municipal legislation, regulations, and guidance.

5. PURPOSE OF MULTI-MEDIA HUMAN HEALTH RISK ASSESSMENTS

Human health effects are often evaluated based on changes to environmental components and potential effects of those changes. For an effect to occur, there has to be a source (project component or activity) that results in a measurable change to the environment and a corresponding effect on human health (via an operational pathway). Depending on the type of project and activity, environmental media including soil, sediment, drinking water (surface water, groundwater), recreational water, air, and/or country foods (e.g., fish, shellfish, vegetation, wild game) may be affected. Depending on the presence of people (referred to as human receptors) and the types of activities they undertake at or near the proposed project site, changes to the environment may have human health implications. These links between changes to environmental components as a result of the project and human health can then be assessed as part of an HHRA to determine the significance of project related effects.

A well conducted HHRA can provide increased defensibility for the conclusions of an assessment and help verify if identified concerns related to human health are justifiable. An HHRA can be used to provide a quantitative estimate of the likelihood of potential risks in an exposed population, to highlight the need for mitigation measures where there may be elevated exposures, and to guide the development of follow-up monitoring plans, remediation, and/or risk management approaches to reduce any unacceptable risks. Where a proposed project may result in effects to multiple environmental media (e.g., air, soil, water, food) and there are multiple exposure pathways, an HHRA that evaluates all potential exposure pathways together (i.e., multi-media) is a useful tool for estimating potential risks to human health as a result of the project.

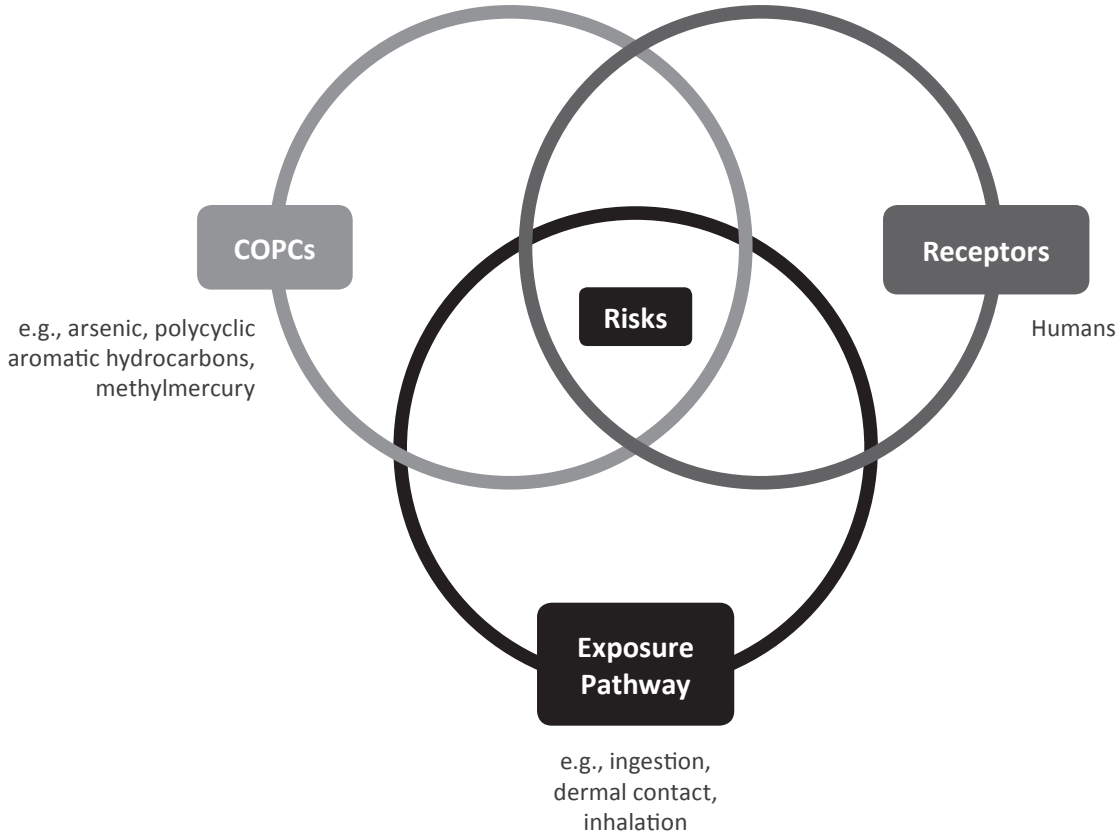
6. DETERMINING THE NEED FOR HUMAN HEALTH RISK ASSESSMENTS

The need to conduct an HHRA and its required scope may vary according to the jurisdiction conducting the assessment. For example, the scope of assessment of Indigenous peoples' health may be different from that of non-Indigenous health due, for example, to their reliance on country foods. Therefore, consideration should be given to whether the proposed project may impact areas used by Indigenous peoples (e.g., areas where country foods are collected, recreational land use, residential areas).

A quantitative HHRA is required when elevated COPC concentrations are predicted in one or more environmental media for a proposed project. The level of detail required to evaluate potential human health effects may vary from project to project, and where there are no predicted pathways that may result in exposure to the population, a qualitative (screening) approach may be sufficient.

For projects with operational pathways and a potential for human exposure to contaminants, a quantitative risk assessment is conducted to provide an estimate of potential human health risks associated with chemicals released at various stages of the proposed project. Further information on the determination of the level of HHRA required is provided in Section 7 of this guidance document.

FIGURE 6.1: Considerations for a Quantitative HHRA



Consideration should be given to the following when determining the need for and level of detail of an HHRA for a proposed project:

- Spatial and temporal extent of the predicted contamination;
- The types and quantities of contaminants predicted to be released (the more toxic and/or the larger the quantity of the chemical, the greater the potential risk);
- Number of environmental media predicted to be impacted (e.g., air, water, soil, country foods);
- Likelihood of human exposure to the impacted media (e.g., drinking water source(s), recreational use of surface water, reliance on country foods);
- Location and proximity of individuals to the impacted areas;
- Sensitivity of individuals (e.g., underlying health conditions, presence of schools, daycares, hospitals, etc.);
- Duration of exposure to COPCs (i.e., residential area vs. seasonal occupancy vs. occasional site use);
- Indigenous concerns related to health, country foods, and use of traditional territory; and
- Public concerns related to health.

The above is not an exhaustive list—professional judgement should always be used when determining the need for and level of detail of an HHRA. Any decision related to the need for and type of HHRA should be described and justified. The results and conclusions reached in the assessment related to human health should be sufficiently detailed and appropriate for the specific project and the type of HHRA undertaken. See the assessment HHRA checklist in Appendix B.

7. HUMAN HEALTH RISK ASSESSMENT METHODOLOGY IN ASSESSMENTS OF PROJECTS

As previously stated in Section 3.0, the methodology for conducting an HHRA in assessments of proposed projects is essentially the same as for an existing contaminated site, although the process is of a much more predictive nature and specific terminology and requirements may vary. Human health risk assessments typically consist of the following:

1. Problem formulation (Section 7.1)
2. Exposure assessment (Section 7.2)
3. Toxicity assessment (Section 7.3)
4. Risk characterization (Section 7.4)
5. Uncertainty assessment (Section 7.5)
6. Conclusions — determination of the extent of the effects and risks (Section 7.6)
7. Recommendations (Section 7.7)

Technical guidance related to the methodology for each of these steps can be found in Health Canada (2012) and detailed methodology on quantitative risk assessment in Health Canada (2010a), and in Appendices B to G of this document. The focus of this document is to outline each of the basic steps with emphasis on information requirements specific to HHRAs.

It is important that the proponent consider input from Indigenous peoples and public consultation processes throughout the assessment and HHRA processes. Information collected may influence the scope of the HHRA, as well as identify data gaps and additional information needs.

Risk assessment is an iterative process and, as such, the scope of the HHRA may need to be revisited as the assessment proceeds and/or as the project scope changes. For example, additional receptors and additional exposure pathways may be added/removed based on preliminary assessments. Where use of conservative assumptions in preliminary assessments identifies potential effects, it is recommended that a more detailed HHRA be conducted to address the uncertainties in the risk assessment.

7.1 PROBLEM FORMULATION

This stage of the HHRA consists of identifying all major factors to be considered in the risk assessment. It is intended to be brief with details about each of the following:

- Identification of study boundaries (Section 7.1.1)
- Identification of current and future COPCs (Section 7.1.2)
- Identification of current and future human receptors (Section 7.1.3)
- Identification of current and future exposure pathways (Section 7.1.4)
- Development of a conceptual site model (CSM) showing the links between COPCs, receptors, and exposure pathways (Section 7.1.5)

Ideally, the problem formulation should be completed as early as possible in the project planning (before submitting the project description), as it will provide information about data needs and gaps, as well as assist in the development of any baseline sampling programs that are temporally and spatially appropriate to fill those data gaps.

7.1.1 IDENTIFICATION OF STUDY BOUNDARIES

During the problem formulation stage of the HHRA, study boundaries need to be defined prior to evaluating potential project-related impacts. These boundaries include both spatial (geographic extent of effects of the project) and temporal (possible duration of environmental effects as a result of various stages of the project) boundaries. Note that spatial and temporal boundaries may differ between various environmental components (e.g., air, water, wildlife). The HHRA should clearly document the assumptions made based on the spatial and temporal boundaries and ensure that human health risks are adequately characterized. For example, if the spatial boundaries defined for the air quality component are the same as those used for the HHRA, they should be reviewed to ensure they encompass the communities, recreational areas, and traditional land use areas that are to be evaluated in the HHRA and/or are of cultural significance to Indigenous peoples that may be using the impacted area. For temporal boundaries, the decommissioning or closure phase of the project is often considered to be the end of the project. However, for projects where infrastructure will remain on-site (such as a tailings impoundment remaining post-closure that may result in exposure of individuals to elevated levels of COPCs), there may be a need to evaluate the post-closure phase for potential health implications.

SPATIAL BOUNDARIES

Spatial boundaries of an environmental assessment should encompass the entire area that may be impacted by the proposed project, not just the proposed project footprint. For example, air emissions can travel great distances before depositing on land and impacting environmental concentrations in soils, water, sediment, and foods. Water discharges can impact surface and groundwater quality downstream of the project location and affect water quality as well as sediment and consumed foods. The HHRA should clearly document the spatial boundaries for assessment in each medium, noting the amount and types of emissions as well as fate and transport of chemicals in the environment for each of the project phases. A proposed project may have multiple spatial boundaries depending on the environmental media of interest. Where pertinent, a smaller local study area (LSA) and a larger regional study area (RSA) should be delineated for each environmental medium that may be impacted.

Maps with appropriate scales, diagrams, and figures should be used to illustrate the spatial boundaries of each environmental medium and all potential current and future human receptor locations in relation to the project site, including distances from the project site(s).

TEMPORAL BOUNDARIES

The HHRA should clearly document the temporal boundaries of the projected impacts to the environment—this will address the timing and lifespan of the potential impacts of the proposed project and may be described based on the various project phases (Section 7.2.2). Temporal considerations for an HHRA may also include the differentiation between acute and chronic exposures to elevated levels of chemicals in the environment and the durations over which chronic exposures may occur. This should include considerations such as the operating life of the project and the length of time a project may have an effect on the environment. For example, if not covered, waste stockpiles may continue to be a source of dust generation and would require the HHRA to consider potential health effects of dust exposure post-closure. Further, as leaching from tailings ponds may affect downstream surface and groundwater quality, water quality may need to be monitored for years after closure (e.g., for a mine).

7.1.2 IDENTIFICATION OF CONTAMINANTS OF POTENTIAL CONCERN

The purpose of this step is to evaluate whether the proposed project will create conditions where chemical concentrations may be increased in environmental media as a result of project activities. This may include emissions from the proposed project, but it may also include dispersion/remobilization of chemicals in the environment that are elevated in baseline conditions. The following considerations may be used in the HHRA to identify which chemicals may be considered as COPCs associated with a proposed project:

- The concentrations of various chemicals that are present in environmental media prior to project commencement (i.e., baseline conditions);
- The concentrations of chemicals that are expected to be emitted by project activities during the construction, operation, decommissioning, and post-closure project phases (where applicable);
- The concentrations that models indicate will be present in various media in areas where there are human receptors;
- The concentrations of chemicals in environmental media that may be incidentally released during project activities (e.g., naturally occurring mercury may be reintroduced into the environment during dam impoundment, or existing contaminated sediment can be re-suspended during dredging/wharf construction, which may then affect previously unimpacted areas or aquatic foods);
- The concentrations of chemicals that may be released as a result of an accident or malfunction and the modelled concentrations of those chemicals into various environmental media that may be impacted in areas where there are human receptors.

All chemicals that may be elevated in environmental media as a result of project activities may be initially considered as COPCs. However, if the modelled concentrations plus the baseline concentrations are calculated to be below guidelines/standards/criteria for the impacted media, the problem formulation phase of the risk assessment may conclude that the chemicals do not need to be carried forward as COPCs in a quantitative risk assessment. In cases where there are no guidelines/standards/criteria available for screening an environmental medium (e.g., country foods), the COPCs will be carried forward into a quantitative risk assessment to determine whether there may be health risks associated with the predicted concentrations.

The concentrations of chemicals in the environment that are used in an HHRA are based on a combination of measured data to document current baseline conditions and modelled data for the predicted future conditions (e.g., air quality modelling and deposition rates, surface water quality predictions).

The problem formulation should identify whether baseline sampling allows for adequate characterization of current baseline concentrations in all potentially impacted environmental media (e.g., an appropriate number of samples collected and analysed for COPCs in each medium, based on project's LSA or RSA). For characterization of baseline concentrations, where environmental monitoring data are used, it is recommended that data be recent and from the actual study area, so they can be considered representative of the baseline conditions. It may be acceptable to use proxy data originating from literature or existing databases (with sufficient justification, identifying how the data are expected to be representative of the site conditions); however, this may weaken the conclusions of an assessment and require sufficiently conservative assumptions. The HHRA should document the limitations and uncertainties regarding data that represent baseline conditions. These limitations should be discussed in the uncertainty analysis of the HHRA (Section 7.5.1). The rationale for using literature sources, other databases (e.g., Environment Canada's National Air Pollution Surveillance database for baseline air quality) or environmental monitoring data to characterize baseline conditions for the HHRA should be clearly described and referenced in the HHRA. Some details about considerations for a sampling program that can be used to assess baseline conditions can be found in the following documents:

- Health Canada. 2010b. *Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRAFoods)*.
- Canadian Council of Ministers of the Environment (CCME). 2016. *Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment*.

The decision to further evaluate a chemical in a quantitative HHRA (also known as "screening in") should consider background levels, predicted concentrations, exceedances of background, exceedances of applicable environmental guideline values, human toxicity, mobility, persistence, and potential to bioaccumulate or biomagnify (Health Canada 2010a). Chemicals should not be screened out of a quantitative HHRA where there is no federal guideline value for that chemical in the impacted medium. Instead, the chemical should be screened/evaluated based on guidelines from other jurisdictions, where such guidelines are available. Where no guidelines exist and if the concentrations of a COPC exceed background concentrations, the chemical should be screened into a quantitative HHRA and evaluated further (unless sufficient justification is provided that the chemical is unlikely to pose a health risk). For instance, it would not be appropriate for a chemical to be screened out of a quantitative HHRA based on a rationale that the predicted concentrations are less than 10% above background, as there is no common justification that such concentrations would not have the potential to impact human health. A rationale would be required on a chemical-specific basis as well as a site-specific basis.

Chemicals of potential concern with no available guideline values and of which levels are predicted to exceed background concentrations should be further evaluated in an HHRA and not screened out based on the lack of a guideline value or low predicted exceedances.

Additional technical detail about screening in chemicals can be found in Appendix C, which presents information related to the following:

- Identification of the chemicals that can be emitted or produced by the project and their potential to be present in environmental media;
- Identification of chemicals that may be elevated in baseline conditions;
- Rationalization/exclusion of innocuous chemicals;
- Identification of chemicals that bioaccumulate or biomagnify;
- Identification of appropriate screening criteria;
- Comparison of chemical concentrations with screening criteria; and
- Selection of COPCs to be included in a quantitative HHRA.

7.1.3 IDENTIFICATION OF HUMAN RECEPTORS

The problem formulation stage also identifies all individuals—referred to as human receptors—that may be impacted by the proposed project currently and in the future. They include those that are present or expected to be present in the future within the spatial boundaries of the project and/or could be impacted by the proposed project as well as individuals with permanent residences or temporary use areas (e.g., cabins, recreational use, seasonal occupancy, occasional use for country foods collection).

When identifying potential receptors, consideration should be given to potentially sensitive receptors and vulnerable populations that may be exposed to increased levels of risk due to physiology, health status, behaviour, and/or lifestyle. Examples include seniors, pregnant or nursing mothers, infants (particularly where COPCs are known to biomagnify or exhibit potential neurotoxic or fetotoxic effects), and consumers of higher quantities of local country foods that may receive greater exposure to COPCs. The HHRA should also identify individuals that may be exposed outside of the spatial boundary. For example, a hunter in the area may bring food back to a non-impacted area where others (family members, community members, elders, etc.) may consume the foods with elevated levels of COPCs.

Information on the types and duration of activities (e.g., fishing, vegetation harvesting, hunting, swimming) of receptors is documented in the problem formulation as well as in the traditional knowledge or socio-economic section of the assessment. If applicable, the unique diets and lifestyles of local people, including reliance on local country foods, should be considered—this information can be used in determining the types of country foods that are collected and analysed in the baseline assessment. This information can be acquired through regional literature sources, as part of early consultation efforts by the proponent with local people and/or by undertaking dietary/consumption surveys (refer to Health Canada, 2018 Guidance on Country Foods).

All receptor locations should be clearly listed in the problem formulation and identified on maps and figures in the report, including the type of receptor location (e.g., residence, cabin, recreational area) and proximity of the receptor location to the project. More detailed information on receptor characteristics are documented in the exposure assessment section of the HHRA.

The problem formulation stage of the risk assessment should also clearly document locations where individuals could be most affected, such as those nearest to the most impacted areas or those that may be exposed to the highest concentrations of COPCs (e.g., in the area of the maximum point of impingement). The document should also clearly identify those areas where there are individuals who may experience less exposure, but who may be at potentially greater risk as a result of higher sensitivity (e.g., hospitals, daycares, retirement homes).

7.1.4 IDENTIFICATION OF EXPOSURE PATHWAYS

The purpose of this step is to identify all potential ways in which individuals can be exposed to COPCs—these are referred to as exposure pathways. An exposure pathway includes consideration of the contaminant source, release mechanisms, transport mechanisms within the relevant environmental medium (or media), points of exposure (receptors), and exposure routes. The exposure route refers to how a person comes into contact with a COPC (e.g., food, water or soil ingestion, inhalation of particulates or volatile compounds, dermal contact).

Information related to applicable exposure pathways should be documented in the problem formulation, which includes all of the ways in which chemicals released from the proposed project may come into contact with individuals. Where individuals may be present in the vicinity of the project, but an exposure pathway is not operable (i.e., there is no exposure), this pathway can be excluded from further analysis with adequate rationale. For example, if individuals do not currently and will not likely in the future consume surface water, groundwater or foods in the area, the report may indicate that these pathways are incomplete and no further evaluation is necessary. Another example would be if a proposed project is not expected to result in groundwater contamination (e.g., marine terminal), the groundwater ingestion pathway could be identified as incomplete and would not require further assessment. All potential pathways of exposure should be considered operable in the HHRA unless evidence-based justification is provided for their exclusion (e.g., individuals do not and will not drink the groundwater, the project will not contaminate groundwater).

In the problem formulation, all complete or operable pathways should be listed together with the applicable receptor groups (diagrams may be useful tools to illustrate potential exposure pathways). Further screening may be conducted to exclude exposure pathways for which the probability of exposure is very low or the potential magnitude of exposure is negligible. Sound justification should be provided for the exclusion of any complete exposure pathway and receptor from further consideration in the risk assessment (Health Canada 2010a).

Potential exposure to COPCs in environmental media for each project phase (construction, operation, maintenance, decommissioning, closure, etc.) should be clearly documented to evaluate how receptors may potentially come in contact with impacted media. Examples of potential exposure pathways to consider are provided in Table 7.1; however, this list is not exhaustive and the problem formulation should clearly document all potential exposure pathways relevant to a specific site.

TABLE 7.1: Examples of Potential Exposure Pathways

Environmental media	Exposure pathways
Soil	Incidental soil ingestion
	Dermal absorption of COPCs from soil adhering to skin
	Inhalation of suspended soil particulates
	Inhalation of vapours migrating from soil to air
Sediment	Incidental sediment ingestion
	Dermal absorption of COPCs from sediment adhering to skin
Surface water	Incidental surface water ingestion during recreational activities
	Ingestion of surface water if used as water for drinking/cooking
	Dermal contact with surface water during recreational activities or bathing/showering
	Inhalation of vapour if used for showering/cooking
Groundwater	Ingestion of groundwater if used as water for drinking/cooking
	Inhalation of vapour if used for showering/cooking
	Inhalation of vapour migrating from subsurface contaminated groundwater to air
	Dermal contact with groundwater if used for bathing/showering
Air	Inhalation of suspended particulates or vapours in air
Country foods	Vegetation: ingestion of vegetation (berries and plants) grown on impacted soil or affected by aerial deposition of COPCs
	Fish and shellfish: ingestion of fish and shellfish harvested from impacted surface water bodies and/or surface water bodies with impacted sediment
	Wild game: ingestion of wild game that may be impacted via consumption of impacted soil, vegetation, sediment, surface water, and/or prey items

7.1.5 CONCEPTUAL SITE MODEL

A key output of the problem formulation stage of a risk assessment is the conceptual site model (CSM). The CSM provides a complete description, usually in schematic or pictorial form, of the COPCs, their sources and release mechanisms, transport pathways, and exposure routes to identified receptors. An illustrated CSM facilitates a clear, common understanding of the potential health risks associated with the proposed project. The CSM, which is qualitative in nature, provides the basis and guidance for the subsequent quantitative HHRA. It also serves to focus attention on the critical aspects of the problem and can be used to guide consultation and risk communication efforts. The CSM may be presented during the proponent's consultation process with Indigenous peoples, members of the public, stakeholders, and regulatory agencies for feedback and possible revisions if exposure pathways were omitted or included where they are not operable. An example of a CSM can be found in Appendix D.

The CSM should consider each phase of the project. If at the end of the problem formulation the report concludes that there are no operable exposure pathway/receptor combinations, then a quantitative HHRA may not be required, and the qualitative HHRA may be presented for technical review.

7.2 EXPOSURE ASSESSMENT

The objective of the exposure assessment is to estimate the concentration of each COPC to which individuals may be exposed. For predictive assessments, exposure to COPCs is predicted using various models to estimate the concentrations of COPCs in the applicable environmental media and in the different assessment scenarios described in Section 7.2.2 below.

The exposure assessment section should clearly document all exposure equations, all receptor characteristics, the concentrations predicted (or measured) in each environmental medium at the receptor location, and include a description of the models used to predict the COPC concentrations in the various media (Health Canada 2010a). The exposure assessment provides the dose of each COPC that individuals may receive, for all receptors that may be impacted, and for all exposure pathways and scenarios identified during the problem formulation (Section 7.1).

Where there are variable emissions or exposures to COPCs during the different project phases, the exposure assessment should be conducted and documented separately and clearly for each project phase. Where specific phases of a project are not predicted to result in exposure to a COPC, the report should present sufficient justification to document why a particular phase was not evaluated (see below).

It is recommended that the risk assessment includes worked calculations for each exposure pathway to allow for technical review of exposure estimates. All input parameters (e.g., receptor characteristics, COPC concentrations) should be included and referenced, and the exposure calculations should be clearly summarized in the report.

SPECIFIC PROJECT PHASES

Where project activities differ substantially in the types of COPCs emitted/released, different project phases should be quantitatively evaluated for their potential health impacts.

Where there are variable emissions or exposures to COPCs during the different project phases, an exposure assessment is conducted for each project phase. Where COPCs are not expected to be released during a specific phase of a project, the report should provide sufficient justification for omission of a quantitative evaluation. For example, the use of diesel generators for power until a transmission line is built could result in higher diesel and volatile organic compound (VOC) emissions during the construction phase of a project, but not during operations. Another example related to the construction phase would be dust generation due to increased vehicular traffic associated with construction activities. The report should clearly identify situations where infrastructure intended to remain on-site following decommissioning or closure (e.g., tailings ponds, landfills, exposed waste rock piles) may have the potential to introduce additional COPCs to environmental media in the future. This information will allow for planning and verifying proposed monitoring and mitigation measures during the post-closure phase to ensure acceptable environmental quality is maintained.

Where the HHRA considers potential accidents and malfunctions, if a quantitative assessment is not possible, a qualitative discussion can be presented, with proposed risk management/mitigation measures to prevent accidents and/or address concerns.

Health Canada's (2012) preliminary quantitative risk assessment guidance provides technical information regarding specific aspects of the exposure assessment and should be consulted for detailed information with respect to the following:

- Characterization of on-site contaminant concentrations
- Characterization of potential receptors
- Exposure frequency and duration
- Exposure equations
- Airborne respirable dust levels
- Models
- Relative absorption factors and exposure via multiple pathways
- Carcinogens

Where there are specific considerations, additional information should be provided, as described in the sections below.

7.2.1 SHORT-TERM EXPOSURE

Short-term exposure may be a consideration for projects where individuals will be in an impacted area only for a short time or where a project results in release of COPCs during specific periods (e.g., construction phase lasting only a few months, harvesters in the area for a short period). Please see Appendix G for further guidance on how to assess short-term exposure.

7.2.2 ASSESSMENT SCENARIOS

It is recommended that, to adequately quantify the overall potential risks to human health, the risk assessment should compare risk estimates under different assessment scenarios associated with the proposed project. These scenarios are relative to existing conditions and in combination with other reasonably foreseeable developments. Four different assessment scenarios should be included in the HHRA, namely: baseline (existing conditions), project alone, baseline plus project, and baseline plus project plus any reasonably foreseeable future development (i.e., cumulative scenario), as appropriate. Assessment scenarios for different phases of the proposed project may also be relevant. These scenarios are described in more detail below.

Human health risks should be calculated for each of the scenarios identified, if warranted and adequate, as each scenario provides useful information for evaluating changes in risk and the relative contribution of risk from each of the scenarios. Although the project scenario alone provides information on risks related to the project only and may be the focus of interest for the regulator, the evaluation of overall risk is required to understand how the project and baseline conditions may impact human health. A cumulative assessment of potential effects of a project may call for the evaluation of cumulative health risks associated with other current and reasonably foreseeable physical activities in the area.

7.2.2.1 BASELINE (EXISTING CONDITIONS) SCENARIO

The baseline scenario represents the current existing levels of chemicals in an area (i.e., it describes the existing conditions for the proposed project area). The baseline levels of chemicals should be documented in order to evaluate the extent of possible environmental changes related to future project activities and the subsequent potential impacts on human health. Comparing predicted COPC concentrations for the proposed project activities to baseline concentrations provides information on the potential impact of the proposed project. Considerations of contributions from approved future developments are captured in the future development scenario under cumulative effects (Section 7.2.2.4).

It is important to include all relevant data related to baseline samples, including the number of samples collected, the number of non-detectable samples, the minimum and maximum concentrations, and any statistical evaluation undertaken (e.g., mean, median, 95% upper confidence limit of the mean [UCLM]).

Measured baseline data are recommended for environmental media that may be impacted, including a sufficient number of samples from each medium to enable a statistical analysis in the LSA (i.e., areas that may be impacted by the proposed project). Relying on literature-based sources and/or on information from historical databases, other projects, and other areas distant from the project area, would limit the representativeness of the baseline data (e.g., baseline air quality data from monitoring stations located several hundreds of kilometres away or in different provinces or countries may not be relevant). If these sources are used, justification should be provided as to their appropriateness.

Depending on the type of project, expected emissions and local land use, it is recommended to collect baseline data for all relevant environmental media to which people may be exposed in order to cover all possible pathways of exposure. Where baseline data are measured, the report should document the type of samples collected (e.g., soil, specific plant/berry species, specific fish species), the number of samples collected, the analytical detection limit, the number of samples with non-detectable COPC concentrations, the minimum and maximum COPC concentrations, and any statistical averaging (e.g., 95% UCLM) used to represent the baseline COPC concentrations in each environmental medium. Information regarding the appropriateness of the selected COPC concentrations to represent baseline conditions in the HHRA should be documented.

7.2.2.2 PROJECT ALONE SCENARIO

The project alone scenario predicts the levels of the COPCs in environmental media associated with releases from the proposed project without considering the additive effects from the baseline scenario. The effects of this scenario on human health should be calculated because it may inform the environmental assessment decision. This scenario also provides an estimate of the project's contribution to overall health effects. From a human health protection perspective, the project alone scenario should evaluate health effects with and without mitigation measures; this will allow for the development of a reasonable worst-case scenario in the event that mitigation will not be as effective as predicted, which can be used in the decision-making process (e.g., development of conditions under which the project will be allowed to proceed). This process is not a requirement for an HHRA; however, if potential risks are identified in the HHRA, then this information would enable regulators to make decisions regarding potential health impacts.

When evaluating potential health risks associated with project activities, it is important to assess risks both with and without proposed mitigation measures.

7.2.2.3 BASELINE PLUS PROJECT SCENARIO

The baseline plus project scenario predicts the effects of the project in addition to the existing conditions, which involves combining the baseline and the project alone scenarios. This scenario is essential to the determination of the human health impacts of a proposed project, as it estimates the minimum potential future environmental conditions that would exist if the proposed project proceeds.

The exposure assessment should be performed for this scenario, similar to that for the project alone scenario, identifying the phases (e.g., construction, operations, decommissioning, closure, post-closure, if applicable) being assessed in addition to existing conditions.

7.2.2.4 CUMULATIVE EFFECTS SCENARIO

The cumulative effects scenario predicts the potential environmental effects of the existing baseline plus project scenario in combination with effects from reasonably foreseeable future activities within the same area of influence. Reasonably foreseeable future activities include projects that are approved but not yet operating, and other proposed or likely developments within the potentially impacted area. This scenario provides an estimate of human health risks in the future when other facilities are also in operation. The risk assessment should address uncertainties associated with future emissions from other future projects that may not be known or predicted with sufficient level of confidence.

7.2.3 CHARACTERIZATION OF EXPOSURE CONCENTRATIONS

The risk assessment should clearly document how the concentrations of the COPCs to which human receptors will be exposed were calculated or estimated in each potentially impacted environmental medium. The risk assessor should ensure that appropriate units are used in the calculations and properly reference laboratory data and/or models used to estimate the exposure concentrations.

The 95% UCLM or any other appropriate statistic may be used as the exposure point concentration to assess the baseline scenario where the majority of data are measured in the environmental media if there are sufficient numbers of samples analysed for each medium (for further discussion, refer to CCME 2016; Health Canada 2010b).

For all exposure calculations, the report should clearly document all input data, with reference to the section of the report(s) where the data were listed as well as justification for any statistics used. A rationale should be provided on the selected statistics used to represent the exposure point concentration, as use of different statistics may lead to different concentrations. Please see Appendix A of Health Canada's (2010a) guidance document on handling datasets with values below laboratory detection limits.

Recent measured site-specific baseline data are always preferred over data from other sources when determining baseline conditions.

Assessment of future exposure and subsequent risks for various phases of the proposed project is based on predicted environmental concentrations. Modelling of future conditions is built on the baseline assessment plus modelled data. For some media, where co-located baseline samples are collected (e.g., berries and soil, fish and surface water or sediment), site-specific bioaccumulation factors can be calculated and used to estimate future exposure concentrations.

There are various models available to estimate concentrations in different media. The selected models should be obtained from sources that have received peer review or regulatory endorsement and must be clearly referenced in the assessment. The exposure point concentrations identified for use in the HHRA should be clearly documented. Where different concentrations of COPCs are expected during different stages of the project, the exposure concentrations and duration of time of the impacts should also be clearly documented in the report. All receptor locations that may be impacted should be identified in relation to the predicted COPC concentrations for each environmental medium.

SOIL CONCENTRATION ESTIMATES

Baseline concentrations of each COPC can be measured in soils. Future impacts to soils can be modelled based on project-specific releases. Concentrations of COPCs in soils may be elevated in future scenarios as a result of direct discharge to soil or aerial deposition of airborne contaminants. If COPCs are released to air, then aerial deposition rates should be clearly identified in the report with all input parameters specified and referenced. The US EPA (2005a) provides a general equation for estimating the maximum incremental change in soil concentration that would be achieved over a specified deposition time. The calculated soil concentrations are added to the measured baseline soil concentration (i.e., the baseline exposure concentration) to obtain the predicted soil concentration of each COPC due to atmospheric deposition.

SEDIMENT, WATER, AND/OR AIR CONCENTRATION ESTIMATES

Baseline concentrations of each COPC can be measured in sediment, water, and air (where applicable). Future impacts to sediment, water, and air can be modelled based on project-specific releases. These media are often predicted in other components of the assessment using fate and transport models.

COUNTRY FOODS CONCENTRATION ESTIMATES

Where a proposed project is expected to result in release of contaminants to the environment and vegetation, animals or aquatic life may be impacted, ingestion of contaminants via food can be a significant pathway of exposure. This exposure pathway may be particularly significant when COPC's possess the ability to bioconcentrate, bioaccumulate or biomagnify in the food chain and/or when the consumption of country foods may constitute a significant portion of a diet. In order to assess the potential health effects associated with increased levels of contaminants in foods grown or obtained near the site, it is necessary to have a measurement of the baseline concentrations of the contaminants in edible foods. If such information is not available, this becomes a significant uncertainty in the risk assessment and has the potential to underestimate potential health risks associated with a proposed project. In order to fully evaluate the potential for health effects, it is important that this information be characterized and properly documented prior to initiation of project activities. Discussion with Indigenous peoples may be required to identify foods that are consumed and their rates of consumption in the project area.

Baseline concentrations of each COPC can be measured in existing foods that may be consumed, with future impacts modelled based on project-specific releases. It is a best practice for the HHRA to document the baseline and predicted future concentrations of COPCs in specific food items (e.g., fish, shellfish, deer, waterfowl, vegetation) that may be affected by the proposed project or that may have cultural significance to local Indigenous peoples. Methods for predicting COPC concentrations in country foods are provided in Health Canada's (2010b) and Health Canada's (2018) guidance documents. Health Canada (2010b) and the US EPA (2005a) provide guidance on modelling vegetation tissue concentrations. Certain COPCs associated with the proposed project may also be present in commercially available foods, as many of the chemicals are naturally occurring (e.g., metals) and/or associated with other anthropogenic processes unrelated to

the proposed project. If it is known that one or more of the COPCs are already elevated in retail food as determined by published data or literature and are likely to become elevated in local country foods due to project activities, the HHRA should consider both potential sources in terms of exposure for threshold acting chemicals. Dietary surveys may be used to collect information about amount of store-bought food versus country foods consumed by local people to inform the exposure assessment regarding contaminant uptake via consumption of food. Details on completing an exposure assessment for food consumption are provided in Health Canada, 2018.

For all media being analysed, appropriate detection limits should be used in the laboratory analysis to allow for an HHRA for each COPC.

Appendix E of this guidance document and Health Canada (2012) provide equations for calculating exposures via ingestion of soil, ingestion of drinking water, ingestion of country foods, inhalation of fugitive dust, inhalation of volatiles, and dermal absorption from soil and water. The equations for soil can be applied to estimate exposure from sediment.

7.2.4 CHARACTERIZATION OF POTENTIAL RECEPTORS

The problem formulation stage identifies all current and potential future human receptors that may be impacted by each phase of the project. In the exposure assessment stage, the quantitative receptor characteristics are assessed and the duration of exposure estimated based on the use of spatial and temporal boundaries during all project phases.

Receptor characteristics and exposure parameters used to quantify the exposure should be based on site-specific information. For example, if a dietary study is completed specifically for the specific project, this information should be used to characterize consumption of potentially impacted country foods by individuals in this area. Region-specific Indigenous peoples dietary preferences are found in the First Nations Food, Nutrition and Environment Study (2016), available at **www.fnfnes.ca**, or there may be other published literature specific to the area of interest. Consultation with local people can also provide information about current and potential future land use as well as permanent and/or seasonal residence locations, and can even be used to identify any underlying health conditions or other unique conditions that may affect exposure (e.g., use of soil/vegetation to dye fabrics that may result in dermal exposure, different local foods only consumed during specific occasions such as ceremonies, specific organ meats consumed, food preparation techniques [e.g., raw, cooked, smoked, salted]). Health Canada (2010b, 2018) provides additional information related to country foods considerations.

If particularly sensitive or vulnerable populations are present or there is substantial concern about exposure to potentially bioaccumulative chemicals (e.g., methylmercury increases in fish and seafood as a result of a proposed hydroelectric dam), baseline and follow-up human biomonitoring studies may be undertaken. Human biomonitoring can reduce the uncertainties in a risk assessment. As it involves sampling human tissues where certain specific chemicals may accumulate (e.g., hair and/or blood for methylmercury, fingernails/toenails for arsenic), it is considered one of the more invasive techniques used to determine potential health impacts. It should be undertaken by trained professionals using standard protocols and sampling methods, with consideration for a variety of factors including ethical considerations (informed consent to provide a sample), sufficient sample numbers, and representativeness of the sample population in terms of age, gender, and any confounding factors that may affect sample results (e.g., presence of mercury dental amalgams when evaluating human exposure to mercury from foods). Health Canada (2015) and Haines et al. (2012) provide details about human biomonitoring.

If site-specific data are not available regarding receptor characteristics, typical exposures for the general Canadian population and Indigenous peoples may be used (Appendix F). If Canadian data are not available, other sources of exposure factors may be found from agencies of other jurisdictions such as the US EPA. However, the risk assessor should ensure that the values used are appropriate for the exposed population, and the report should provide sufficient rationale to justify the use of these values, noting whether they are conservative or may result in an underestimate of exposure. Without adequate justification, it is not appropriate to assume an arbitrary percentage consumption rate of local foods (unless the assumption is that 100% of local foods are consumed, which is conservative).

For areas where country foods are consumed, the HHRA should consider the differences in consumptions rates throughout the year. Where foods are not consumed continuously (e.g., seasonal consumption patterns), the HHRA should identify the potential exposure in the most exposed time frame. For instance, the quantity of local berries consumed in the spring/summer would be expected to be higher than the consumption over the rest of the year when berries are not in season; however, it is also possible that berries picked could be frozen and then consumed throughout the year. Depending on when specific country foods are consumed (information which may be collected as part of a dietary survey), seasonality of consumption may be considered as a short-term exposure (i.e., if large doses of COPCs are expected to be consumed over a short period of time) in the risk assessment. It is important that the exposure assessment characterizes the exposure to each COPC associated with consumption of seasonal foods during the period of elevated exposure, without averaging out this exposure over the year (see Appendix G for a discussion on dose averaging in short-term exposures). The exposure should not be averaged over a longer time frame unless accompanied by scientific rationale relevant to averaging of exposure on a chemical-specific basis. Health Canada (2010b) provides further information on selecting appropriate country food ingestion rates.

7.3 TOXICITY ASSESSMENT

The toxicity assessment stage involves identifying the potential toxic effects of COPCs and selecting or developing toxicity reference values (TRVs). Toxicity reference values are issued by a variety of national and international agencies for the purpose of characterizing risks or potential risks associated with exposure to environmental contaminants. For non-carcinogenic chemicals, the TRV is the daily dose that is deemed tolerable or acceptable (i.e., safe). For carcinogenic chemicals, the TRV is referred to as slope factor (SF) (relating to exposure dose) or unit risk (UR) (relating to exposure concentration, typically in air or, in some cases, in water).

Toxicological reference values should be summarized for all identified COPCs for each route of exposure. This section of the report could also include a brief summary of the key health concerns associated with exposure to elevated levels of each contaminant, discuss both cancer and non-cancer endpoints, and differentiate effects by exposure route (oral, dermal, inhalation), as appropriate. The toxicity assessment provides an estimate of how much exposure to a chemical can occur without any anticipated adverse health effects (threshold effect chemicals) or establishes a relationship between the exposure dose of a chemical and the probability of developing an adverse health effect (non-threshold effect chemicals). Threshold chemicals are assumed to have a threshold level below which no adverse effects are anticipated to occur. The health effect can be either non-cancerous or cancerous (e.g. arsenic). In contrast, non-threshold chemicals are considered to have some level of risk for effects at any level of exposure. Typically carcinogenic chemicals are non-threshold chemicals but some non-carcinogens can also act as non-threshold (e.g. lead).

THRESHOLD ACTING CHEMICALS

Toxicological reference values are expressed as tolerable daily intakes (TDIs) or reference doses (RfDs) for the oral pathway, and as reference concentrations (RfCs) for the inhalation pathway. An RfD is an estimate of daily oral exposure, while an RfC is an estimate of continuous inhalation exposure for the human population (including susceptible subgroups) that is likely to be without an appreciable risk of adverse effects during a lifetime. Reference dose and concentration are generally derived for chronic exposure periods (i.e., several years to a lifetime). However, if shorter exposure periods are possible, sub-chronic RfDs and RfCs may need to be used in the HHRA to assess intermittent or seasonal exposures (Appendix G).

NON-THRESHOLD CHEMICALS

An SF is the upper-bound increased cancer risk from a lifetime exposure to a chemical. A UR is the upper-bound incremental lifetime cancer risk estimated, which results from continuous exposure to an agent at a concentration of 1 $\mu g/m^3$ in air. Health Canada (2010a, 2010c) provides further information on how TRVs are developed.

For HHRAs, most TRVs can be obtained from published sources. Occupational exposure limits are not applicable in an HHRA conducted for an assessment of a project, as occupational values are limited to a workplace scenario. Health Canada's TRVs should be employed where available; however, values can be obtained from other regulatory agencies. Sources for TRVs may include the following:

- Health Canada
- US EPA's (2016) Integrated Risk Information System;
- World Health Organization
- National Institute for Public Health and the Environment (Netherlands)
- Agency for Toxic Disease Registry
- California Environmental Protection Agency

The supporting documentation for any TRV should be reviewed to ensure that it is current and appropriate, and rationale for the selection of TRVs for each COPC should be provided.

7.4 RISK CHARACTERIZATION

Risk characterization is the quantification of the estimated risks resulting from exposure to COPCs predicted as a result of activities from a proposed project. Risks are quantified by comparing the estimated exposure (Section 7.2) with the TRV for each COPC (Section 7.3). The risk characterization stage includes a determination of whether or not the predicted risks are below recommended target levels where risks are determined to be acceptable or essentially negligible. Both carcinogenic and non-carcinogenic risks are calculated using the equations provided in Appendix E and presented in Health Canada's (2010a) guidance document. For threshold chemicals, a hazard quotient (HQ) is calculated (Appendix E); while for non-threshold chemicals, risk is generally characterized as an incremental lifetime cancer risk (ILCR) (Section 7.4.2 and Appendix G). Health Canada (2010a) provides additional technical information about calculating risks.

Hazard quotients and/or ILCRs should be clearly documented for each COPC and receptor, and provided for each of the potential exposure pathways identified in the problem formulation for each assessment scenario. The information should be clearly tabulated, with worked examples provided and all input parameters identified. Risk estimates should also be presented for the total exposure from all exposure routes by summing the HQs or ILCRs of the individual exposure pathways, as appropriate (where COPCs affect similar target organs and have similar mechanism of action).

7.4.1 THRESHOLD CHEMICALS

For HHRAs, a target HQ of 1.0 is considered applicable for threshold chemicals, assuming all potential exposure media and pathways are considered, including background dietary intake. Where an HHRA evaluates only project-related exposures (excluding background estimated daily intake for sources not related to the project, including consumer products, food, air, and water), a target HQ of less than or equal to 0.2 will be deemed negligible to compensate for the exposures not taken into consideration. It is not appropriate to apply a target HQ of 1.0 to assess the incremental increases associated with the project alone scenario, as the total exposure may exceed that target and result in unacceptable risks. However, to assess the potential risks associated with human exposure to contamination, the HQ generated for the baseline plus project scenario for each COPC identified should be used as much as possible. Background exposures should include all exposures not associated with the proposed project (including retail foods as applicable). An HQ less than 1.0 for a particular COPC (baseline plus project scenario) indicates that risks associated with this contaminant are likely negligible. If the HQ is greater than 1.0 for the baseline plus project scenario (i.e., the predicted exposure concentration is greater than the TRV), further consideration is warranted regarding either reducing uncertainty in the risk assessment or identifying mitigation measures to reduce exposure to contaminants for which calculated HQs were higher than 1.0.

The estimated exposure and TRV must be presented in the same units and reflect the same time frame (e.g., chronic exposure or sub-chronic exposure).

It is critical that the estimated exposure and TRV have the same units and reflect the same time frame (i.e., acute, sub-chronic, chronic). For example,

- a chronic exposure with units of mg/kg bw/d should be divided by a TDI also with units of mg/kg bw/d;
- a sub-chronic exposure concentration with units of mg/m^3 should be divided by a sub-chronic tolerable concentration also with units of mg/m^3.

The TDI or RfD represents a conservative estimate of human dose that will not cause any health effects in the vast majority of the population. The extent by which an RfD must be exceeded before health effects could occur is expected to vary on a chemical-specific basis. Risk characterization should discuss the predicted adverse effects depending on the calculated results and chemical's characteristics.

Where HQs are less than the target value of 1.0 or 0.2, the risk assessment may conclude that there are no anticipated human health risks associated with current and future exposure to COPCs (assuming that exposures have been conservatively estimated and that the calculations are accurate). Where the target values are exceeded, it is recommended that the HHRA be refined to reduce uncertainty and/or that mitigation measures are identified that would reduce exposure to COPCs in media which result in unacceptable risks.

7.4.2 NON-THRESHOLD CHEMICALS

For chemicals with no threshold for effects (typically carcinogens), only exposures to COPCs that result from project activities are considered in the determination of the ILCR (i.e., project alone scenario). The estimated exposure (amortized as appropriate) is multiplied by the appropriate SF or UR to derive a conservative estimate of the potential ILCR associated with that exposure. The ILCR calculation is presented in Appendix E.

Where pathway-specific SFs or URs exist, the risks via oral plus dermal exposure and the risks via inhalation should be estimated separately. In other cases, the cancer risks posed by simultaneous inhalation/dermal/oral exposure should be estimated where an oral TRV is used to estimate potential risk associated with the three exposure routes.

An ILCR represents the increased probability of an individual developing cancer over a lifetime as a result of exposure to a carcinogenic COPC associated with the project (i.e., incremental risk above the typical background risk that exists). Health Canada (2012) considers the acceptable ILCR to be one in one hundred thousand (1×10^{-5}). An ILCR greater than 1×10^{-5} is indicative of a potential health concern that should be more closely examined. An ILCR of less than 1×10^{-5} is considered essentially negligible (Health Canada 2012). Since carcinogenic risks are expressed in incremental terms, presenting ILCRs for the project alone scenario allows for the evaluation of risks independent of background exposure. However, the evaluation of overall risk (background exposure plus incremental risks) will help to understand how the project plus baseline may impact human health. If other approved projects in the area are known to also produce carcinogenic COPCs, it is recommended to assess the cumulative effects by calculating incremental risks taking into account exposure to all developments.

7.4.3 CHEMICAL MIXTURES

Unless there is compelling science of other factors for additivity, for simultaneous exposure to multiple COPCs, non-cancer HQs should be assumed to be additive and summed for those chemicals which have similar target organs/effects/mechanisms of action. Where the estimated total HQ is less than or equal to 1.0, these risks will be deemed negligible. Risk estimates for chemicals with unique target organs/effects/mechanisms of action should be shown individually (Health Canada 2010a).

For carcinogens with the same target organ and form of cancer, the risks should be assumed to be additive and summed. The total cancer risk in such cases will be deemed to be “essentially negligible” where the estimated total ILCR is less than or equal to 1×10^{-5} (Health Canada 2010a).

An additive effect occurs when the combined effect of several chemicals is equal to the sum of the effects of each individual chemical (i.e., where more than one COPC is expected to impact the same target organ via the same mechanism of action).

7.4.4 BASELINE SCENARIO EXCEEDING ACCEPTABLE RISK LEVELS

In situations where the baseline health risks are calculated to exceed acceptable risk levels, these exceedances should be noted for the specific COPC, exposure pathways, and relevant human receptors (e.g., baseline exposure to cadmium already exceeds an acceptable HQ of 1.0 for individuals in an area or a region before the predicted project effects are added). All assumptions and uncertainties should be explicitly described in order to evaluate the level of conservatism used in the assessment and whether additional work may be needed to refine the baseline risks (e.g., more sampling of environmental media, more realistic exposure scenarios [e.g., assuming less than 100% of time spent at the LSA/RSA]). However, it is not uncommon, particularly when projects are proposed in northern locations, that levels of some metals (e.g., cadmium, lead, mercury) are already high in certain species (e.g., caribou, moose, fish, geese) or in their organs (e.g., liver, kidney) being utilised as country foods. If the calculated risk levels are substantially higher than acceptable levels (e.g., moderate consumption of this country food is predicted to exceed the 90th percentile total dietary exposure estimates), the proponent may need to inform local health authorities. Various provincial and territorial departments and agencies have a role in monitoring foods that may be contaminated and issuing consumption advisories. Health Canada can also provide general information about the development and communication method of consumption advisories.

If the project is expected to result in increased levels of any COPC that exceed acceptable risk levels in the baseline scenario, additional sampling is usually suggested in order to ensure the protection of human health, with a focus on species and organs predicted to have increased levels of COPCs. Sampling at both on-site and external reference locations would contribute to establishing reliable background levels and serve as benchmarks for future assessments. Such information would help identify additional mitigation/risk management options (e.g., additional treatment of discharged water, dust management plans, reduction in diesel-powered equipment), with a focus on exposure pathways most likely to be impacted.

7.5 UNCERTAINTY AND SENSITIVITY ASSESSMENT

The evaluation of uncertainty and variability associated with risk estimates, and sensitivity of risk estimates to changes in key parameters used in modelling exercises are critical parts of the HHRA process. Uncertainty and sensitivity analyses should be performed for all risk estimates (either qualitatively or quantitatively).

7.5.1 UNCERTAINTY

Since all risk assessments in predictive assessments are based on models, the uncertainty of estimates, which can result from insufficient or estimated data, inaccurate transmission or uptake factors or coefficients, depends on the accuracy of the model parameters and assumptions. Uncertainty originates also from an incomplete understanding of the processes being modelled and the necessary simplifications of reality by computer models. This uncertainty does not necessarily invalidate the model output or the risk estimate; however, acknowledging and describing the uncertainty and the quality of the input assumptions help with interpreting risk estimates. A certain degree of uncertainty can be reduced given sufficient time and resources to expand and refine the data available (Health Canada 2010a). The uncertainty assessment can be either qualitative or quantitative depending on the level of complexity of the risk assessment and the types of uncertainties identified (Health Canada 2010a).

Data gaps and/or assumptions made when conducting the assessment may lead to an underestimation or an overestimation of potential human health risks, or result in the development of inappropriate risk management strategies and/or monitoring/follow-up programs. In order to account for these data gaps and assumptions, a discussion on uncertainties and variability in all stages of the HHRA framework must be included in the uncertainty section.

Uncertainty can be reduced in a more detailed risk assessment, where additional data are available. The conservatism employed in the HHRA also builds upon the conservatism inherent in predicting chemical concentrations in environmental media, which serve as primary inputs to the risk assessment. However, not all assumptions are equally conservative, and the uncertainty associated with the assessment needs to be identified in the report. Some sources of uncertainty related to multimedia HHRAs include, but are not limited to, the following:

- Baseline data collected to characterize baseline exposures (e.g., the quality and quantity of samples);
- Use of data from other sources or locations to represent baseline conditions at the site in the absence of baseline data;
- Input data (and the inherent variability of these inputs) used for environmental fate and transport modelling (e.g., wind speed and wind direction for air modelling, stream flow rates for surface water modelling);
- Use of modelled data to predict future project-related emissions (e.g., air quality models, surface water dispersion models), extrapolation based on existing data;
- Application of surrogate data for one type of country food on other types of country foods for which there are no data (e.g., use of moose tissue COPC data to represent COPC concentrations in all large mammals);
- Use of models to predict COPC concentrations in other environmental media (e.g., aerial deposition modelling to predict future soil and vegetation concentrations, uptake models to predict future contaminant concentrations in aquatic biota from surface water and sediment concentrations);
- Use of generic receptor characteristics to estimate exposure doses (e.g., food consumption rates, exposure frequencies);
- Representativeness of statistical values (e.g., 95% UCLM, maximum concentrations) used to represent COPC concentrations;
- Limited knowledge about future land use and future receptor exposures;
- Confidentiality issues associated with Indigenous knowledge regarding historical, current, and potential future land use, including preferred country foods collection areas;
- Human exposure to multiple chemicals;
- Extrapolation of TRVs from animal studies to humans; and
- Lack of TRVs for certain chemicals.

The overall uncertainty in the risk assessment and degree of confidence and conservatism (i.e., over – or underestimation of risk) should be discussed. Key assumptions that may affect the degree of conservatism should be highlighted. Where appropriate, large data gaps should be identified, along with recommendations for addressing these data gaps as appropriate (e.g., additional baseline sample collection, future monitoring programs to validate model predictions) (Health Canada 2010a).

7.5.2 SENSITIVITY ANALYSIS

A sensitivity analysis helps identify the effect of parameters and/or assumptions of the models used on the results of the risk analysis. This procedure can effectively increase the level of confidence in the risk assessment if changes in highly uncertain or variable parameters result in minor changes in the risk estimates. Conversely, the sensitivity analysis can identify parameters that influence the results the most and alert the risk assessor to the need for additional data collection, which could significantly increase the degree of confidence in the risk assessment.

Mitigation measures may also be recommended in other components of the assessment. These measures typically focus on operational or institutional measures that can be taken to reduce exposure or remove exposure pathways. It would be important to consider the risks if such mitigation measures should fail during the sensitivity analysis and the impact this may have on human health. For example, the HHRA evaluates human exposure to airborne dusts assuming that the proposed mitigation (e.g., watering unpaved roads and waste rock piles) will reduce dust levels by 90%. However, if sprayers are unable to achieve this level of reduction during particularly dry periods, the predicted human health risks may be underestimated. Provision of estimated risk with and without mitigation measures will enable reviewers to identify the required level of effort.

7.6 DETERMINATION OF THE EXTENT OF THE EFFECTS AND RISKS

The results of the HHRA should be summarized to determine the extent of the predicted effects. The COPCs with an HQ or ILCR greater than the acceptable aforementioned target values should be carried forward to establish the risks they may pose to human health. It is not necessary to determine the effects for COPCs for which HQs or ILCRs are below acceptable target values since these COPCs would be considered to present a negligible health risk.

The HHRA component of an assessment uses a specific approach to classify residual effects and assess risks because several criteria (i.e., geographical extent, duration, frequency, and reversibility) are already integrated into the risk estimates and, therefore, are not considered independent variables. Extent of the effects and risks to human health in an environmental assessment can be evaluated based on the following:

- Context, which focuses on the comparison of the risk estimates of the assessment scenario with those of the baseline scenario to evaluate changes that could be attributed to the proposed project or the project in combination with future developments;
- The magnitude of the risks, as indicated by the HQ and/or ILCR calculations; and
- The degree of conservatism and uncertainty in the analysis.

If mitigation is being recommended to address unacceptable risks, the determination of the level of risk should discuss the level of risk both prior to and after applying mitigation.

The items that should be considered when determining the level of risk are presented in Table 7.2.

TABLE 7.2: Determination of Human Health Risks

Residual effects criteria	Analysis criteria	Discussion
Context	Comparison of assessment scenarios (e.g., baseline scenario with baseline plus project and future developments)	For each assessment scenario, determine whether risk estimates of the baseline plus project scenario and future development scenario are higher than those of the baseline scenario and by how much.
Magnitude	Identification of key exposure pathways	Identify key pathways that are contributing to the risk estimates and describe relative contributions to help understand the degree of conservatism and uncertainty in the risk estimates.
	Magnitude of risk estimates and cumulative risk estimates in the assessment scenarios (e.g., project alone, baseline plus project, baseline plus project plus any reasonably foreseeable future development)	For each assessment scenario, identify affected receptors and receptor locations, and determine the magnitude of the estimated risk level compared to the baseline level for the COPC in question. Some considerations that may influence the evaluation of the magnitude of an effect include: • natural variability, normal fluctuations or shifts in baseline conditions (e.g., if the population has already been adversely affected by other physical activities or natural change, vulnerable sub-populations) • scale at which magnitude is considered (e.g., the percentage of a population affected may represent 80% at the local level and 5% at the regional level)
Prediction confidence and uncertainty	Conservatism and uncertainty in predictions	Identify the sources of uncertainty related to the predictions and the deposition rates used to predict COPC concentrations (e.g., uncertainty related to emission rates and mitigating factors). Indicate whether the prediction is most likely an overall overestimate, underestimate or reasonable estimate of COPC concentrations.
	Conservatism in the exposure assumptions	Identify the sources of uncertainty in the exposure assumptions used in the exposure dose calculations (e.g., whether an average or a reasonable maximum consumption rate was used in the exposure estimates).
	Conservatism in the TRVs	Identify the sources of uncertainty in the key studies used to derive the TRV and the uncertainty factors that were applied to derive the TRV.
Determination of an overall risk		Provide an overall rating of risks based on the ratings and uncertainties described above (negligible, low, moderate or high), which includes a rationale. Discuss this rating.

7.7 RECOMMENDATIONS

The report should include recommendations for mitigation of exposure that may lead to unacceptable health risks for the assessed phases of the project and for environmental media that may be impacted. Mitigation aims to eliminate, reduce or control adverse environmental effects related to a project. Where high risk is identified in the HHRA, the mitigation measures that may be required should be described. Risk estimates should also be presented with and without any proposed mitigation measures. It is recommended that all projects minimize environmental emissions to the greatest extent possible using measures that are technically and economically feasible; hence guidelines should not be considered as "pollute-up-to" levels. Health Canada adheres to the principles of the Canada-Wide Standards, and its successor the Air Quality Management System, which include Keeping Clean Areas Clean and Continuous Improvement (CCME 2000), and expects proponents to act as good corporate citizens to minimize the effects of their projects on human health and the environment. Health Canada collaborates with the CCME on developing and updating the Canadian Environmental Quality Guidelines (CCME 1999). For example, CCME's Air Management Committee work includes recommending priorities for cooperative action on existing and emerging air quality issues and overseeing the implementation of the collective aspects of the Air Quality Management System. In 2012, CCME issued a guidance document on air zone management, which provides guidance on how provinces and territories can implement air zone management in order to help achieve the Canadian Ambient Air Quality Standards, drive continuous improvement, and keep clean areas clean.

Health Canada expects that appropriate mitigation and monitoring measures will be proposed, particularly in the following situations:

- Potential risk is predicted for human health.
- There is a high degree of uncertainty regarding the project's effects on the environment.
- The project contribution leads to a large deterioration in environmental quality over and above the existing levels.
- The project is proposed for a region that is already experiencing environmental pressures from other development projects.

The environmental assessment documentation should provide information on the mitigation measures addressing operable pathways where unacceptable risks have been identified. Examples of mitigation measures include dust suppression, replacement of combustion engines with electric motors, treatment of runoff water, and clearing of areas before they are flooded. If possible, the report should include details of modelling studies, and any monitoring or past experience with a mitigation strategy to outline the anticipated effectiveness of a specific measure. If substantial baseline contamination exists at or near the project sites, the potential for environmental contamination introduced by project-related activities may necessitate consideration of additional mitigation measures.

8. MONITORING

8.1 WHEN AND WHY TO MONITOR

For some projects, monitoring during the various project phases may be advisable to determine the accuracy of the HHRA predictions, help verify whether the assumptions used were appropriate, and assist with implementing or modifying mitigation measures (i.e., adaptive management). The extent of monitoring will depend on the project activities, predicted health effects, and predicted COPC concentrations—particularly those predicted to approach unacceptable risk levels. Monitoring activities may be a part of a follow-up program to validate that predictions made during the assessment are accurate and/or to determine the effectiveness of the mitigation measures.

Health Canada encourages the monitoring of contaminants in environmental media to validate that predictions are accurate (in particular when risk estimates approach acceptable levels and there is concern that they may have underestimated risks) and/or determine the effectiveness of the mitigation measures. Also, it is good practice to monitor specific chemicals when elevated risk linked to their emissions is predicted or reported, or the project is predicted to contribute significantly to the elevation of COPC levels above baseline concentrations. Monitoring is also advisable if there are Indigenous peoples present and/or public concerns expressed about the possibility of adverse health effects. Monitoring would help evaluate whether or not the models used in the HHRA resulted in an underestimation or overestimation of health risks. If monitoring results show levels of COPCs higher than predicted, it is recommended to redo the HHRA and reassess the effectiveness of the proposed mitigation measures.

The questions below can be used as a starting point to assist in determining if monitoring of a project's effects on COPC levels in environmental media is appropriate:

- Is there public concern about the possibility of contamination?
- Are local people more sensitive to project-related contaminants (e.g., due to pre-existing health conditions such as asthma, or as a result of exposure to other projects in the area such as multiple industries emitting air pollutants resulting in increased rates of acute respiratory effects)?
- Is there uncertainty about one or more predicted COPC concentrations in any of the environmental media as a result of project activities?
- Based on predicted COPC levels in environmental media, are there likely exceedances of HQ/ILCR targets or are HQs/ILCRs close to the targets?
- Are baseline contaminant levels already elevated or is there avoidance of certain areas due to a fear of contamination?
- Is there a history of contamination in areas close to the proposed project area?
- Is there potential for new COPCs to be released, emitted or mobilized as a result of project activities? (New COPCs are chemicals not on the domestic substances list under the *Canadian Environmental Protection Act,* 1999 or chemicals with limited data on uptake into country foods species and/or human health effects.)
- Are new technologies and/or chemicals being used during the project activities?

8.1.1 MONITORING PLANS

Key considerations in developing a monitoring plan include the following:

- Which COPCs to monitor in which environmental media;
- When to start monitoring;
- Where to monitor;
- The frequency and duration of monitoring;
- What types of equipment should be used for monitoring (e.g., real-time vs. bulk sampling, passive vs. active samplers);
- What specific country foods to monitor (e.g., specific vegetation/berries, fish, terrestrial species) and what tissues of each to sample (e.g., muscle or organs of mammals, whole fish or fillets);
- What detection limits are appropriate for each COPC and tissue types;
- Timing of sample collection, including seasonal variations (e.g., the availability of country foods is seasonally dependent; air concentrations may vary seasonally at receptor locations due to wind and other factors); and
- A communication and action plan.

For any monitoring plan, it is important that a representative number of samples be collected during different seasons, at locations where potential human receptors may be affected, with special emphasis on worst-case locations for exposure. Upon request, Health Canada may also make available information or knowledge on the siting of monitoring stations for regions with an appreciable human presence (e.g., permanent residences, seasonal or temporary residences).

If monitoring indicates that predicted COPC concentrations were underestimated or overestimated or if the project scope has changed, the risk assessment may be refined to take into consideration new available data (as part of adaptive management). Assuming that the conditions remain the same, the risk assessment update should focus on the exposure pathways responsible for the highest risks. Additional or alternate mitigation options may be considered at this stage if there is a concern that risks were underestimated or conditions have changed such that there is a potential for unacceptable human health risks.

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APPENDIX A: GLOSSARY

Term	Definition
Assessment scenarios	Baseline (without the project), project alone, baseline plus project, and baseline plus project plus any reasonably foreseeable future development (cumulative scenario).
Country foods	Any food that is trapped, fished, hunted, harvested or grown for subsistence or medicinal purposes, outside of the commercial food chain, and that is not regulated under the *Food and Drugs Act*, including, but not limited to, the following: • Aquatic and terrestrial fauna fished, trapped, hunted, and/or harvested (e.g., game animals and birds, fish, and seafood) for domestic consumption • Produce harvested from naturally occurring sources (e.g., berries, seeds, leaves, roots, and lichen) • Plant tissues (e.g., roots, bark, leaves, and seeds) ingested for medicinal or other uses (e.g., teas) • Produce (e.g., fruits, vegetables, and fungi) grown in gardens and/or home orchards • Aquatic and terrestrial fauna (and its by-products) produced for domestic consumption but not for market (e.g., ducks, chickens or other fowl, eggs, and dairy products).
Environmental media	Air, soil, sediment, surface water, groundwater, and terrestrial and aquatic flora and fauna.
Exposure pathway	Any means by which a human receptor can become exposed to a potential contaminant of concern in an environmental medium, and includes inhalation, ingestion, and dermal contact.
Human receptor	In general, in an assessment, it is any person who is currently or may in the future be impacted by project activities.
Human receptor location	Within the context of an assessment, locations where people may be present either temporarily (e.g., recreational activities) or permanently (residences, communities).
Indigenous peoples	Also referred to as Aboriginal peoples, and include people who identify as First Nation, Inuit, and/or Métis residing on and off-reserve.
Multi-media HHRA	Human health risk assessment that evaluates human exposure to contaminants in more than one environmental medium (e.g., air, soil, water, and foods).
Non-threshold chemical	A chemical that is considered to have some level of risk of adverse effects at any level of exposure greater than zero. Typically, non-threshold chemicals are considered to be carcinogens.
Project phase	Construction, operation, decommissioning/closure, and/or post-closure
Responsible authority	Federal department or agency responsible for conducting an EA. Under the *Canadian Environmental Assessment Act, 2012*, it is the Canadian Environmental Assessment Agency, Canadian Nuclear Safety Commission, the National Energy Board or the federal authority prescribed by regulations that performs regulatory functions.
Retail food/commercial food	Any food that is sold commercially for purchase such as at a grocery store.
Sensitive human receptor	Any person who may have heightened sensitivity to exposure to contamination and can include individuals with acute or chronic health conditions (e.g., asthma, diabetes), infants/toddlers, pregnant women, and elders.
Threshold chemical	Chemical for which no adverse human health effects are expected to occur below a certain dose. Threshold chemicals are typically non-carcinogenic chemicals.

APPENDIX B: CHECKLIST FOR A HUMAN HEALTH RISK ASSESSMENT AS PART OF A PROJECT ASSESSMENT

✓	Item	Section in EA	Comments
	1. Does the report include a description of baseline conditions at the project location, including current air, soil, groundwater, surface water, and country foods contaminant concentrations (as applicable)?		
	2. Has the proposed project been adequately described in terms of physical setting by maps and site plans?		
	3. Does the problem formulation include a statement of goals (e.g., to establish whether potential human risks exist in order to determine whether or not the project can proceed)?		
	4. Have the scope and complexity of the risk assessment been adequately described (i.e., qualitative vs. quantitative risk assessment)?		
	5. Is the complexity of the assessment appropriate? Appropriateness can be based on: • The nature of the project (particularly if it is a new and/or large undertaking that involves or may involve in the future appreciable levels of contamination); • The number and types of contaminants involved; • The availability of applicable screening criteria and toxicity data; • The estimated/predicted exposure concentrations; • The number and complexity of pathways for human exposure; • The location and sensitivity of human receptors; • The quality of the baseline project data; • The desire by the proponent/responsible authority for additional justification/precision regarding the potential risks associated with a proposed project; and • The level of public concern.		
	6. Has adequate baseline data been collected? In particular, have contaminants expected to be produced during project activities been analysed for baseline concentrations in the appropriate media?		
	7. Has a conceptual model been presented and does it appear to be complete? It should include the following: • All potential contamination sources • All potential COPCs • All critical receptor groups • All potential exposure pathways		
	8. Were the information sources for determining the COPCs identified (e.g., from other similar projects, documents from the specific sector)?		
	9. Have all relevant COPCs been identified? Is there sufficient information to determine whether or not all relevant COPCs for all project phases have been identified?		
	10. Has a rationale been provided for all omitted COPCs?		

✓	Item	Section in EA	Comments
	11. Are there contaminants that have been identified but not further evaluated in the HHRA? Has a rationale for their exclusion been provided?		
	12. Have the locations and proximity of all existing and potential future human receptors to the project site been identified?		
	13. Have the most sensitive current and potential future human receptors been identified along with their locations and proximity to the project site (sensitive receptors would include schools, daycares, hospitals, and retirement homes)?		
	14. Have the COPCs been evaluated using the most conservative guideline available? If not, has a rationale been provided?		
	15. Have the maximum predicted COPC concentrations in all relevant media been used in the HHRA? If not, has justification been provided for using other values?		
	16. Have all relevant current and potential future exposure pathways for the most sensitive receptors been described? Is there sufficient information to determine that all relevant exposure pathways for the most sensitive receptors have been described?		
	17. Have all incomplete exposure pathways been described and a rationale provided for their exclusion?		
	18. Have data gaps related to existing information been identified? If so, is there any information about how these gaps will be reduced/ minimized (e.g., monitoring, follow-up)?		
	19. Have potential COPC concentrations been calculated for the various environmental media?		
	20. Have the COPCs concentrations been compared to federal and/or provincial guidelines/standards to determine which contaminants will be further evaluated in the HHRA?		
	21. Have the most sensitive potential receptors been assessed in the HHRA (i.e., residential toddler for non-carcinogens and lifetime receptor for carcinogens)? If not, has a rationale been provided for the use of less sensitive receptors?		
	22. Have the expected exposure durations been identified for all relevant receptors (e.g., 24 hours/day, 365 days/year for residents)? Has justification been provided for using exposure durations lower than the maximum values (e.g., 24 hours/day, 90 days/year for a seasonal cabin user)?		
	23. If applicable, have cumulative effects associated with all other potential projects been included in the HHRA as a future development scenario?		
	24. Were the uncertainties identified within each stage of the HHRA described either qualitatively or quantitatively?		
	25. Were the pathways, sensitive receptors, and COPCs that had the greatest impact on the results of the risk assessment identified and associated uncertainties discussed in particular? For example, has the exceedance of the total ILCR of 1×10^{-5} been discussed in the risk assessment along with associated uncertainties?		
	26. Where the uncertainties evaluated to determine whether some of them are unacceptable (for ex. due to the extent of variation) and if more information is required to accurately determine the potential risk to humans?		

✓	Item	Section in EA	Comments
	27. Have conclusions regarding the risks posed by the identified risks, and a conclusion about the acceptability of the identified uncertainties and data gaps been provided?		
	28. Were any specific assumptions or professional judgments made earlier in the risk assessment reiterated in the conclusions of the risk assessment with appropriate justification?		
	29. If non-negligible risks or unacceptable uncertainties/data gaps were identified, have related recommendations been included. (e.g., need for additional data collection, proposed mitigation, monitoring, follow-up or other risk management measures)?		
	30. Have worked examples for one carcinogen and one non-carcinogen for each applicable pathway been included? Do these examples provide a step-by-step method showing the risk calculations and how the results were derived?		
	31. Has a follow-up program been developed to evaluate the accuracy of the predictions in the HHRA?		
	32. If potentially non-negligible risks have been identified, has a risk management plan—describing appropriate mitigation and/or monitoring to ensure that there are no non-negligible risks to humans—been prepared?		
	33. If there is no risk management plan, have mitigation measures intended to reduce the risks to acceptable levels been described? Has monitoring been proposed in the absence of mitigation? If not, has adequate justification been provided to explain why mitigation and/or monitoring are not necessary?		
	34. Has adaptive management been considered should the predicted risks do not align with monitoring/follow-up results?		
	35. If applicable, is the monitoring program sufficiently detailed for Health Canada to review its adequacy?		

APPENDIX C: ADDITIONAL INFORMATION ABOUT SCREENING CHEMICALS OF POTENTIAL CONCERN

The following presents technical information that can be used to screen chemicals for further assessment in the HHRA. These steps should be completed in order to ensure that potential COPCs are not unnecessarily excluded from further assessment:

- Identify the chemicals that can be emitted or produced by the project and their potential to be present in environmental media.
- Identify chemicals that may be elevated in baseline conditions.
- Rationalize/exclude innocuous chemicals.
- Identify chemicals that bioaccumulate or biomagnify.
- Identify appropriate screening criteria.
- Compare chemical concentrations to screening criteria.
- Select COPCs to be included in a quantitative HHRA.

IDENTIFY CHEMICALS RELEASED AS A RESULT OF THE PROJECT

The types of chemicals that may be elevated by project activities are dependent on the specific project. The COPCs to be characterized for a proposed project are often detailed in the project-specific terms of reference or environmental impact statement guidelines. The baseline data collected for the HHRA should reflect the types of chemicals (e.g., metals, dioxins/furans such as polychlorinated dibenzodioxins [PCDDs] and polychlorinated dibenzofurans [PCDFs], petroleum hydrocarbons [PHCs], VOCs associated with vehicle emissions, polycyclic aromatic hydrocarbons [PAHs], and process chemicals such as hydrogen cyanide for gold extraction) for each medium to be evaluated in the multi-media assessment.

IDENTIFY CHEMICALS THAT MAY BE ELEVATED IN BASELINE CONDITIONS

An inventory of all sources of emissions and potential chemicals that may increase as a result of the proposed project should be used as the starting point in the determination of COPCs. Table C.1 provides some examples of typical contaminants by project activity type and/or industrial sector; however, this is not an exhaustive list nor is it a substitute for professional judgement. A specific list should be identified for each stage of each project (i.e., construction, operation, decommissioning, and post-closure, if applicable).

TABLE C.1: Examples of Typical Contaminants of Potential Concern by Activity Type/Industrial Sector

Industry	Sub-sector	Potential contaminants
Construction and transportation		Dependent on types of construction vehicle or mode of transportation. For vehicles burning fossil fuels, associated contaminants may include PAHs, metals, and trace elements (e.g., arsenic, copper, lead, manganese, sulphur, zinc), and fine particulate matter (i.e., $PM_{2.5}$ and VOC[1]).
Electric power generation and transmission	Hydro-electric	Methylmercury (methylation process occurring during the inundation of reservoirs).
	Nuclear	Radionuclides[2].
Mining (general), extraction, and smelting	Aluminium	Metals (particularly aluminium based on local geology), fluorides, PAHs, and PCDDs/PCDFs in smelting.
	Coal	PAHs, total suspended particulates (TSP), PM_{10}, and $PM_{2.5}$.
	Gold	Chromium, arsenic, mercury, cadmium, cyanide, PAHs, and PCDDs/PCDFs (smelting).
	Mixed metals	Metals and trace elements (depending on the content of ore and the natural environment), PAHs, PCDDs/PCDFs (smelting), TSP, PM_{10}, and $PM_{2.5}$.
	Nickel	Metals including nickel, aluminium, cadmium; PAHs, and PCDDs/PCDFs (smelting).
	Ferrous/steel	Metals including manganese, tin, and zinc; PAHs, PCDDs/PCDFs, TSP, PM_{10}, and $PM_{2.5}$ (smelting).
	Uranium	Metals and trace elements (e.g., arsenic, cadmium), radionuclides[2] including uranium, radium 226, lead 210, and polonium 210.
Petroleum production, distribution, processing, and storage	Bitumen (oil sands) extraction	PAHs, PHCs, heavy metals, and trace elements (e.g., aluminum, arsenic, cadmium, chromium, iron, lead, mercury, molybdenum, nickel, selenium, sulphur, vanadium, zinc).
	General	Metals (e.g., lead), PHCs, benzene, toluene, ethylbenzene, xylenes, methyl tert-butyl ether, and PAHs.
	Liquid natural gas	Methane and other VOCs.
	Coal gasification	Metals, PAHs, and PHCs.

[1] Exposure to volatile chemicals and particulate matter is generally assessed under *Guidance for Evaluating Human Health Impacts in Environmental Assessment: Air Quality* (Health Canada 2016).

[2] Exposure to radionuclides is assessed under *Guidance for Evaluating Human Health Impacts in Environmental Assessment: Radiological Impacts* (Health Canada 2017a).

EXCLUDE INNOCUOUS CHEMICALS

Several naturally occurring chemicals—such as calcium, magnesium, and potassium—are included in routine analytical chemical analyses. Government agencies often do not develop regulatory criteria for these and other innocuous chemicals (Health Canada 2010a). The rationale for exclusion of these chemicals should be recorded so that the decision process is understood, transparent, easily retraced, and verifiable.

IDENTIFY CHEMICALS THAT BIOACCUMULATE OR BIOMAGNIFY

Consumption of country foods is often identified as a potential exposure pathway in an HHRA; however, there are currently no guidelines protective of this exposure pathway. Therefore, chemicals emitted by the proposed project that tend to bioaccumulate or biomagnify up the food chain should be retained as COPCs in the multi-media HHRA, unless sufficient evidence is available to exclude them. Examples of chemicals that bioaccumulate or biomagnify include, but are not limited to, polychlorinated biphenyls, certain pesticides, dioxins/furans, and mercury/methyl mercury.

Chemicals that are hydrophobic (tendency to accumulate in lipids rather than water) and resistant to degradation have the potential to bioaccumulate and possibly biomagnify in food webs. The criteria used to assess bioaccumulation potential are typically bioconcentration factors (BCFs), bioaccumulation factors (BAFs), and the log octanol-water partition coefficient (K_{ow}). Bioaccumulation factors are preferred over BCFs or log K_{ow} because they take into account uptake through all pathways including diet, which is an important consideration for identifying biomagnifying chemicals. Bioconcentration factors, typically measured under controlled laboratory conditions, only consider uptake from water via dermal and respiratory surfaces and may not be indicative of a chemical's potential to biomagnify. Log K_{ow} is the poorest predictor of bioaccumulation and potential biomagnification as it only expresses a chemical's inherent potential to accumulate in fatty tissues (i.e., lipophilicity) and does not consider any metabolic transformation or dietary accumulation. However, published data for log K_{ow} and BCFs are generally much easier to obtain from the literature than are BAFs.

Various agencies in Canada, the United States and elsewhere have published criteria for identifying bioaccumulative and persistent organic chemicals for the purpose of screening new and domestic chemicals for hazard. For example, Environment Canada (2003) considers chemicals with a BAF or BCF greater than 5,000 or a log K_{ow} greater than 5 to have persistent and bioaccumulative properties. The HHRA should provide rationale, with references, for all assumptions made in the report.

IDENTIFY APPROPRIATE SCREENING CRITERIA

To be considered appropriate for the purpose of screening COPCs, criteria should be risk-based, scientifically defensible, up-to-date, and acceptable to the governing regulatory agencies (Health Canada 2010a). Federal screening criteria available from Health Canada (e.g., guidelines for Canadian drinking water quality) and the Canadian Council of Ministers of the Environment should be considered. Screening criteria from provincial and territorial jurisdictions should also be considered to satisfy potential provincial and territorial stakeholders and also where federal criteria do not exist.

Where no Canadian jurisdiction has established a human health-based environmental quality guideline for a particular chemical, criteria derived by agencies in other jurisdictions (e.g., US EPA) may be used, with appropriate adjustments (Health Canada 2010a). A detailed rationale for the use of the criterion should be provided. The rationale should include the basis for the criterion and any adjustments that were made to the criterion.

Currently, human health-based screening criteria for sediments are not available. Therefore, sediment concentrations may be screened against available human health-based soil quality criteria for residential/parkland use for a direct sediment contact scenario. Only the human health-based criteria for the relevant corresponding sediment exposure pathways should be considered. For example, if incidental ingestion of and dermal contact with sediments are the only operable pathways, then human health-based soil quality criteria for dermal contact and incidental ingestion would be considered relevant sediment screening values. When using soil quality criteria to screen sediment data, it is important to note that the criteria were developed based on exposure factors specific to human interactions with soil. Given that human exposure to sediment is typically different from human exposure to soil (e.g., potentially greater dermal adherence and ingestion rates), soil quality criteria may not be sufficiently protective of human health for some sediment exposure scenarios, particularly when people are expected to visit an area regularly to participate in high-contact activities. In this case, site-specific sediment screening values may be derived.

Currently, there is also a lack of human health-based screening criteria for foods that may live and grow in areas impacted by the proposed project, such as vegetation (berries and plants) and the animals that consume them (e.g., wild game). For this pathway, the COPCs that have a tendency to bioaccumulate or biomagnify up the food chain, or those identified for other media (e.g., soil, surface water, air) should be retained for the food ingestion pathways.

For any chemical without a screening criterion, professional judgement should be used to determine whether or not that chemical should be retained as a COPC; rationale should also be provided in the report on a chemical-specific basis for any chemical that may be elevated but is excluded from the HHRA. Consideration should be given to the toxicity of the chemical and comparison to similar chemicals for which criteria are available.

Where available, the concentrations should also be compared to regional background concentrations based on local geochemistry. Information on background concentrations for a limited number of inorganic elements is available from the Geological Survey of Canada and some provincial sources (Health Canada 2010a). Because some concentrations may be naturally elevated, this step involves consideration of background data to determine if the predicted concentrations are a natural anomaly. Rationale for inclusion or exclusion of any chemicals should be provided in the HHRA.

COMPARE CHEMICAL CONCENTRATIONS TO SCREENING CRITERIA

Contaminants of potential concern are chemicals of which concentration(s) may become elevated in environmental media as a result of project-related activities, and which have the potential for adverse health impacts based on documented scientific evidence or suspected causal relationships. Therefore, a screening approach is recommended for chemicals whereby a comparison to environmental quality guidelines is applied. The baseline plus project scenario is typically used to identify COPCs as it estimates the potential future environmental conditions that would exist if the proposed project is approved and proceeds. A chemical should be retained as a COPC if the predicted maximum concentration in the baseline plus project scenario exceeds the selected regulatory criterion. If the predicted baseline plus project scenario concentrations are below the appropriate health-based screening criterion for all applicable environmental media, then it can be excluded as a COPC. However, chemicals identified as of special concern (for example, methylmercury in hydroelectric projects) as part of the project scope should be retained as COPCs and evaluated in the HHRA.

If chemical concentrations are considered elevated but not directly related to the project in question, the risk assessor may still consider retaining the chemical as a COPC in the HHRA to provide a thorough evaluation of health risks associated with the proposed project.

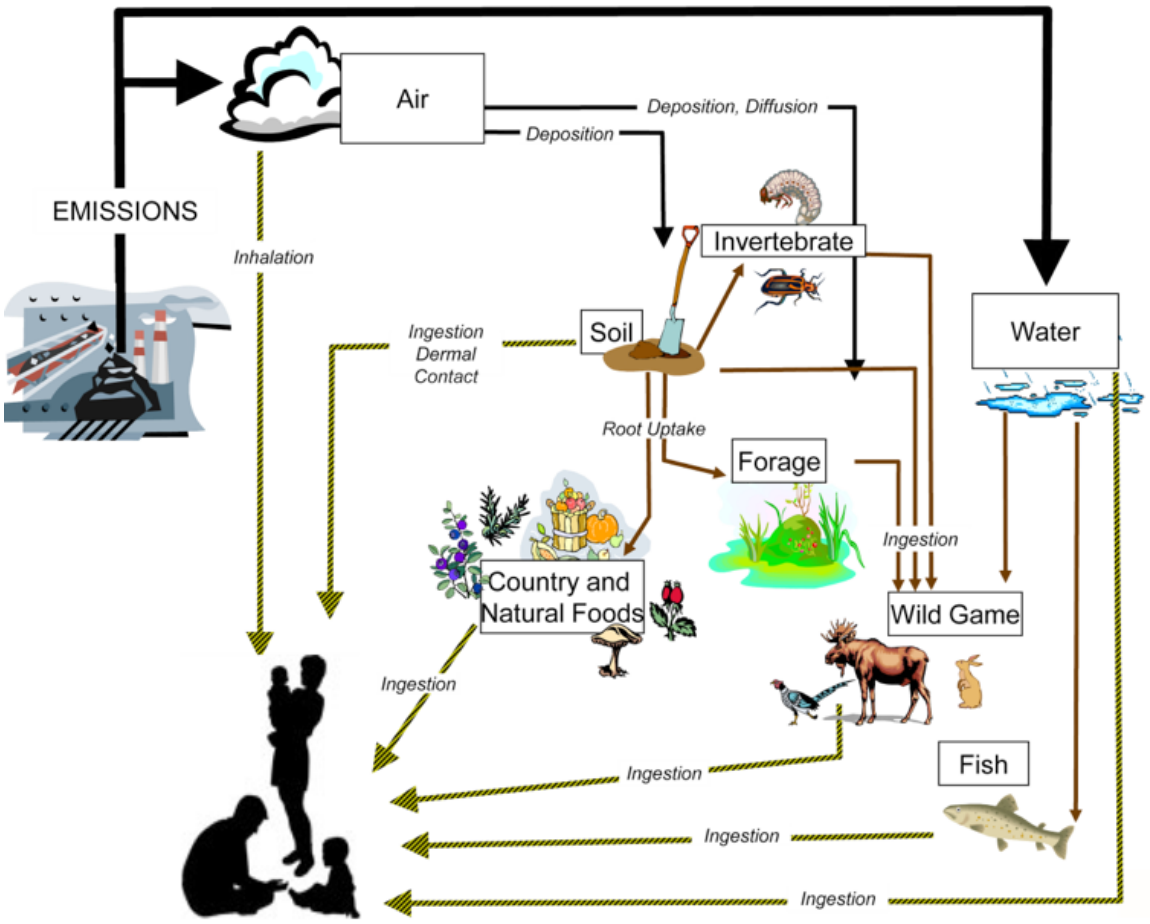
SELECT COPCS TO BE INCLUDED IN A QUANTITATIVE HHRA

The final list of COPCs and the media they have been retained in should be summarized. Decisions made to eliminate chemicals should also be documented clearly throughout the screening process. As multi-media HHRAs evaluate the exposure to a chemical from multiple pathways, a chemical retained as a COPC in one medium should also be evaluated in other media to obtain an estimate of potential risks associated with total exposure. For instance, since airborne contaminants, which may accumulate over time, will result in deposition to soil, sediment, surface water, and foods, the HHRA would include consideration of all potentially impacted media, not just air.

Consideration should be given to the potential toxicity of each COPC and whether sufficient toxicity information is available to effectively assess potential risks. If a chemical identified as a COPC lacks a TRV from a regulatory agency, the HHRA should identify whether toxicity data are available to create a de novo TRV (Health Canada 2010a). This should be discussed in the toxicity assessment and the uncertainty sections of the risk assessment.

Approaches to assess volatile chemicals and particulate matter are discussed in *Guidance for Evaluating Human Health Impacts in Environmental Assessment: Air Quality* (Health Canada 2016).

APPENDIX D: EXAMPLE OF A CONCEPTUAL SITE MODEL



Source: Intrinsik Corp.

APPENDIX E: EQUATIONS FOR EXPOSURE ASSESSMENT AND RISK CHARACTERIZATION

Recommended general equations for dose estimation are presented below; not all variables are necessarily represented in every equation.

INADVERTENT INGESTION OF CONTAMINATED SOIL

The predicted intake of each contaminant via ingestion of contaminated soil is calculated as follows:

$$\text{Dose (mg/kg bw/day)} = \frac{C_S \times IR_S \times RAF_{Oral} \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_S = concentration of contaminant in soil (mg/kg)

IR_S = receptor soil ingestion rate (kg/d)

RAF_{Oral} = relative absorption factor from the gastrointestinal tract (unitless)

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

BW = body weight (kg)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

DERMAL ABSORPTION FROM CONTAMINATED SOIL

The predicted intake of each contaminant via dermal contact with contaminated soil is calculated as follows:

$$\text{Dose (mg/kg bw/day)} = \frac{[(C_S \times SA_H \times SL_H) + (C_S \times SA_O \times SL_O)] \times RAF_{Derm} \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_S = concentration of contaminant in soil (mg/kg)

SA_H = surface area of hands exposed for soil loading (cm^2)

SL_H = soil loading rate to exposed skin of hands (kg/cm^2-event)

SA_O = surface area exposed other than hands (cm^2)

SL_O = soil loading rate to exposed skin other than hands (kg/cm^2-event)

RAF_{Derm} = relative dermal absorption factor (unitless)

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

BW = body weight (kg)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

INHALATION OF FUGITIVE DUST

EXPOSURE ESTIMATION FOR CHEMICALS WITH TRVS EXPRESSED AS TDIS

The predicted intake of each contaminant via inhalation of dust entrained into the air is calculated as follows:

$$\text{Dose (mg/kg bw/day)} = \frac{C_S \times P_{Air} \times IR_A \times RAF_{Inh} \times D_1 \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_S = concentration of contaminant in soil (mg/kg)

P_{Air} = particulate concentration in air (kg/m)

IR_A = receptor air intake (inhalation) rate (m /day)

RAF_{Inh} = relative absorption factor by inhalation (unitless)

D_1 = hours per day exposed/24 hours

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

BW = body weight (kg)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: P_{Air} may be directly measured or may be estimated. Alternately, C_A = airborne concentration (mg/m) may be directly measured, negating the prediction of airborne concentration using C_S and P_{Air}. D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

EXPOSURE ESTIMATION FOR CHEMICALS WITH TRVS EXPRESSED AS TOLERABLE CONCENTRATIONS

The predicted intake of each contaminant via inhalation of dust entrained into the air is calculated as follows:

$$\text{Dose (mg/m}^3\text{)} = \frac{C_S \times P_{Air} \times RAF_{Inh} \times D_1 \times D_2 \times D_3 \times D_4}{LE}$$

Where:

C_S = concentration of contaminant in soil (mg/kg)

P_{Air} = particulate concentration in air (kg/m^3)

RAF_{Inh} = relative absorption factor by inhalation (unitless)

D_1 = hours per day exposed/24 hours

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: P_{Air} may be directly measured or may be estimated. Alternately, C_A = airborne concentration (mg/m^3) may be directly measured, negating the prediction of airborne concentration using C_S and P_{Air}. D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

INHALATION OF VOLATILE CHEMICALS

EXPOSURE ESTIMATION FOR CHEMICALS WITH TRVS EXPRESSED AS TDIS

The predicted intake of COPCs via inhalation of vapours is calculated as follows:

$$\text{Dose (mg/kg bw/day)} = \frac{C_A \times IR_A \times RAF_{Inh} \times D_1 \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_A = concentration of contaminant in air (mg/m^3)

IR_A = receptor air intake (inhalation) rate (m^3/day)

RAF_{Inh} = relative absorption factor by inhalation (unitless)

D_1 = hours per day exposed/24 hours

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

BW = body weight (kg)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: C_A may be directly measured or may be estimated from soil-borne or groundwater-borne concentrations of volatile COPCs. D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

EXPOSURE ESTIMATION FOR CHEMICALS WITH TRVS EXPRESSED AS TOLERABLE CONCENTRATIONS

The predicted intake of COPCs via inhalation of vapours is calculated as follows:

$$\text{Dose (mg/m}^3\text{)} = \frac{C_A \times RAF_{Inh} \times D_1 \times D_2 \times D_3 \times D_4}{LE}$$

Where:

C_A = concentration of contaminant in air (mg/m^3)

RAF_{Inh} = relative absorption factor by inhalation (unitless)

D_1 = hours per day exposed/24 hours

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: C_A may be directly measured or may be estimated from soil-borne or groundwater-borne concentrations of volatile COPCs. D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

INGESTION OF CONTAMINATED DRINKING WATER

The predicted intake of each contaminant via ingestion of contaminated drinking water is calculated as follows:

$$\text{Dose (mg/kg bw/day)} = \frac{C_w \times IR_w \times RAF_{Oral} \times D_2 \times D_3 \times D_4}{BW \times LE}$$

Where:

C_w = concentration of contaminant in drinking water (mg/L)

IR_w = receptor water intake rate (L/d)

RAF_{Oral} = relative absorption factor from the gastrointestinal tract (unitless)

D_2 = days per week exposed/7 days

D_3 = weeks per year exposed/52 weeks

D_4 = total years exposed to site (for assessment of carcinogens only)

BW = body weight (kg)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: C_w may be directly measured or may be estimated from soil-borne or groundwater-borne concentrations of COPCs. D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

INGESTION OF CONTAMINATED FOODS (PRODUCE, FISH, GAME, ETC.)

The predicted intake of each contaminant via ingestion of contaminated food is calculated as follows:

$$\text{Dose (mg/kg bw/day)} = \frac{(\sum [C_{Foodi} \times IR_{Foodi} \times RAF_{Orali} \times D_i]) \times D_4}{BW \times 365 \times LE}$$

Where:

C_{Foodi} = concentration of contaminant in food *i* (mg/kg)

IR_{Foodi} = receptor ingestion rate for food *i* (kg/day)

RAF_{Orali} = relative absorption factor from the gastrointestinal tract for contaminant *i* (unitless)

D_i = days per year during which consumption of food *i* will occur

D_4 = total years exposed to site (for assessment of carcinogens only)

BW = body weight (kg)

365 = total days per year (constant)

LE = life expectancy (years) (for assessment of carcinogens only)

Note: Concentrations of contaminants in foods can be measured directly or can be predicted. D_3 and D_4 should be evaluated on a chemical-specific basis, and amortization requires consideration, particularly when taking into account exposures posed by chemicals with developmental (fetal) effects.

WORKED EXAMPLE FOR THE ESTIMATION OF A TODDLER RESIDENT'S EXPOSURE DOSE OF BARIUM

In this example, the problem formulation indicated the following potential exposure pathways for barium associated with the post-closure phase of a project where barium concentrations in soils were predicted to be elevated: incidental ingestion of soil, dermal contact with soil, inhalation of soil dust, ingestion of drinking water, and ingestion of berries from the site. Sample calculations of exposure doses are shown for a toddler (7 months to 4 years inclusively) resident living in the area predicted to be impacted by the proposed project. This example provides calculations for the project-only scenario (i.e., it does not include background exposure).

EXPOSURE CONCENTRATIONS

- C_s = 300 mg/kg in soil
- C_{gw} = 0.02 mg/L in groundwater (drinking water)
- C_{Foodb} = 0.03 mg/kg in berries

The toxicity assessment did not identify a TRV for dermal exposure; therefore, a relative dermal absorption factor of 0.1 was applied (Health Canada 2010c).

RECEPTOR CHARACTERISTICS

Receptor characteristics are based on typical values specified by Health Canada (2012), which should be updated if new values are published:

- Body weight (*BW*) = 16.5 kg
- Soil ingestion rate (IR_S) = 0.08 g/d
- Water ingestion rate (IR_W) = 0.6 L/d
- Air inhalation rate (IR_A) = 8.3 m^3/d
- Exposed skin surface area – hands (SA_H) = 430 cm^2
- Exposed skin surface area – arms (SA_A) = 890 cm^2
- Exposed skin surface area – legs (SA_L) = 1690 cm^2
- Soil loading to skin – hands (SL_H) = 1 x 10^{-4} g/cm^2/event
- Soil loading to skin – arms and legs (SL_A and SL_L) = 1 x 10^{-5} g/cm^2/event

Site-specific toddler berry ingestion rates were determined by conducting a survey for this example.

- Berry ingestion rate (IR_b) = 30 g/day

Exposure doses are calculated below.

INCIDENTAL SOIL INGESTION

$$\text{Dose (mg/kg/d)} = \frac{C_s \times IR_s \times RAF_{Oral} \times ET}{BW}$$

$$\text{Dose (mg/kg/d)} = \frac{300\ mg/kg \times 0.08\ g/d \times 0.001\ kg/g \times 1 \times 1}{16.5\ kg}$$

Dose = 1.5×10^{-3} mg/kg/d from incidental soil ingestion

DERMAL CONTACT WITH SOIL

$$\text{Dose (mg/kg/d)} = \frac{C_s \times \Sigma (SA_i \times SL_i) \times RAF_{Derm} \times EF \times ET}{BW}$$

$$\text{Dose (mg/kg/d)} = \frac{300\ mg/kg \times (430\ cm^2 \times 1 \times 10^{-4}\ g/cm^2/event + 2580\ cm^2 \times 1 \times 10^{-5}\ g/cm^2/event) \times 0.001\ kg/g \times 0.1 \times 1 \times 1)}{16.5\ kg}$$

Dose = 1.3×10^{-4} mg/kg/d from dermal contact with soil

INHALATION OF FUGITIVE DUST

$$\text{Dose (mg/kg/d)} = \frac{C_S \times IR_A \times RAF_{Inh} \times ET}{BW}$$

$$\text{Dose (mg/kg/d)} = \frac{0.000001\ mg/kg \times 8.3\ m^3/d \times 1 \times 1}{16.5\ kg}$$

Dose = 5.0×10^{-7} mg/kg/d from inhalation of fugitive dust

INGESTION OF GROUNDWATER

$$\text{Dose (mg/kg/d)} = \frac{C_{gw} \times IR_W \times RAF_{GIT} \times ET}{BW}$$

$$\text{Dose (mg/kg/d)} = \frac{0.02\ mg/L \times 0.6\ L/d \times 1 \times 1}{16.5\ kg}$$

Dose = 7.3×10^{-4} mg/kg/d from groundwater ingestion

INGESTION OF BERRIES

$$\text{Dose (mg/kg/d)} = \frac{C_b \times IR_b \times RAF_{GIT} \times ET}{BW}$$

$$\text{Dose (mg/kg/d)} = \frac{0.03\ mg/kg \times 0.03\ kg/d \times 1 \times 1}{16.5\ kg}$$

Dose = 5.5 x 10^{-5} mg/kg/d from berry ingestion

Total ingestion exposure dose = 1.5 x 10^{-5} + 1.3 x 10^{-6} + 0.073 = 0.073 mg/kg/d
Total inhalation exposure dose = 0.05 mg/kg/d
Total exposure dose = 1.5 x 10^{-5} + 1.3 x 10^{-6} + 0.073 + 0.05 = 0.12 mg/kg/d

BW = body weight (kg)
CF_{Foodi} = concentration of contaminant in food type "*i*"' (mg/kg)
C_{gw} = concentration of contaminant in groundwater (mg/L)
C_S = concentration of contaminant in soil (mg/kg)
EF = exposure frequency (events/d)
ET = exposure term (unitless)
IR_A = air inhalation rate (m^3/d)
IR_b = berry ingestion rate
IR_{Foodi} = ingestion rate of food type "*i*" (kg/d)
IRS = soil ingestion rate (kg/d)
IR_w = water ingestion rate (L/d)
RAF_{Oral} = relative absorption factor from the gastrointestinal tract (unitless)
RAF_{Inh} = relative absorption factor for inhalation (unitless)
RAF_{Derm} = relative dermal absorption factor (unitless)
SA_i = exposed skin surface area for body part "*i*" (cm^2)
SL_i = soil loading to skin for body part "*i*" (kg/cm^2/event)

RECOMMENDED GENERAL EQUATIONS FOR RISK CHARACTERIZATION

HAZARD QUOTIENT

$$HQ = \frac{\text{Estimated Exposure (µg/kg bw/day)}}{\text{TDI (µg/kg bw/day)}}$$

or in the case of airborne contaminants with a tolerable air concentration in units of µg/m^3:

$$HQ = \frac{\text{Air Concentration (µg/m}^3\text{)} \times \text{Fraction of Time Exposed}}{\text{Tolerable Air Concentration (µg/m}^3\text{)}}$$

INCREMENTAL LIFETIME CANCER RISK

$$ILCR = \text{ILifetime Average Daily Dose } (\mu\text{g/kg bw/d}) \times \text{Cancer Slope Factor } (\mu\text{g/kg bw/d})^{-1}$$

or in the case of airborne contaminants with a unit risk value in units of (µg/m^3)$^{-1}$:

$$ILCR = \text{Air Concentration } (\mu\text{g/m}^3) \times \text{Fraction of Time Exposed} \times \text{Cancer Unit Risk } (\mu\text{g/m}^3)^{-1}$$

APPENDIX F: HUMAN RECEPTOR CHARACTERISTICS

Health Canada has identified five age groups[1] into which the physical characteristics of the human population should be classified for most risk assessments (Health Canada 2010a):

- Infant (0 to 6 months inclusive)
- Toddler (7 months to 4 years inclusive)
- Child (5 years to 11 years inclusive)
- Teen (12 years to 19 years inclusive)
- Adult (20 years to 80 years inclusive)

Exposure characteristics typically include, but are not limited to, the following:

- Body weight
- Soil/sediment ingestion rate
- Air inhalation rate
- Water ingestion rate
- Exposed skin surface area
- Soil/sediment loading to exposed skin
- Food ingestion rates
- Frequency and duration of exposure

Although default human receptor characteristic values are often used in HHRAs, receptor characteristics and exposure parameters used to quantify the exposure should ideally be based on site-specific information to provide for a more realistic estimation of risks. If site-specific data are not available, typical exposures for the general Canadian population and Indigenous peoples provided by Health Canada (2012) may be used. If Canadian data are not available, other sources of exposure factors may be found from international jurisdictions such as the US EPA.

Typical receptor characteristics are summarized in Table F.1 below; however, not all information that may be required for an HHRA in an environmental assessment is summarized in this table. Where additional sources are used to characterize receptor characteristics, such as food consumption patterns and exposures while swimming, references should be provided in the report, and justification should be given for any assumptions based on professional judgement (e.g., time spent in specific locations).

[1] This division into five age groups is currently under revision.

TABLE F.1: Recommended Human Receptor Characteristics

Receptor characteristics	Units	Infant	Toddler	Child	Teen	Adult	Source (as cited in Health Canada 2012)
Age		0 to 6 months	7 months to 4 years	5 to 11 years	12 to 19 years	≥ 20 years	Health Canada 1994
Age group duration	year	0.5	4.5	7	8	60	Based on an 80-year lifespan
Canadian general population							
Body weight	kg	8.2	16.5	32.9	59.7	70.7	Richardson 1997
Soil ingestion rate	kg/day	0.00002	0.00008	0.00002	0.00002	0.00002	CCME 2006; Wilson Scientific and Meridian 2006; MassDEP 2002
Inhalation rate	m^3/day	2.2	8.3	14.5	15.6	16.6	Allan et al. 2008 Allan et al. 2009
Water ingestion rate	L/day	0.3	0.6	0.8	1.0	1.5	Richardson 1997
Time spent outdoors	h/day	1.5[a]	1.5[a]	1.5[a]	1.5[a]	1.5[a]	Richardson 1997
Skin surface area							
Hands	cm^2	320	430	590	800	890	Richardson 1997
Arms (upper and lower)		550	890	1,480	2,230	2,500	
Legs (upper and lower)		910	1,690	3,070	4,970	5,720	
Total body		3,620	6,130	10,140	15,470	17,640	
Soil loading to exposed skin							
Hands	kg/cm^2/event	1×10^{-7}	1×10^{-7}	1×10^{-7}	1×10^{-7}	1×10	Kissel et al. 1996, 1998
Surfaces other than hands		1×10^{-8}	1×10^{-8}	1×10^{-8}	1×10^{-8}	1×10^{-8}	

Source: adapted from Health Canada's guidance document (2012)

[a] Data not available; however, time spent outdoors may be assumed to be equivalent to that of adults if the infant, toddler or child is assumed to be accompanied by a parent or guardian during outdoor activity.

APPENDIX G: EVALUATING HUMAN HEALTH RISKS FOR CHRONIC AND LESS-THAN-CHRONIC EXPOSURES TO CHEMICALS

1. INTRODUCTION

This appendix highlights the fundamentals of Health Canada's current approach regarding the evaluation of cancer and non-cancer health risks from exposure to chemicals present at a location impacted by a proposed project, where health effects in an assessment are predicted to be related to chronic (or lifetime) and/or less-than-chronic (less-than-lifetime or short-duration) exposures. Other guidance documents on HHRA are listed on the Health Canada's website (**www.hc-sc.gc.ca/ewh-semt/contamsite/docs/index-eng.php**) and may be obtained by contacting the Contaminated Sites Division at **hc.cs-sc.sc@canada.ca**.

1.1 PURPOSE

The main purpose of this appendix is to provide general information about situations where human access to an area impacted by a proposed project may be infrequent and/or short in duration. Short-duration exposures at an impacted area may be associated with activities that occur over a relatively short period of time, such as seasonal activities (e.g., gardening, camping, occasional visits due to a remote location), or with certain occupational activities (e.g., construction and underground service installation). As a result of these short-duration exposure scenarios, health risks from short-duration exposure often need to be addressed in an assessment.

As health effects due to less-than-chronic (or less-than-lifetime) exposure may differ from those resulting from chronic or lifetime exposure, evaluating short-duration exposure risks may require different approaches. Health Canada's guidance documents on human health preliminary quantitative risk assessment (2012) and detailed quantitative risk assessment (2010a) mainly address chronic or lifetime exposures. In addition, Health Canada's *Interim Guidance on Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites* (2013) presents an updated cancer risk assessment approach that is applicable to both lifetime and less-than-lifetime exposures. However, this interim guidance is often mistaken as applicable to less-than-lifetime or short-duration exposures only.

1.2 BACKGROUND

The significance of exposure to chemical contaminants is typically characterized by comparison with TRVs derived from epidemiological or toxicological studies with comparable exposure patterns (i.e., chronic exposure compared to a TRV derived from a chronic study; short-duration exposure compared to a TRV derived from a short-duration study). Application of a TRV originally developed for a different exposure duration or pattern than the exposure of interest can introduce significant uncertainty in characterizing health risks.

Toxicological reference values for carcinogens are often based on the results of animal studies where the animals were exposed on a daily basis throughout their adult lifespan. Human exposures at an area impacted by a proposed project may mirror this pattern of exposure, but more often, exposure occurs for only a portion of the lifetime (i.e., exposure will be less than 24 hours/day, 365 days/year, 80 years/lifetime) or may be intermittent. Exposure may occur during childhood or in utero, which are life stages not represented in standard cancer bioassays. In the case of non-carcinogenic effects, most TRVs are for chronic exposure and are derived from studies involving long-term exposures of at least 6 months. An uncertainty factor is applied for those that are based on sub-chronic studies (i.e., more than 30 days and up to 10% of the lifespan, which is approximately 90 days for rodents) to extrapolate to chronic exposure. As with cancer risk, uncertainty in risk characterization of non-cancer effects arises when human exposures are of a much shorter duration.

The current practice of characterizing health risks associated with short-duration exposures involves averaging a short period of exposure or several intermittent short-duration exposures over a longer duration (i.e., mathematically spreading out a short-duration dose over a longer period). It assumes toxicity to be linearly proportional to the magnitude and duration of exposure. For example, it assumes an exposure of 365 μg/kg bw/day for 1 day, 36.5 μg/kg bw/day for 10 days, and 1 μg/kg bw/day for 365 days to be toxicologically equivalent, which could be untrue.

The following issues related to dose averaging (sometimes referred to as dose amortization) have been raised (Health Canada 2013):

- The potential for underestimating chronic health risks due to the practice of time averaging of exposures. This issue arises for both cancer and non-cancer risk assessments.
- The possibility of acute/subchronic non-cancer effects due to elevated exposures that exceed chronic TRVs have not been considered.
- The variability in sensitivity among different life stages may not have been fully considered. For example, the prenatal and neonatal periods, childhood, adolescence, and peri-menopausal and senior life stages as well as genetic predisposition are currently not included in standard adult animal bioassays used for deriving estimates of cancer potency.

2. CARCINOGENIC EFFECTS

This section describes approaches to assessment of cancer risks resulting from lifetime and less-than-lifetime exposures to chemical carcinogens evaluated in assessments of projects. These approaches (with supporting scientific analysis) as well as detailed guidance, equations, worked examples, and an analysis of dose-averaging issues in less-than-lifetime exposures for cancer effects are described in Health Canada's aforementioned interim guidance document.

2.1 LIFETIME EXPOSURE

2.1.1 NON-THRESHOLD CARCINOGENIC EFFECTS

The approach to cancer risk assessment varies according to the mode of action at the tumour site in question. Unless there is evidence to support a threshold mode of action, the current approach assumes a linear dose-response relationship at low doses (i.e., non-threshold). The ILCR is calculated as a product of the lifetime daily dose (or concentration) and the TRV, expressed as cancer slope factor (or inhalation unit risk).

The US EPA approach (2005b, 2005c) has been adopted as the interim default recommendation for contaminated site risk assessments, which is discussed further in Health Canada's (2013) interim guidance document. The ILCR can be estimated by summing the risks from each discrete life stage exposure period. The receptor who is exposed throughout all life stages in a lifetime is often referred to as a "composite" receptor. This approach takes into consideration potential varying sensitivity of the different life stages to the carcinogenic agent. Equation 1 below summarizes the recommended approach to cancer risk assessment:

$$\mathrm{ILCR} = \sum_i (\mathrm{SF} \times \mathrm{ADAF}_i \times \mathrm{LADD}_i)$$

Where:
SF = adult cancer slope factor (per mg/kg-day)
ADAF_i = age-dependent adjustment factor for life stage i
LADD_i = dose received during life stage i averaged over a lifetime (mg/kg-day)

For non-threshold carcinogens acting through a mutagenic mode of action[2], it is recommended that ADAFs be applied to the cancer slope factor (or inhalation unit risk) with exposure averaged over a lifetime to account for varying sensitivities of the age-specific exposure periods. Health Canada (2013) developed default ADAFs by adjusting the US EPA's ADAFs to be consistent with the age groups recommended by the Contaminated Sites Division. These default factors can be applied when age-specific cancer slope factors (or inhalation unit risks) or chemical-specific data are not available. When the mode of action is unknown or the burden of proof for a threshold mode of action has not been met, the Contaminated Sites Division recommends a non-threshold approach to cancer risk estimation; in this case, default age-specific adjustment is not recommended (i.e., ADAF = 1 for all life stages). However, for all carcinogenic effects, adjustments to the cancer slope factor can be made on a chemical-specific basis if supported by experimental data.

2.1.2 THRESHOLD CARCINOGENIC EFFECTS

When there are sufficient data to ascertain the mode of action at the tumour site in question and to conclude that the dose-response relationship is not linear at low doses, a threshold approach can be applied. For these threshold carcinogenic effects, the TRVs are expressed as tolerable daily intakes or concentrations, the intakes or concentrations to which it is believed that a person can be exposed daily over a lifetime without deleterious

[2] Please consult US EPA for the most updated list of carcinogens the US EPA has determined to act via a mutagenic mode of action for reference.

effects. Polychlorinated dibenzo-p-dioxins (commonly known as dioxins) provide an example of chemicals that are associated with threshold carcinogenic effects when exposures are high, whereas lower environmental concentrations are associated with other threshold non-carcinogenic responses. Human exposure is compared to these TRVs, where appropriate, to determine health risks.

2.2 LESS-THAN-LIFETIME EXPOSURE

2.2.1 NON-THRESHOLD CARCINOGENIC EFFECTS

The same risk equations (i.e., equation 1) and ADAFs apply to the estimation of cancer risks from less-than-lifetime exposure to a chemical that elicits non-threshold carcinogenic effect.

2.2.2 THRESHOLD CARCINOGENIC EFFECTS

Dose averaging of short-duration exposure (i.e., intermittent or seasonal activities, occasional visits, or certain occupational activities) for threshold carcinogenic effects can be performed in the same way as for chemicals with threshold non-carcinogenic effects appearing in Section 3.2 below. The carcinogenic short-duration TRV should match as closely as possible the duration of exposure at the impacted area; the TRVs must be developed for the same (or longer) duration as the exposure of interest. In addition, the anticipated effects of the dose-averaged exposure should remain biologically equivalent to the unadjusted exposure.

2.2.3 OTHER (NON-CARCINOGENIC) CONSIDERATIONS

It should be noted that short-duration exposures to carcinogenic agents may also elicit non-cancer health effects. For carcinogenic contaminants that may elicit both non-carcinogenic and carcinogenic health effects, the potential risk of non-carcinogenic effects need to be evaluated, in addition to risk from the carcinogenic endpoint. Please refer to Section 3.2 for the basic principles related to the assessment of the potential for non-cancer health effects from short-duration exposure.

3. NON-CARCINOGENIC EFFECTS

3.1 CHRONIC EXPOSURE

Information on evaluation of non-cancer effects from chronic exposures can be found in Health Canada's (2010a) guidance document.

3.2 LESS-THAN-CHRONIC EXPOSURE

Non-cancer effects from short-duration exposures can be evaluated for the most critical receptors accessing an impacted area. This evaluation includes consideration of the most sensitive (which is chemical-specific) and the most exposed relevant receptors/life stages. For chemicals with non-carcinogenic effects, a tiered approach to risk assessment is recommended, requiring higher levels of toxicological expertise as one moves to higher tiered assessments.

The initial screening step to assess chemicals with non-carcinogenic effects involves comparing an unadjusted daily exposure (i.e., without dose averaging and using an exposure term of "1") to a chronic TRV (which is based on the most sensitive endpoint and life stage, including developmental toxicity). For these chemicals, health effects are not anticipated if target risk levels are not exceeded. If target risk levels are exceeded, a more detailed evaluation (i.e., higher tiered assessment) is required to characterize the potential for health effects since the initial tier is a conservative screening approach designed to eliminate those chemicals which do not need to be considered further. This tiered approach is required in order to minimize costs associated with HHRAs and to ensure that appropriate attention is given to the chemicals which may be of concern and which may require additional work.

Higher tiered assessments compare exposure to short-duration TRVs developed for a similar (or longer) duration as the exposure scenario of interest. In the absence of short-duration TRVs, de novo TRVs of appropriate duration can be derived as per Health Canada's (2010a) guidance document. Alternatively, the assessment ends at the screening level (without dose averaging) using chronic TRVs. Higher tiered assessments may consider dose averaging in defining the exposure estimates, provided that appropriate, scientifically-based rationale is provided in the assessment report. Higher tiered assessments may also involve physiologically-based-pharmacokinetic modelling, which is not typically conducted in environmental assessments with the exception of very large and complex HHRAs. For example, when a multi-media HHRA that exceeds the target risk level is deemed overly conservative based on evidence from the scientific literature, the risk assessment can be further refined to reduce uncertainty. Like bioavailability testing, physiologically-based-pharmacokinetic modelling is one of the tools that can be used to further reduce uncertainty.

It is important that dose averaging does not underestimate the potential for threshold effects. The HHRA practitioner should not assume that the unadjusted daily short-duration exposure rate is toxicologically equivalent to the adjusted daily exposure rate (which is lower in value) over the long period, without a sound basis for doing so. Instead, exposure should be averaged over the total actual exposure period (e.g., if a person is exposed continuously for 20 days, the total dose should be averaged over 20 days and not over a period longer than 20 days) and compared to the appropriate TRV.

When dose averaging is being considered, the Health Canada's (2010a) guidance document recommends that it be supported by appropriate scientific rationale on a chemical-specific basis (with supporting TRVs—acute, subchronic, chronic) to indicate why the approach is adequately protective of human health for the exposure period considered. Firstly, the selected TRV should match as closely as possible the duration of exposure at the impacted area; the TRVs must be developed for the same (or longer) duration as the exposure of interest. Secondly, the anticipated effects of the dose-averaged exposure should remain biologically equivalent to the unadjusted exposure. In all cases, the risk assessor should provide an analysis of the relevant toxicological information in support of the TRVs applied or derived for assessment of short-duration exposures. Considerations should include the following:

- the mode of action of the chemical,
    - if toxicity is primarily driven by contaminant concentration, or
    - if toxicity is primarily driven by time-integrated exposure (concentration or dose multiplied by time or expressed as the area under the concentration-time curve), or
    - if toxicity is primarily driven by both the contaminant concentration and time-integrated exposure;
- the duration of effects (i.e., reversibility of the effect in between periods of exposure);
- the likelihood of exposure during a specific window of susceptibility or sensitive life stage; and
- the whole-body elimination half-life of the chemical or its active metabolites.

For some chemicals, sufficient toxicokinetic and/or toxicodynamic data may not be available to satisfy the requirements needed to adequately consider the chemical-specific feasibility of dose averaging. In such cases, an exposure term of "1" may be more appropriate.

Notwithstanding the phased approach above, an exposure term of "1" (i.e., no dose averaging) should be considered on a chemical-specific basis where developmental effects are concerned, as these effects may result from exposures during a particular window of susceptibility. For instance, where a chemical may have teratogenic effects (e.g., structural birth defects in a developing fetus exposed for just a few days of gestation), the elevated exposure over a short time period requires consideration to ensure that this exposure will not exceed a TRV for this endpoint, even for one day.

Sections 3.2.1 and 3.2.2 of this appendix provide a brief description of the higher tiered assessments that would be most applicable to HHRAs in assessments of projects.

3.2.1 SINGLE EXPOSURE

Short-duration TRVs with comparable exposure periods can be used for short-duration exposures. These less-than-chronic duration TRVs can be either obtained from other regulatory agencies or derived based on literature values as per Health Canada's (2010a) guidance document. If short-duration TRVs are not available, an analysis can be conducted based on relevant dose-response information from toxicity studies. It is also important to consider whether the short-duration exposure might elicit health effects at a later date, or earlier biological key events that might progress to these health effects.

3.2.2 REPEATED AND INTERMITTENT EXPOSURES

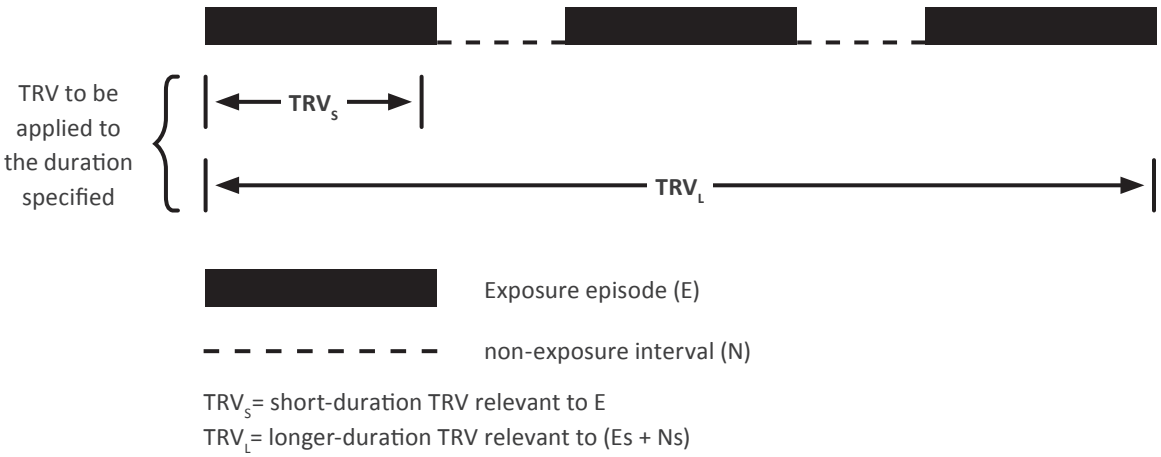
It is important to note that most TRVs intended for short-duration exposures are derived assuming one-time exposure and not repeated intermittent exposure events. Intermittent exposures can happen at impacted areas where individuals access the area multiple times, but for a short period each time. Repeated exposures may result in different health effects than a single exposure, particularly if the chemical can build up in the body over time. In order to evaluate the potential for threshold effects when exposures are intermittent,

it is recommended that the HHRA identify a suitable duration TRV that addresses intermittent exposures or compares the intermittent exposure to a suitable longer-duration TRV. A suitable longer-duration TRV would be one that has been developed for a duration equal to or longer than the combined exposure duration (i.e., sum of exposure episodes and non-exposure intervals). Dose averaging may not be appropriate here, particularly if the chemicals (or their active metabolites) have long elimination half-lives. In situations where dose averaging cannot be supported, the exposure scenario can be effectively treated as continuous, with daily exposure rate equal to the highest daily exposure rate among all exposure episodes. This type of risk assessment would require rationale from a toxicologist to support the TRV and anticipated exposure. As in the tiered approach above, if the assumption of chronic exposure is sufficient for the purpose of the HHRA, then further assessment would not be required.

In certain cases where the elimination half-life is relatively short compared to the intervals between exposure, if effects are reversible and recovery from these effects is rapid (i.e., recovery time shorter than the interval between exposures), it may be adequate just to apply a short-duration TRV to each discrete exposure period. Rationale (with references) should be provided in the HHRA. The potential for biological effects associated with each exposure episode to accumulate during non-exposure periods may have an impact on the assessment. In these situations, though the chemical (or its active metabolite) has been virtually eliminated before re-exposure occurs, biological changes will likely progress with repeated insults to cause adverse effects. The use of short-duration TRVs for HHRA of repeated exposures should therefore be justified on a case-by-case basis and include a discussion of uncertainties and the potential for over – or underestimating risks.

The analysis to be conducted for intermittent exposure is illustrated in the following figure, which highlights that the short-duration TRV selected should be consistent with the (repeated or intermittent) discrete exposure episode.

FIGURE G.1: Analysis Required for Selecting Appropriate TRVs for Assessing Non-Cancer Effects Associated with Intermittent Exposures.



Source: Haber et al., 2016.

4. EXAMPLES OF SHORT DURATION EXPOSURES

The following examples illustrate assessment of non-cancer effects for short-duration exposures. The appropriateness of dose averaging for non-carcinogenic effects needs to be determined on a chemical-specific basis because the mode of action, the duration of effects, and the whole-body elimination half-life of each chemical are different. The basic principles applied to dose averaging are summarized below.

1. If the chemical (or active metabolite) cannot be eliminated entirely before the next exposure, no dose averaging is supported.
2. If the chemical is eliminated entirely but its effect persists beyond the non-exposure interval, the mode of action determines if dose averaging can be supported:
    a) No dose averaging can be supported if toxicity is primarily driven by contaminant concentration.
    b) Dose averaging may be appropriate if toxicity is primarily driven by time-integrated exposure.

If a lifestage is particularly sensitive to the action of the chemical, this is also considered to be chemical-specific and has to be factored in. All such considerations need to be provided and fully referenced in the report.

A screening assessment is usually recommended at the outset, comparing the exposure (without dose averaging) to an appropriate chronic TRV. A TRV based on developmental effects can be considered a chronic TRV. If the HQ is greater than the target value (refer to Health Canada 2010a), then further assessment is required.

4.1 SCENARIO 1

5 days per week, 1 week per year, 35 years

This scenario involves an exposure episode of 5 days, which is repeated once a year for 35 years. In this case, a short-duration TRV (≥ 5 days) with no dose averaging would apply. Additional assessment is needed if the chemical (or active metabolite) cannot be eliminated entirely before the next exposure occurs (i.e., 1 year later) or the effect accumulates (and does not reverse) between exposures. Generally, provided that elimination mechanisms are not saturated, approximately 97% of the chemical present in the body would have been eliminated (often considered a complete removal) after a period of five whole body elimination half-lives has elapsed since the end of the last exposure. Since this exposure is repeated over 35 years, the additional assessment would involve a chronic TRV. Whether dose averaging is appropriate or not will depend on the factors indicated in Section 3.2.2 of this appendix.

4.2 SCENARIO 2

1 day every 2 weeks, 26 weeks per year, 60 years

This scenario involves a one-day exposure every other week. It is necessary to evaluate whether there is any effect resulting from this one-day exposure. Additional assessment is needed if the chemical (or active metabolite) cannot be eliminated entirely before the next exposure occurs (i.e., 2 weeks later) or the effect accumulates (and does not reverse) between exposures. Generally, a chemical can be considered completely eliminated from the body if the non-exposure interval is ≥ 5 x whole body elimination half-life. Since this exposure is repeated over 60 years, the additional assessment would involve a chronic TRV. Whether dose averaging is appropriate or not will depend on the factors indicated in Section 3.2.2 of this appendix.

4.3 SCENARIO 3

Daily exposure for 4 months in a lifetime

This scenario involves exposure to a carcinogenic chemical for a period of four months in a lifetime (e.g., during remediation activities). Health Canada (2013) provides further detail on the required assessment for this type of exposure scenario. In summary, it is necessary to evaluate whether there is a risk of developing cancer above the target ILCR resulting from the four-month exposure. However, even if there is no increased risk above the target ILCR level, it is necessary to consider whether the short-duration exposure to the carcinogen might also have non-carcinogenic effects associated with the short-duration exposure. In this case, a short-duration TRV may be identified and additional assessment is needed.