FEDERAL CONTAMINATED SITE RISK ASSESSMENT IN CANADA:

Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA)

VERSION 3.0

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PREFACE

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

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

This guidance document was developed to assist federal custodial departments with the consistent assessment of human health risks posed by federal contaminated sites across Canada. It defines the applicability of a preliminary quantitative risk assessment (PQRA) and provides a standardized methodology and human receptor characteristics to conservatively assess potential human health risks associated with exposure to contaminants resulting from historical activities at federal contaminated sites. This guidance is relevant in the early steps of the *DMF* but can also be used in the latter steps.

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

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

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

SUMMARY OF REVISIONS

Federal Contaminated Site Risk Assessment in Canada: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 reflects numerous revisions to text and tables relative to Version 2.0 (2012). Significant technical revisions to this document include the following:

- Changes to the document to reflect the fact that PQRA is no longer being used as a ranking tool under the Federal Contaminated Sites Action Plan (FCSAP) for funding eligibility;
- Addition of an explanation of when the use of PQRA-level risk assessment is appropriate for sites (not related to ranking of sites);
- Removal of the section on due diligence;
- Removal of the section on contaminated sites versus contaminated properties;
- Emphasis added to the problem formulation step, as this is a key component of HHRA, and further description of its scope and objectives;
- Expanded guidance on identification and screening of contaminants of potential concern (COPCs);
- Replacement of the problem formulation checklist with a conceptual site model (CSM) example;
- Expanded guidance on determination of exposure point concentrations in various environmental media;
- Changes in recommended human receptor characteristics: addition of sediment ingestion rates, removal of food ingestion rates and discussion of site-specific values;
- Additional information on the assessment of threshold and non-threshold effects;
- Updated guidance on combined exposure to multiple chemicals;
- Removal of tables of potency equivalence factors for carcinogenic polycyclic aromatic hydrocarbons and on toxic equivalency factors for dioxins, furans and certain polychlorinated biphenyls; this information is available in the updated version of the Health Canada guidance document for Toxicity Reference Values (HC, 2021); and
- Addition of a new appendix containing information on assessment of less-than-chronic exposures to chemicals at contaminated sites.

ABBREVIATIONS AND ACRONYMS

ADAFs	age-dependent adjustment factors
B[a]P	benzo[a]pyrene
BTEX	benzene, toluene, ethylbenzene and xylenes
CCME	Canadian Council of Ministers of the Environment
COPC	contaminant of potential concern
CSM	conceptual site model
DQRA	detailed quantitative risk assessment
ESA	environmental site assessment
FCSAP	Federal Contaminated Sites Action Plan
FIGQGs	Federal Interim Groundwater Quality Guidelines
GSC	Geological Survey of Canada
HC	Health Canada
HHRA	human health risk assessment
HQ	hazard quotient
ILCR	incremental lifetime cancer risk
LADD	lifetime average daily dose
PAHs	polycyclic aromatic hydrocarbons
PBPK	physiologically based pharmacokinetic
PCBs	polychlorinated biphenyls
PCDDs	polychlorinated dibenzo-*p*-dioxins
PCDFs	polychlorinated dibenzofurans
PHCs	petroleum hydrocarbons
$PM_{2.5}$	particulate matter with aerodynamic diameter equal to or smaller than 2.5 µm
PM_{10}	particulate matter with aerodynamic diameter equal to or smaller than 10 µm
PQRA	preliminary quantitative risk assessment
P/T	provincial/territorial
QA/QC	quality assurance/quality control
RAF	relative absorption factor
RPF	relative potency factor
SF	slope factor
TC	tolerable concentration
TCDD	tetrachlorodibenzo-*p*-dioxin
TDI	tolerable daily intake
TEF	toxic equivalency factor
TRV	toxicological reference value
UR	unit risk
US EPA	United States Environmental Protection Agency

1.0 INTRODUCTION

1.1 BACKGROUND

Human health risk assessments (HHRAs) are conducted to varying levels of detail and complexity, depending on the goals of the assessment, the extent of available data and the results or outcomes of the initial steps.

The uncertainties associated with a risk assessment can be reduced when reliable and sufficient data are available on the:

1) nature and extent of site contamination;
2) land uses and time-activity patterns;
3) chemical-specific toxicity; and
4) physical site conditions.

Data gaps in one or more of the above elements are not uncommon at contaminated sites. Since all risk estimates are, by nature, uncertain to some degree, professional judgement is required by risk assessors. For this reason, it is important that all assumptions in a risk assessment be supported by scientific rationale, noting uncertainties where they exist and their implications on the resulting risk estimates.

An HHRA is often an iterative process. This process may lead risk assessors and managers to identify and address data gaps and modify the original scope of the assessment, which in turn may result in the need for more data collection or a re-assessment of previous assumptions.

Although the methods to be used for an HHRA can be standardized somewhat, it is equally important that the level of detail and expenditure of resources are appropriate to the intended application of the assessment.

In the context of the Federal Contaminated Sites Action Plan (FCSAP), HC has described two different types of HHRA: **preliminary quantitative risk assessment (PQRA)** and **detailed quantitative risk assessment (DQRA)**.

The purpose of a **PQRA** is to quantify, on the basis of conservative assumptions, the degree of *potential* human health risks posed by the presence of contamination at a subject site. In certain cases, a PQRA may provide sufficient information to enable a risk management decision to be made. However, for more complex sites or to reduce uncertainties, a **DQRA** (HC, 2010a) is more commonly recommended. PQRAs and the more in-depth DQRAs are not always independent, but often represent incremental or progressive layers of an iterative HHRA process (from more simplified and conservative to more complex and refined). For further details on the relationship between and applicability of PQRAs and DQRAs, see **Section 1.3**.

Both PQRAs and DQRAs involve professional judgment based on relevant science and a clear scientific rationale. International, national and provincial/territorial (P/T) governmental agencies offer a wide variety of advice and direction regarding the conduct of HHRAs, and each risk assessor may access and rely on the available advice and guidance differently. This introduces variability within estimates of chemical exposures and risks. Standardized guidance was developed at the federal level to assist with the consistent assessment of potential risks posed by contaminated sites under federal custodianship across the country.

The original HC PQRA guidance was designed to rank sites in a consistent manner with regard to potential human health risks. However, since the results of a PQRA are no longer used within FCSAP to rank and prioritize federal sites for subsequent action and remedial funding, this guidance document has been updated in order to allow more flexibility at this assessment level (e.g., for exposure and risk estimates, the selection of exposure point concentrations or other input parameters could be more site-specific and based on available data). This document has also been updated to reflect more recent science.

PQRAs may be useful to conservatively identify sites where no further action is required for protection of human health, provided that sufficient and adequate environmental data are available to characterize the contamination at the site. Accordingly, completion of a PQRA is intended to provide custodial departments with an estimate of potential risks at a site and may help inform whether there are data gaps that need to be addressed prior to initiation of a DQRA, completion of a risk management plan or identification of risk-based decisions. However, if the results of the PQRA identify a potential for unacceptable human health risks, this does not necessarily imply that actual site conditions are unacceptable or that remediation is required. In such cases, a DQRA may allow for a more precise quantification of risks and a better assessment of actions that may need to be taken. The decision made in regard to the level of detail required for the HHRA will be site-specific. Even though the two forms of assessment are often iterative and the distinction between them becomes a matter of degree, HC has published both PQRA and DQRA guidance documents to support the FCSAP program and the needs of the custodians through all the steps of the program.

In addition to this guidance document, DQRA guidance (HC, 2010a) and other HC guidance documents (HC 2010b-g, 2013, 2017a-c, 2018, 2021), as well as guidance that may be published in the future, may be useful in completing a risk assessment. HC can be reached by email at **hc.cs-sc.sc@canada.ca** to request guidance documents or to request further support.

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

1.2 PURPOSE

This document defines the applicability of a PQRA and offers guidance for its completion in the specific context of FCSAP. It provides an overview of standard methodology required to quantitatively and conservatively assess potential chemical exposures and associated human health risks at federal contaminated sites, including standardized receptor characteristics.

The approaches presented here are designed specifically for the assessment of sites that are the property and/or the responsibility of federal agencies. For properties being divested to a private party or to P/T or municipal government agencies, or for assessments that address human health risks from off-site migration of contamination (e.g., to an adjacent P/T water body or neighbouring private property), HHRAs may have to be completed in accordance with P/T regulatory requirements. These local regulatory requirements may differ from the standardized methods described in this guidance document. When the assumptions, methods and interpretations being employed in such cases vary from those presented here, the differences should be noted in the risk assessment, particularly if they lead to divergence in HHRA conclusions.

Although the guidance offered here is prescriptive in nature, it is not designed or intended as a substitute for the professional judgment of a qualified and experienced risk assessment practitioner. It is recognized that many contaminated sites will present unique situations that are not specifically addressed in this document. HHRAs should be complete and address all relevant risks that may be associated with contamination at a site. The methods described below should not be viewed as a "black box" of equations and assumptions that negate the need for professional judgment. However, where possible and appropriate, the guidance provided here should be used. When it is determined that alternative or unique approaches are required, these must be sufficiently documented and described to enable a technical review of the risk assessment.

HC has noted a variety of issues in the conduct and reporting of HHRAs. These are summarized in **Table A1** of **Appendix A**. Risk assessment practitioners and site managers are encouraged to review this table, as these issues are the most common causes of delay in the HHRA technical review process.

HC's goals with respect to HHRA are to protect human health and to establish confidence that potential human health risks have been properly evaluated. HHRAs should be conducted and reported in a manner that allows for evidence-based decision making that is:

- **Transparent** – it is readily obvious what was done and why;
- **Reproducible** – all results can be reproduced by technical reviewers from the information and data contained in the report;
- **Defensible** – results can be defended scientifically and with confidence; and
- **Complete** – all relevant chemicals that may be found as a result of historical activities have been assessed in relevant environmental media; all receptors, exposure pathways and risks have been considered.

1.3 PRELIMINARY QUANTITATIVE RISK ASSESSMENT VERSUS DETAILED QUANTITATIVE RISK ASSESSMENT

While the terms PQRA and DQRA are sometimes used to describe distinct levels of risk assessment, they often represent incremental or progressive layers of an **iterative approach**[1] (ranging from less detailed to more refined risk assessments). As such, the actual degree of detail, complexity and accuracy may vary among risk assessments conducted at either level. It is possible that both a PQRA and a DQRA could be completed for a site at different stages of assessment, depending on the data available from the site investigation.

Some general characteristics of PQRAs and DQRAs are outlined in **Table 1**.

[1] *Iterative approach*, in the context of HHRAs, involves repeating the process while adding incremental or progressive layers of refinement, detail and complexity. As such, while PQRAs and DQRAs can be considered as stand-alone processes in certain situations, they may also be part of an iterative evaluation.

Table 1: Some Characteristics of PQRAs and DQRAs

Characteristic	PQRA	DQRA
Environmental Media Sampled and Characterized	Generally, limited to chemical concentrations in soil and potentially groundwater. If the site is aquatic, may include surface water and sediment.	Extensive: multiple environmental media sampled as warranted for the site. Media may include soil, groundwater, soil vapour, indoor air, sediment, surface water, biota. Media are likely to be characterized physically (e.g., soil grain size, hydraulic conductivity) and chemically (e.g., organic carbon content, buffering capacity).
Quantity of Data	Limited: generally restricted to data collected during an environmental site assessment (ESA) for confirmation of contamination and very limited delineation of hot spots (may require supplemental assessment).	Extensive: generally includes a sampling plan designed to provide reliable and representative quantification of the contaminant concentrations in each environmental medium.
Statistic Used to Represent Contaminants of Potential Concern (COPC)* Level(s) at the Exposure Point	Maximum measured concentration or estimate of an upper bound of concentration (e.g., 95% upper confidence limit of the mean (UCLM), 90th percentile); other statistics may be used according to the available data.	Generally, a measure of central tendency (e.g., mean, median, mode) based on the available data; or key parameters describing the underlying statistical distributions (e.g., percentiles, variance, 95% lower and upper confidence limits of the mean, probability or cumulative distribution functions).
Use of Modelling	Modelling may be used if data for media other than soil (and perhaps groundwater) are not available.	Generally, measured data will be available for all environmental media that are expected to be impacted and/or that contribute significantly to exposure; modelling may also be used.
Characterization of Receptors	Generally, limited to standard and conservative assumptions.	Site-specific, particularly with respect to the nature and extent of land use and time-activity patterns (when and how the land is used by receptors); quantification of receptor characteristics tends toward greater precision and less uncertainty.
Risk Characterization	For threshold effects, risk characterization is based on 20% of the tolerable daily intake (TDI) because exposure from background sources (unrelated to the site) is not quantified (i.e., target hazard quotient [HQ] of 0.2). For non-threshold carcinogens, risk characterization is based on an acceptable incremental lifetime cancer risk (ILCR) of 1×10^{-5} (ILCR is independent of background sources) for federal contaminated sites.	For threshold effects, risk characterization can be based on 100% of the TDI when exposure from background sources is quantified (i.e., target HQ of 1). For non-threshold carcinogens, risk characterization is based on an acceptable ILCR of 1×10^{-5} (ILCR is independent of background sources) for federal contaminated sites.

Note: These are only generalizations. PQRAs and DQRAs cannot always be precisely defined, but often form part of an iterative approach from less detailed to more detailed HHRAs (DQRAs can incorporate some characteristics of PQRAs and vice versa).

* For the definition of what constitutes a COPC, see **Section 2.4.1**.

1.3.1 PRELIMINARY QUANTITATIVE RISK ASSESSMENT (PQRA)

A PQRA is an assessment of human health risks that typically applies a high level of conservatism in estimating exposure. For this reason, if negligible or acceptable human health risks have been identified using the conservative PQRA methods, and if the site has been adequately characterized (e.g., sufficient and adequate analyses for all suspected site contaminants and in all relevant environmental media and areas of potential concern in order to have a reasonable certainty of measuring the maximum or near maximum concentration), then no further work may be required to assess potential health risks.

A PQRA may be used as a screening level risk assessment or to identify whether data gaps exist in the ESA or in other exposure assumptions. The PQRA can also inform data requirements for assessing potential human health risks (e.g., impacts to country foods or other media, delineation of contamination, etc.) prior to undertaking a DQRA.

In order for the site to be adequately characterized for the purpose of an HHRA, all sources of contamination should be identified, as well as the lateral and vertical extent of contamination. Sufficient data should be available to identify an exposure point concentration for each COPC (the maximum measured concentration is recommended where data are insufficient to delineate the contamination). Further, if there are impacts to groundwater, the groundwater plume should be defined and potential impacts on human receptors on-site or downgradient of the site should be identified. Other media potentially affected should be addressed in the risk assessment with measured or modelled data.

Custodians may choose to use PQRA results without conducting a DQRA under these circumstances:

- In considering the cost and feasibility of the proposed risk management/remediation approach versus the cost of a more detailed study;
- If the PQRA identifies that the conservative estimates of health risks are highly unacceptable, such that remediation or risk management (e.g., covering of soils) is required without further assessment, and that the completion of a DQRA would not result in a significantly different assessment of risks or of actions to be taken; and
- As a conservative assessment for sites that are not complex (e.g., sites for which few environmental media are involved or for which there is not a large degree of variability across the site in terms of human activities, contaminant types and concentrations, as well as other site conditions) or for those that require only a screening level quantitative risk assessment.

If potential risks are identified in a PQRA, a DQRA may be conducted in order to reduce uncertainties in the exposure assumptions (if this approach is deemed appropriate for the site). This may require a supplemental site assessment to address data gaps and better characterize the contamination in various media at the site. Therefore, when a PQRA determines that, for conservative estimates of exposures, potentially unacceptable human health risks exist, it may be appropriate to undertake a DQRA before defining remedial or risk management options.

If a PQRA is to be used as a basis for risk management decisions, it should clearly identify how the assessment is adequate to support risk management, and note any data gaps and/or uncertainties associated with the PQRA.

1.3.2 DETAILED QUANTITATIVE RISK ASSESSMENT (DQRA)

The purpose of a DQRA is to produce a more accurate (i.e., with less uncertainty), robust, and representative estimate of risks than that generated by a PQRA, in which more conservative assumptions are used. Although the level of detail of such an HHRA can vary considerably, a DQRA typically uses more comprehensive site characterization data and more representative or site-specific exposure information.

In some cases, a DQRA may be much more intensive than a PQRA, or, in others, it may not vary considerably as some sites may require only small changes to the exposure assessment of a PQRA to provide more site-specific estimates of risk in a DQRA. The level of detail for a DQRA will depend on the site. Overall, a DQRA is typically the appropriate tool for risk assessment of most contaminated sites to inform risk management/mitigation decisions.

A DQRA may include a more robust assessment of exposure (e.g., via vapour intrusion, food ingestion, bioavailability of chemicals) and risks associated with short-duration exposures. The need for a greater level of detail is usually assessed in the context of the benefits of reduced uncertainty in the risk estimates as compared with the costs and resources needed to collect additional data and conduct a more detailed assessment.

A DQRA may be particularly appropriate if there is a large degree of variability across the site in terms of human activities, contaminant types, concentrations, and the number of media impacted as well as other site conditions.

Guidance on conducting DQRAs for federal contaminated sites can be found in HC (2010a), which is available by contacting HC at **hc.cs-sc.sc@canada.ca**.

1.4 ADDITIONAL HEALTH CANADA GUIDANCE

HC has published a number of guidance documents related to the assessment of human health risks associated with the presence of contaminants in various media resulting from historical activities at federal contaminated sites. These include guidance on preparation of a statement of work for an HHRA, toxicological reference values, peer review checklists and supplemental guidance for specific environmental media, as described below. They can be requested by email at **hc.cs-sc.sc@canada.ca.** Use of most of these guidance documents is more common in a DQRA where additional media are considered and/or estimates of exposure are further refined.

Foods that are grown at, harvested from or affected by a contaminated site may be included in a risk assessment. **Country foods** may refer to traditional foods or to foods that are not for commercial sale (e.g., subsistence living, backyard gardens, berry bushes). For contaminated sites that may have an impact on country foods, refer to the guidance document *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRA$_{Foods}$)* (HC, 2010e).

For the assessment of contaminated sites that may include exposure via **vapour intrusion** (migration of volatile chemicals from contaminated groundwater or soil into the indoor air), guidance is provided in *Federal Contaminated Site Risk Assessment in Canada: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites* (HC, 2010g). The guidance should be employed in conjunction with the *Canada-Wide Standard for PHCs in Soil*, established and published by the Canadian Council of Ministers of the Environment (CCME, 2008a-c), and *A Protocol for the Derivation of Soil Vapour Quality Guidelines for Protection of Human Exposures via Inhalation of Vapours* (CCME, 2014).

For sites presenting **radiological risks**, refer to the guidance document *Federal Contaminated Site Risk Assessment in Canada, Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment (DQRA$_{RAD}$)* (HC, 2010c) and contact HC.

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment of Air Quality (HC, 2017a) provides guidance and information on key issues and methods with regard to HHRAs of **chemicals in air** at federal contaminated sites.

Where **settled indoor dust** is likely an important exposure medium, its characterization, in addition to soil analyses, may be justified for the purpose of risk management or evaluation of mitigation measures. The document *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Indoor Settled Dust (HHRA$_{DUST}$)* (HC, 2018) provides information to assist in the derivation of human health-based dust screening concentrations and to assess exposure to COPCs in indoor dust.

There may be unique considerations for **aquatic sites** (marine and freshwater environments) that are not covered in HC's general guidance documents; for example, receptor characteristics and exposure scenarios for aquatic sediment sites may differ from terrestrial sites. The document *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment of Contaminated Sediments: Direct Contact Pathway* (HC, 2017b) provides information related to evaluation of human exposure to chemicals in sediments via direct contact (i.e., incidental ingestion, dermal contact and inhalation of particulates).

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Oral Bioavailability of Substances in Soil and Soil-like Media (HC, 2017c) provides methods for incorporating **relative oral bioavailability** adjustments in risk assessments. Relative oral bioavailability adjustments may allow for more accurate risk estimates and provide support for site-specific remediation targets.

1.5 CURRENT AND INTENDED FEDERAL USE

A PQRA may be based on the conditions of current land use to estimate potential on-site risks for people currently frequenting the site. A PQRA can also be prepared for one or more intended federal uses for the site, particularly if these will be significantly different from current conditions.

Land uses of adjacent or nearby properties should also be considered in HHRAs, if potential migration of chemicals from current or historical activities (e.g., by soil erosion, by the movement of surface water or groundwater) may affect neighbouring properties (e.g., residential areas beside an industrial site). As previously mentioned, if there is potential for off-site migration of contaminants, consultation with another regulatory jurisdiction (e.g., P/T government agency) may be required, and their requirements may also need to be addressed.

2.0 REPORT CONTENT

It is important that each risk assessment report is able to "stand alone" and to fully reference the reports where the relevant site investigation data are presented. All relevant information, together with references (e.g., for equations, assumptions, models), should be provided for technical review. However, this does not mean that all information needs to be incorporated into the risk assessment report, rather, all the information used to support the risk assessment should be clearly referenced and relevant reports provided to allow for technical review. This will enhance the transparency of the report and allow for evidence-based decision making by custodians managing the site.

The guidance that follows is organized according to subject areas that HC recommends be included in a PQRA report. It is recognized that writing styles or standard corporate report formats may vary somewhat from those outlined below; alternative report formats are acceptable as long as all of the requested information is presented.

2.1 EXECUTIVE SUMMARY

A brief synopsis of the site, the definition of the problem, the results and conclusions of the PQRA, and any recommendations stemming from the analysis should be presented in the executive summary. In particular, any assumptions in the risk assessment that constrain the use(s) of the site or have implications for risk management measures should be noted. For example, if the risk assessment assumes no direct contact with contaminated soil because of a cap acting as a barrier, this should be identified in the executive summary as it could have implications for risk management (i.e., a recommendation stemming from the PQRA in this case could be that the barrier should be maintained as part of risk management).

2.2 INTRODUCTION

The goals and scope of the PQRA should be clearly defined in the introduction. For example, one or more of the following objectives might be applicable:

- To assess the potential human health risks posed by exposure to contaminants for current use and conditions;
- To ascertain the need for additional site assessment data and/or a more detailed risk assessment;
- To establish whether there is a need to identify risk management measures and/or site-specific remediation goals; and
- To assess the potential human health risks associated with intended federal use(s) and conditions.

The introduction should also identify the client department and the risk assessor(s) undertaking the PQRA.

2.3 DESCRIPTION OF THE SITE

A brief but complete description of the site should be provided, including a summary of all site characteristics that may be pertinent to the understanding and assessment of potential exposures on-site (and off-site, if applicable). This section presents the critical aspects of the environmental site assessment(s) (ESA; also called environmental site investigation or site characterization) and of other relevant studies/data sources.

Subsections may include, but not necessarily be limited to:

- Site identification;
- Site owner;
- Site location;
- Current site use (and intended use, if relevant);
- Off-site land use and potential receptors (and potential impacts, if relevant);
- Land-use history (may include off-site historical land use, if relevant);
- Built environment (surface cover, buildings and other infrastructure);
- Topography;
- Geology;
- Hydrogeology and hydrology, specifying the current or potential uses of groundwater and surface waters (e.g., drinking water source, irrigation, recreational activities);
- Distance to the nearest community (e.g., Indigenous community, village, town, city);
- An estimate of the size of the population of the nearest community;

- Summaries of previous ESAs, sampling, analysis, risk assessments, and remediation activities undertaken at the site with reference to the appropriate reports;
- Summary of on-site contamination for each environmental medium (e.g., surface/subsurface soils, each water table), including identification and description of any high concentration areas, free product plumes (light or dense non-aqueous phase liquids), etc.; and
- Local or regional background concentrations of COPCs (as available and appropriate).

The site description should be supported through inclusion of figures depicting the site location, historical and current uses (and, where appropriate, those of adjacent or nearby properties), the built environment, all sampling locations, locations where exceedances of applicable criteria are observed (and for which chemical or chemical group) and/or delineation of high concentrations/concentration gradients across the site, the spatial extent of free product (where applicable), hydrogeology and hydrology features, location of drinking water source(s) or wells, etc.

2.3.1 IDENTIFYING ALL RELEVANT POTENTIAL CONTAMINANTS

The PQRA report should identify whether adequate data were obtained in the ESA(s) for all substances that may be associated with current and historical land uses at the site (or off-site if relevant) and for all pertinent environmental media and locations (i.e., areas of potential environmental concern). A list of potential contaminants that are commonly associated with various governmental and industrial sectors is presented in **Appendix A** (**Section A.2** and **Table A2**). However, the list is not intended to be exhaustive, and professional judgment, following review of historical and current site activities (and off-site, where necessary), will ultimately dictate the substances to be included in a supporting sampling and analysis plan.

2.3.2 CONCENTRATIONS OF CHEMICALS IN ENVIRONMENTAL MEDIA

The validity and adequacy of chemical concentration data for use in HHRAs of contaminated sites are largely dependent on the adequacy of the ESAs. Refer to CCME (2016) for guidance on ESAs of contaminated sites, including sample collection/analysis methods, data management, and preparation of sampling and analysis and quality assurance plans.

The amount of characterization data required for chemical screening at the problem formulation stage may be different from that required to quantify exposure concentrations in the exposure assessment. For example, chemicals are typically screened using maximum measured concentrations. Although this requires adequate sampling to capture the highest concentrations, further sampling is typically needed to establish concentrations that are more representative of exposure at the site (e.g., mean or upper confidence limit).

Additional sampling may be required before completion of an HHRA if some relevant environmental media or areas of potential concern have not been sampled sufficiently with respect to sample locations and number and types of analysis carried out. This is important because a lack of data would be identified as an uncertainty associated with the risk assessment.

The report should present all pertinent data regarding concentrations of chemicals across different environmental media at the site. These will be drawn from all previous sampling efforts, not only the most recent data collection survey, although historical data may be excluded with justification (e.g., when historical data do not reflect the current conditions at the site). For each sampled medium (e.g., soil, sediment, groundwater, surface water, vegetation), table(s) presenting all pertinent analytical results should be provided at the problem formulation stage. These table(s) should also include: units, sampling date, number of samples, maximum concentrations, detection limits, number (or proportion) of non-detects, and number (or proportion) of samples with concentrations

above applicable criteria. Other statistical information (e.g., range of values, percentiles [90th, etc.], mean, median, upper 95% UCLM, according to the available data and HHRA objectives) may be relevant and valuable at this step of the assessment. Such information may also be used in the exposure assessment (see **Section 2.6**) to establish exposure point concentrations.

For soil and sediment samples, the depth at which samples were collected should also be indicated. It is necessary that the sample population is adequate for statistics, if applied to estimate exposure point concentrations in each area of potential environmental concern. For example, concentrations of chemicals in surface soil samples may not be similar to concentrations in soils at depth, unless the soils have been shown to be homogeneous. Similarly, the report should identify the particle-size range of soils analyzed for chemical concentrations.

The ESA should provide data adequate to estimate direct exposure to soil contaminants (via ingestion, dermal absorption or inhalation of suspended particulate matter) at the site. Direct exposure to soil contaminants will relate predominantly to "surface" soils (surface soils are defined by CCME (2006) as those within the uppermost 1.5 m of the soil profile), unless there are activities at the site that may result in direct contact with soils at depth. The surface layer of soil that typically contributes to incidental exposures may be the top 5–10 cm, provided that the soils are not subject to gardening, tilling, excavation, etc. However, this does **not** imply that 5–10 cm of clean soil is considered an adequate surface cover layer for purposes of risk management, nor does it imply that this would be reflective of the depth for contact with soils at all sites. A risk management plan may be used to address contamination where less than the top 1.5 m of soil is considered in the HHRA. The depth of the "surface layer" to which people may be directly exposed may vary depending on site-specific conditions. The potential for soil erosion and on-site human activities (e.g., gardening, recreational activities, site maintenance), particularly those that may compromise the integrity of the surface cover and soils in place, should be considered. The assumed depth that defines surface soil should be clearly stated in the HHRA report and the characterization data should relate to that same definition of surface soil.

To assess risks from direct contact with contaminants in soils, sample collection could target the surface soil horizon as defined by CCME (2006), ranging from surface to 1.5 m below surface, or another site-specific depth of surface soil different from that definition, with appropriate rationale. Data from soils at greater depths may be important for the assessment of vapour intrusion and/or of groundwater quality (soils may affect on-site or off-site groundwater use for drinking water or other purposes). Data from the deeper soil horizon may also be important to characterize future potential exposure if subsurface soils may become exposed.

When appropriate, summarized soil data (e.g., maximum concentrations, number of samples analyzed, proportion of non-detects) should be presented separately for surface soils and subsurface soils, as well as for different microenvironments (defined as smaller areas of the site that are characterized by distinct concentration ranges of COPCs and/or by distinct patterns of use by people that access the site). In the statistical analysis of soil data, it is generally not advisable to combine data from contaminated areas with data from areas not affected by the contaminant source, as this may underestimate the concentrations to which people may be exposed if they spend more time in the affected areas.

The particle-size range of soil is also an important factor in the sampling, chemical analysis, and exposure assessment. Soil adherence to skin (for dermal absorption and incidental soil ingestion via hand-to-mouth transfer) increases as soil particle size decreases (Richardson et al., 2006). It is also possible that chemical concentrations may not be uniform across all soil particle-size fractions, since chemical concentrations may increase with decreasing particle size (Bright et al., 2006). Data for bulk soils with a particle size of < 2 mm are typically used in a risk assessment, but in some cases chemical analyses on finer fractions (i.e., < 250 µm) may be considered. HC (2010a; 2017c) guidance provides more information on this topic.

The laboratory performing the chemical analyses should be accredited by the Canadian Association for Laboratory Accreditation, the Standards Council of Canada or a similar organization, such as the Programme d'accréditation des laboratoires d'analyse in Québec.

2.4 PROBLEM FORMULATION

As the initial stage of the risk assessment process, problem formulation identifies COPCs, receptors, and exposure pathways, and provides the basis for the next stages of the HHRA.

Specifically, problem formulation subsections will include, but are not limited to, the following:

- Screening and identification of COPCs in each environmental medium;
- Identification and description of potential human receptors;
- Identification and description of operable exposure pathways; and
- Conceptual site model development, summarizing sources, pathways and receptors.

Justification should be provided for any chemicals and/or receptors that are screened out, or for exposure pathways that are deemed inoperable.

The report should also clearly state the limitations, uncertainties or gaps associated with chemical concentrations and other available data, and identify whether existing data are sufficient to meet HHRA needs. As part of the problem formulation, the risk assessor may also refine the HHRA needs in terms of additional data collection and other information (where relevant).

A thorough problem formulation should be provided, including a rationale for the assumptions made as well as discussion of any uncertainties associated with the data, assumptions, and results presented. In some cases, the problem formulation stage may provide sufficient rationale to conclude the risk assessment process. It may also provide information related to risk management or remediation.

2.4.1 SCREENING AND IDENTIFICATION OF CONTAMINANTS OF POTENTIAL CONCERN

The purpose of chemical screening at the problem formulation stage is to identify chemicals that have the potential to pose risks to human health. This step requires review of site characterization data in the ESA reports as well as review of historical activities to confirm that all potential contaminants have been considered. COPCs are carried forward to the subsequent stages of the risk assessment.

In HHRA, COPCs are defined as follows:

- Those chemicals for which the **maximum** on-site concentration exceeds appropriate human health-based environmental quality criteria (e.g., human health guidelines or standards); and
- Those chemicals for which the **maximum** on-site concentration exceeds local or regional background concentrations (discussed in **Appendix B**); or
- Those chemicals for which no human health-based criteria or background data exist.

Any chemical that has a maximum concentration exceeding an appropriate screening criterion for the protection of human health and that was not excluded as a result of a comparison with background concentrations is classified as a COPC for further assessment. Should an appropriate comparative criterion not be identified for a particular chemical and measured concentrations exceed background concentrations, the chemical is retained

as a COPC and carried forward to the risk assessment. Further, laboratory detection limits should be lower than the applicable screening criteria to allow for comparison. Any chemical for which the detection limit is greater than the screening criterion should be retained as a COPC.

Chemicals known to be essential elements are screened into the risk assessment unless sufficient rationale can be provided for their exclusion (e.g., comparison with environmental quality criteria or background concentrations, analysis of toxicological information).

This guidance applies to sites where discrete (non-composited) samples have been collected and analyzed. It is recommended that risk assessments are based on discrete samples in order to better identify potentially contaminated areas. If only composite samples (≥ two samples combined as one) have been collected, the site custodian and/or risk assessor should consult HC for further direction, as guidance related to the HHRA would depend on the ESA data and site use patterns.

For each contaminated medium, chemical screening involves the identification of appropriate human health-based environmental quality criteria for current and/or intended federal land use scenarios. Land uses of adjacent or nearby properties may be relevant if there is a potential for off-site migration of chemicals.

The human health-based quality criterion that is the lowest applicable for the land use (e.g., residential, commercial), and according to the current or intended use of the federal site in question, should be applied for screening of COPCs.

It is, however, advised to present human health-based criteria for each of the applicable exposure pathways (e.g., direct contact, indoor inhalation of vapours infiltrating from contaminated soil or groundwater, ingestion of groundwater) and not only the most stringent ones for the land use category. This will better demonstrate which pathways are critical and provide the basis and guidance for further data collection or for the risk assessment.

The report should identify whether the anticipated exposure and physical conditions at the site are consistent with those considered in the criteria development process (e.g., type, frequency or intensity of human exposure). It should also document whether precluding factors may rule out the use of some human health-based quality criteria (e.g., the presence of preferential pathways between the contamination and the building, or shallow contamination below the building). Where site-specific conditions differ from those assumed in criteria derivation and where these values may not be sufficiently protective, it is advisable to retain the chemical as a COPC.

Owing to the interrelationship of exposure pathways, receptors, and COPCs, chemical screening is conducted in conjunction with the screening of receptors and exposure pathways and considers the specific physical site characteristics (and, sometimes, off-site characteristics). This involves identification and documentation of the sources of contamination, release mechanisms, fate and transport mechanisms, exposure media, receptors, and exposure routes. In particular, depending on land use scenarios and chemical parameters, the data collected and reviewed could relate to the current or likely uses of groundwater, the presence or likely presence of backyard gardens, buildings (their location and characteristics), surface cover, agricultural activities (crop, dairy or meat production for human consumption), etc. The development of an initial conceptual site model indicating sources of contamination, exposure pathways and receptors is recommended as part of the chemical screening against human health-based environmental quality criteria.

2.4.1.1 SOIL SCREENING GUIDELINES

In HHRAs, COPCs in soils are identified by comparing the **maximum** on-site concentrations with the CCME *Canadian Soil Quality Guidelines* (CCME, 1999, and subsequent updates) for the protection of human health. However, if more recent screening values are available from regulatory agencies, they may be used, with rationale. At federal contaminated sites where petroleum hydrocarbons may be present, the pathway-specific Tier 1 level standards of the *Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil* (CCME, 2008a) are also used for screening.

If federal properties are to be divested to P/T jurisdiction or if off-site migration of contamination may occur, consultation with both federal and P/T authorities may be necessary to confirm that appropriate protocols have been followed and that relevant criteria have been satisfied.

When CCME human health soil quality guidelines/standards are not available for a particular substance, P/T guidelines or standards based on human health may be used, with appropriate adjustments as necessary (see below). Where no Canadian jurisdiction has established such a human health-based soil quality criterion for a particular chemical, criteria derived by other jurisdictions, such as the United States Environmental Protection Agency (US EPA), may be used.

When soil quality criteria from sources other than CCME are adopted for chemical screening purposes, they may need to be adjusted, as necessary, so that they are consistent with CCME guidelines/standards. For example, if the health-based criteria for non-threshold carcinogens are derived on the basis of a target incremental cancer risk of 1×10^{-6} (one in one million), they can be adjusted to a target incremental risk of 1×10^{-5} (one in 100 000) in accordance with HC's essentially negligible risk level (refer to **Appendix C**). For chemicals with toxicological reference values (TRVs) based on non-threshold effects, criteria from other jurisdictions, such as the US EPA's *Regional Screening Levels (RSLs) – Generic Tables* (US EPA, 2020), may be based on an HQ of 0.1. These guidelines may be adjusted to make them approximately equivalent to CCME guidelines/standards, which are generally based on an HQ of 0.2 for exposure in soil.

Please contact HC for advice on adjustments to criteria from other jurisdictions. If criteria other than those developed by CCME are used for screening, a detailed rationale should be provided, including the basis for the criteria and any adjustments applied.

2.4.1.2 GROUNDWATER SCREENING GUIDELINES

For chemicals in potable groundwater, *Guidelines for Canadian Drinking Water Quality – Summary Table* (HC, 2020) may be used for screening COPCs on federal sites, or, in the absence of guidelines from HC, other similar criteria may be applied with supporting rationale. However, the application of HC's Guidelines (HC, 2020) or similar criteria would remain the choice of the custodian if the groundwater is not a current or anticipated source of drinking water.

Where volatile substances are present in groundwater, and inhalation is a relevant exposure pathway, the risk assessor should confirm that the vapour migration to indoor air pathway has been considered in the screening criteria used. Volatile chemicals in groundwater should be screened by comparing the **maximum** measured on-site concentrations with the appropriate values in *Guidance Document on Federal Interim Groundwater Quality Guidelines* [FIGQGs] *for Federal Contaminated Sites* (Environment Canada, 2016) until Canadian environmental quality guidelines for groundwater are available. For volatile chemicals lacking FIGQGs, criteria from other jurisdictions may be used, or the substances should be brought forward into the risk assessment if no screening criteria are available.

The report should identify whether impacted groundwater may support uses other than drinking water consumption, e.g., irrigation, livestock watering, or may affect other media (e.g., surface water or surface soils) potentially involving a human exposure. In the absence of appropriate screening criteria to assess those pathways, the presence of substances for these specific pathways may be further evaluated in the risk assessment.

When there is evidence of off-site migration of groundwater contamination (or where this may be suspected), appropriate jurisdictional (e.g., P/T) requirements need to be identified.

2.4.1.3 LOCAL AND REGIONAL BACKGROUND SCREENING

Many substances that are found at contaminated sites occur naturally and/or are widely distributed in the environment (e.g., some metals, polycyclic aromatic hydrocarbons [PAHs], polychlorinated dibenzo-*p*-dioxins/polychlorinated dibenzofurans [PCDDs/PCDFs]), and levels of substances may vary regionally. The CCME soil quality guidelines may be set at levels that are below regional background levels in some areas. In such cases, it may be appropriate to compare on site-concentrations to reliable background data to ascertain whether or not the concentrations of substances at the site may result from site-related anthropogenic sources. Estimates of background concentrations may be determined from local or regional surveys (e.g., from federal or provincial databases) of relevant media (e.g., soil, groundwater, surface water or sediment), if available, or from collection and analysis of samples from suitable reference areas. The background/reference site data should be free of anthropogenic point source influence with regard to the substances of interest. Speciation of metals may be important in the determination of background concentrations as compared with site-related contamination. A thorough rationale should be provided for any background concentrations presented in the HHRA (e.g., from a P/T authority or from sampling in the ESA).

If on-site measured concentrations are within the range of local or regional background conditions, the substance can be excluded from further consideration as a COPC, unless it is to be specifically retained as part of the project scope. However, if on-site concentrations of a substance are found to be within the range of regional or local levels but significantly higher than levels considered protective of human health, it would be prudent to retain it as a COPC for further evaluation. If a COPC found regionally at elevated levels (i.e., above appropriate guidelines) is not retained for further evaluation, the risk assessment report should indicate that the health risks associated with the substance have not been evaluated.

A further discussion of background levels is presented in **Appendix B**.

2.4.2 IDENTIFICATION OF POTENTIAL HUMAN RECEPTORS

In the problem formulation stage of the risk assessment, all potential human receptors (i.e., people who may be exposed to COPCs from the site) should be identified. This includes people who are on the site regularly or intermittently, as well as people off-site who may be affected by the contamination in some way.

The receptors identified will be dependent on the land use. Potential receptors may also include occupants of neighbouring properties if off-site migration of contamination has occurred or is feasible. In these cases, the land use of the neighbouring property, and not the federal land use, will determine relevant off-site receptor groups.

Contaminated sites on agricultural, residential and recreational lands are typically assessed for risks to the health of members of the general public. Institutional facilities (schools, hospitals, etc.) are assessed for members of the general public, with age groups, exposure frequency and duration of exposures commensurate with the type of facility. Commercial or industrial lands are assessed for both the general public and employees if both receptor groups have access.

Commercial sites are differentiated with regard to those with daycare facilities and those without. Commercial sites with daycare facilities would require a risk assessment specific to the infants, toddlers, and children who attend those facilities. For industrial or other work-related sites to which public access is controlled or restricted, the key receptor group is typically employees. Employees are assumed to be adults only (including women of childbearing age and pregnant women), unless jobs typically conducted by youth during summer employment are identified (e.g., tree planting, landscaping).

Within each receptor group, all age groups that may be exposed to COPCs from the site should be identified. The age groups to consider are: infants (0 to 5 months of age inclusive, i.e., 0 to <6 months of age), toddlers (6 months to 4 years of age inclusive), children (5 to 11 years of age inclusive), teens (12 to 19 years of age inclusive) and adults (≥20 years of age).

Key receptor groups (i.e., who may receive the most exposure or are most sensitive to toxicants) should be identified and evaluated (e.g., infants, toddlers, consumers of higher quantities of local foods). Sites known to be frequented by members of Indigenous communities or that are in close proximity to such communities should be evaluated for risks to those population groups, since they may use the site in a manner which is different from that of the general public (e.g., increased use of traditional foods that may be impacted by contaminants in environmental media).

A detailed justification should be provided for any receptor and/or age groups being excluded from the risk assessment.

2.4.3 IDENTIFICATION OF OPERABLE EXPOSURE PATHWAYS

The objective of exposure pathway identification at the problem formulation stage is to identify and screen pathways of potential concern. For risk assessment purposes, an exposure pathway consists of a contaminant source, a mechanism of chemical release, a retention or transport medium, a point of potential contact with the contaminated medium (exposure point), and an exposure route. The exposure route (ingestion, inhalation, dermal contact) refers to the route by which a chemical physically contacts or enters the body.

For an exposure pathway to exist, all components of the pathway must be present. Owing to this interrelationship between chemicals, receptors, and exposure pathways, it is important that the screening of exposure pathways be conducted in conjunction with the screening of receptors and COPCs.

Exposure to contaminants at a site may occur by several means, including, but not limited to:

- Incidental ingestion of contaminated soil;
- Dermal absorption from contaminated soil adhering to exposed skin;
- Ingestion of indoor settled dust or dermal contact with indoor dust that has been affected by contaminated soil;
- Inhalation of suspended contaminated soil/dust particles while outdoors/indoors;
- Indoor inhalation of vapours originating from contaminated soil or groundwater;
- Outdoor inhalation of vapours originating from contaminated soil or groundwater;
- Ingestion of contaminated groundwater or surface water used as a source of drinking water;
- Ingestion of produce/vegetation grown on contaminated soil or irrigated with contaminated water;
- Ingestion of produce/vegetation impacted by deposition of contaminated dust;
- Ingestion of livestock or wild game that may have elevated tissue concentrations of COPCs;
- Ingestion of fish or shellfish that may have elevated tissue concentrations of COPCs;

- Inhalation of vapour and dermal absorption from contaminated water while showering or bathing;
- Ingestion or dermal absorption from contaminated water/sediment during water activities such as swimming, wading, walking/playing on the beach; and
- Ingestion of contaminated breast milk by infants.

One or more exposure pathways may not be operable (or may not exist) at a given contaminated site. Operable and inoperable (or insignificant) exposure pathways should be identified, with detailed justification.

It should be noted that the assessment of indirect exposure pathways (e.g., ingestion of produce/livestock/fish, indoor inhalation of vapours originating from soils/groundwater) may require supplemental sampling and/or modelling to predict cross-media transfer, exposure point concentrations in secondary media, etc. The complexity of such models or other necessary methods may not be consistent with the simpler screening-level PQRA. As a result, more detailed risk assessment is typically warranted (as described in HC's DQRA guidance [HC, 2010a]).

2.4.4 CONCEPTUAL SITE MODEL DEVELOPMENT

A key output of the problem formulation stage of a risk assessment is the **conceptual site model (CSM)**. The CSM provides a complete description of all pathways of exposure to COPCs that have the potential to contribute to human health risks, starting from the source and ending with the critical receptors. Thus, information is included on sources of contamination, release mechanisms, fate and transport within and between environmental media, exposure points, exposure routes (ingestion, inhalation, dermal), and critical receptors. Uncertainties associated with the data available to support the risk assessment should also be clearly stated and the report should identify whether additional data are required, prior to finalizing the CSM and completing a quantitative PQRA. The CSM is usually presented in a narrative form supported by either a schematic format (see example in **Figure 1**), a pictorial or tabular format, or a checklist (see HC, 2010a).

Consolidating this information into a CSM facilitates a clear and common understanding of the issues associated with the site for the benefit of risk assessors, site managers, and stakeholders. It may also provide the basis of and guidance for a further quantitative risk assessment (e.g., by helping to define the goals, scope, and level of detail). The CSM serves to focus attention on the critical aspects of the problem and can also be used to guide stakeholder consultations and risk communication.

The tasks conducted during the problem formulation stage should indicate whether potential exposure pathways exist and describe the added value of a further quantitative risk assessment to site assessment and site management decisions.

Not all identified COPC/pathway/receptor combinations necessarily need to be further evaluated quantitatively; for example, a quantitative assessment is not required if a qualitative analysis identifies that certain pathways are inoperable, or that the level of potential exposure is negligible (e.g., if there is no possibility for a person to come into contact with the contamination). Pathways may also be excluded on the basis of monitoring data showing that the pathway is not currently active, or on the basis of mitigative measures that effectively prevent exposure; such situations may change with time and may require ongoing management or monitoring.

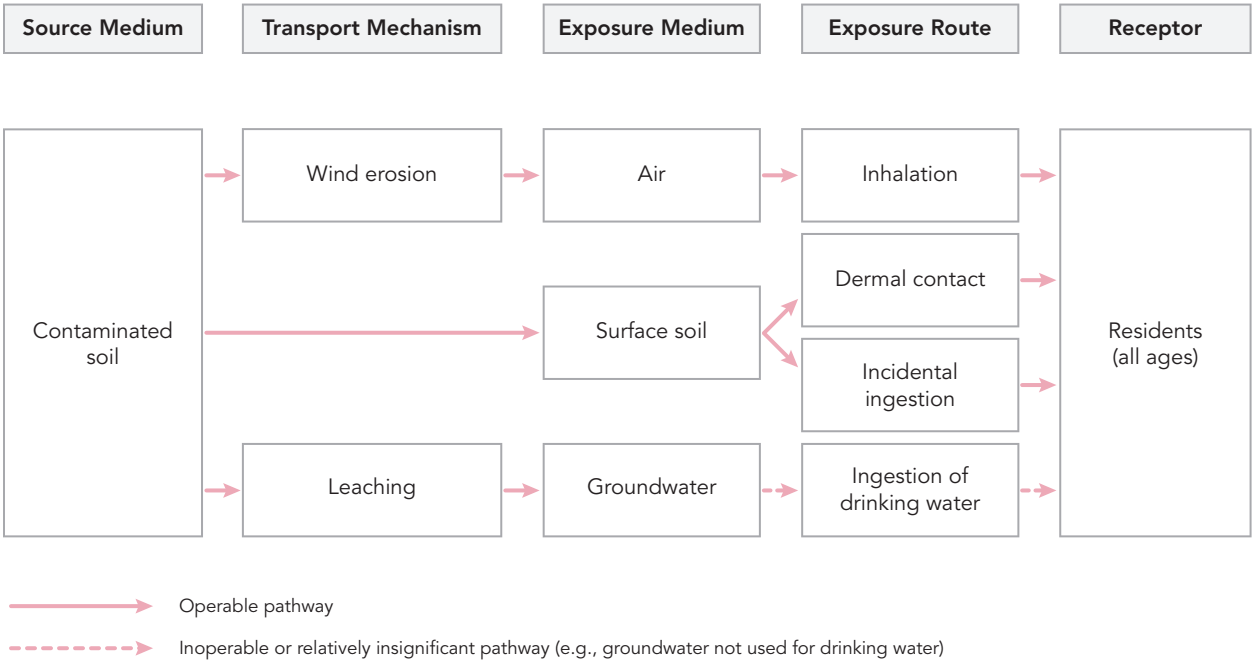
A sound justification is required before excluding any COPC, exposure pathway or receptor from further consideration. Contamination level (i.e., in comparison to appropriate human health-based environmental quality criteria), spatial and temporal distribution of the contamination, physico-chemical/toxicological properties of the COPCs, locations and types of human activities, site conditions (e.g., surface cover, building characteristics) and other considerations, are part of the overall analysis.

In summary, the CSM should clearly identify which exposure pathways, COPCs and receptors are carried forward for quantitative evaluation in the risk assessment, and provide rationale for any exposure pathways, COPCs and receptors that are not carried forward for further evaluation (e.g., inoperable pathways).

Problem formulation and CSM development can also assist in the identification of any additional information and environmental data needed to adequately assess potential health risks. Linkages also exist between problem formulation and other considerations outside the risk assessment process, including regulatory issues, stakeholder consultation, public outreach and risk communication, as well as broader societal and risk management issues. As regulatory and societal issues often drive risk management, it is important that these issues be considered early on, during problem formulation.

At the conclusion of the problem formulation stage, an interim technical report may be prepared. While this report may ultimately form a section or chapter of the more in-depth (quantitative) risk assessment report, in its interim form it should stand alone. It should present data, methods, assumptions, rationale, results of the COPC screening, receptor and exposure pathway identification steps and the CSM, along with a description of uncertainties, conclusions, and recommendations stemming from this first step of the HHRA. For some sites, this report may provide sufficient rationale to conclude the risk assessment process at this stage or may provide insights on risk management or remediation options. In other cases, the problem formulation stage will form the preliminary step in a further quantitative determination of risks, the elements of which are covered in the following sections.

Figure 1: Example of a CSM in Flow Chart Format



2.5 TOXICITY ASSESSMENT

In the context of HHRA for federal contaminated sites, the toxicity assessment stage involves identifying the potential toxic effects of COPCs and selecting or developing toxicological reference values (TRVs). This information is used in combination with the estimated exposures for risk characterization. The toxicity assessment is performed for each chemical and exposure route identified as being of concern in the problem formulation stage. The toxicity assessment could also be carried out for different age groups if age-specific TRVs are available. Factors that can affect toxicity must also be considered (e.g., exposure duration, bioavailability, metal speciation).

A brief summary of the key health concern(s) associated with exposure to each COPC should be provided in the PQRA report. This information may be referenced from HC documents where applicable. This is important for determining whether COPCs may have additive effects. The summary should discuss both cancer and non-cancer TRVs for each exposure route (ingestion, dermal contact, inhalation), including the associated exposure duration and critical health effects.

For the purpose of risk assessment, the key classification of chemicals is based on the type of dose–response relationship, specifically whether the toxic effect is considered to be threshold or non-threshold. A threshold adverse health effect is one that occurs only once a certain dose (the threshold) is exceeded. A non-threshold adverse health effect is considered to have some potential to occur at any dose (i.e., linear dose–response curve, no threshold). The type of dose–response relationship (threshold or non-threshold) determines the method and assumptions used for deriving TRVs.

In general, unless proven otherwise, chemicals causing toxic effects other than cancer are assumed to exhibit a threshold dose–response curve, and the TRV is expressed as a tolerable daily intake (TDI) (may also be referred to as a reference dose [RfD] or acceptable daily intake [ADI]) or a tolerable concentration (TC) – the intake or concentration to which it is believed that a person can be exposed daily over a lifetime without deleterious effects.

On the other hand, for most carcinogens, a threshold dose cannot be defined for their carcinogenic effects, and a linear dose–response curve is assumed. The slope of the dose–response relationship is referred to as the slope factor (SF) (relating to exposure dose) or unit risk (UR) (relating to exposure concentration, typically in air or in some cases in water). However, for some carcinogens, there are sufficient data on the mode of action to conclude that the carcinogenic effect does exhibit a threshold dose–response relationship. In these cases, the threshold approach can be applied and the TRVs for these threshold carcinogens are expressed as TDIs or TCs.

For each COPC, the source (reference) of each TRV and the pathway(s) to which it is being applied should be identified. HC TRVs should be employed, where available, for the characterization of potential human health risks. These TRVs are presented in *Federal Contaminated Site Risk Assessment in Canada: Toxicological Reference Values (TRVs), Version 3.0* (HC, 2021). For substances with no HC TRVs (or for which HC TRVs are not current and more recent values have been published by other regulatory or advisory agencies), other TRVs may be obtained from the following agencies, or from other regulatory or advisory agencies:

- Other HC published TRVs
- US EPA Integrated Risk Information System: **https://cfpub.epa.gov/ncea/iris/search/index.cfm**
- World Health Organization – various sources:
  www.inchem.org | **http://apps.who.int/food-additives-contaminants-jecfa-database**
- Agency for Toxic Substances and Disease Registry: **www.atsdr.cdc.gov/toxprofiledocs/index.html**
- California Environmental Protection Agency: **https://oehha.ca.gov/chemicals**

For substances that lack a TRV from regulatory or advisory agencies, please contact HC. If risk assessors prefer to apply TRVs other than the ones available from HC (e.g., more recent toxicological information has been used by a different agency), these TRVs may be employed, but the PQRA report should contain a scientifically defensible rationale (including the basis, method of derivation, level of protection, uncertainty or confidence level, any modifications made to the TRV, references) to support such use.

2.6 EXPOSURE ASSESSMENT

In the context of HHRA, the exposure assessment stage involves estimating the amount of a chemical coming into contact with or absorbed by human receptors per unit time (e.g., daily intake or dose). Exposure assessment is conducted for chemicals, human receptors/receptor age groups, and exposure pathways that were identified as being of concern in the problem formulation stage. Exposure assessment is composed of three main steps which are detailed in the following subsections:

1) Measurement/modelling of chemical concentrations;
2) Human receptor characterization; and
3) Exposure estimation.

As the two driving components of a quantitative HHRA, the exposure assessment and toxicity assessment are completed before risk characterization is undertaken. Information from the exposure assessment, such as frequency and duration of exposure (e.g., short-duration versus long-duration), can affect the toxicity assessment. A summary of considerations for short-duration exposure assessment is presented in **Appendix D**. The mode of toxic action or some toxicological aspects of COPCs can also affect how the exposure assessment is performed. The TRVs and exposure doses should be expressed in the same units (i.e., if the exposure is expressed as a daily dose per unit body weight, the TRV should be in the same units).

In a risk assessment, exposure can be assessed for all potential human receptor groups/age groups identified. Such information is particularly valuable in public consultations and communications. However, the risk assessment may provide exposure and risk estimates only for critical receptors, with appropriate rationale. The critical receptor is normally the member of the applicable receptor group who is expected to receive the highest exposure to a COPC or who is most sensitive. Composite receptors (i.e., for whom lifetime exposure is considered) may also be used to assess potential risks for non-threshold carcinogenic effects.

This section of the risk assessment report should include all equations, as well as all the input data and assumptions that were used to estimate exposure (e.g., chemical-specific parameters, receptor characteristic assumptions, exposure point concentrations).

Examples of worked calculations should be included in the PQRA report, perhaps as an appendix, with at least one worked example for exposure (and also risk) estimates for a substance with a threshold adverse health effect and one for a substance with a non-threshold health effect; intermediate steps and all input parameters should be included. Where exposures to some COPCs are calculated differently from others, a sample calculation for these substances should be provided. Summary tables reporting all calculated exposures should be presented in the report.

All information noted above should be provided in a manner that facilitates technical review.

If the assumptions and equations presented in this guidance document do not apply for the site in question, the risk assessor should discuss concerns with the client department and HC. Where appropriate, alternative assumptions and/or equations may be employed. However, the PQRA report should contain a clear rationale (with citations) to support the use of alternative methods or assumptions.

2.6.1 MEASUREMENT/MODELLING OF CHEMICAL CONCENTRATIONS

The determination of chemical concentrations in various environmental exposure media is a critical component of the exposure assessment. For each COPC, an estimated concentration is required at the exposure point for each environmental medium of interest (e.g., soil, groundwater, surface water, sediment, indoor air, outdoor air, food).

The exposure point concentration may be the maximum concentration or a different statistic that represents reasonable maximum exposure (e.g., 95% UCLM, 90th percentile, or other statistic) for people at the site. The value used to estimate exposure for each medium will depend on the available data.

If the data are sufficiently numerous, rigorous, and representative of the contamination and exposure at the site, statistical treatment of on-site data may be carried out to determine a measure of central tendency (e.g., arithmetic mean) or another statistic in place of a reasonable maximum value for each medium and/or area of potential environmental concern. The use of a value other than a maximum should be fully justified (e.g., with adequate, valid and sufficient data). This value should be representative of the spatial distribution of contamination, as well as the manner in which individuals may use the site, taking into account where activities occur and the exposure conditions (e.g., type of use, frequency and duration). In all cases, values should be selected in a manner that does not underestimate potential health risks for critical receptors; particular attention should be given to the adequate assessment of areas with elevated contamination. The DQRA guidance (HC, 2010a) should be consulted for additional information.

Chemical concentrations can be estimated using two general approaches:

1) Direct measurements (i.e., sampling and chemical analysis of environmental media at the site); and/or
2) Environmental modelling (i.e., using mathematical models to predict chemical concentrations in exposure media).

2.6.1.1 DIRECT MEASUREMENTS

Direct measurements generally provide the most accurate estimate of current chemical concentrations in the environment if sufficient and valid samples are collected. The sampling strategy and the level of sampling effort required will be governed by the goals and scope of the risk assessment, the size of the site, the distribution of the contamination (spatially and temporally), the type of human activities, the site conditions (e.g., surface cover, buildings), etc.

More detailed technical considerations for environmental sampling and analysis are provided in CCME (2016), and it is recommended that this guidance be used for sampling environmental media at federal contaminated sites.

2.6.1.2 ENVIRONMENTAL MODELLING

Models may be used to estimate the concentrations of COPCs in various media to which people may be exposed, such as groundwater, surface water, indoor or ambient air, produce and vegetation, fish and wild game.

Sufficient information should be provided to allow technical review of environmental modelling, including equations, input data, assumptions, modelled concentrations, and rationale. Uncertainties associated with the models used should be identified in the risk assessment report, with an indication of whether uncertainties and/or assumptions may result in an underestimate or overestimate of concentrations in environmental media. Risk assessors should demonstrate that the models used are validated or generally accepted. Any model employed should be fully referenced and include a rationale for its selection.

When contaminated airborne soil particles (e.g., from wind-blown or vehicular erosion of soils) are considered, models may be used to estimate corresponding airborne COPC concentrations.

If site-specific data are not available to estimate concentrations of airborne particulate matter that may be generated from wind erosion of soils at a contaminated site (measured or modelled), a default airborne concentration of respirable particulate matter (≤ 10 µm aerodynamic diameter [PM_{10}]) of 0.76 µg/m^3 may be used (US EPA, 1996, as cited in US EPA, 2019). This value is not an estimate of typical ambient PM_{10} concentrations as it is based on modelled data to estimate wind erosion of soils, and this value is not applicable for use at sites where soils may be subject to other activities such as vehicular erosion, excavation, etc. Vehicle traffic on unpaved surfaces can generate considerably greater suspended dust levels. Dust levels from unpaved roads vary according to climatic conditions, traffic levels and the texture and nature of the road surface material (Claiborn et al., 1995). When site-specific data are not available, for sites where vehicle traffic on contaminated unpaved surfaces is a concern, a default dust level of 250 µg/m^3 may be used, based on the average of measured downwind PM_{10} data from roadside experiments (Claiborn et al., 1995).

The concentration of each COPC in respirable airborne soil dust should be assumed to be equal to the exposure point concentration used to estimate exposures in surface soil. A contaminated site HHRA addresses the potential risks associated with COPCs adsorbed to soil particulates that may become suspended in air, but typically does not address potential health effects associated with ambient levels of particulate matter (e.g., particulate matter with aerodynamic diameter equal to or smaller than 2.5 µm [$PM_{2.5}$], PM_{10}). While inhalation of elevated levels of such particulate matter may pose a health risk under any circumstances, in the context of a contaminated site HHRA, the focus is typically on the assessment of risks associated with the inhalation of COPCs adhering to the particulate matter suspended in air (e.g., airborne dust generated from contaminated soils). Also of interest are indirect pathways associated with suspended dust, such as deposition on produce or vegetation that may be consumed. These should be considered in the quantitative risk assessment if relevant.

In the absence of air samples, concentrations of volatile COPCs in indoor or outdoor air may be modelled using the methods presented by CCME (2014) and/or HC (2010g), with the consideration that, in some cases, models are not applicable (e.g., because of precluding factors).

COPC concentrations in groundwater and in surface water may be estimated from the methods described by CCME (2006) or other validated models, with references.

Modelling COPC concentrations in vegetation, fish, and wildlife may use diverse bioaccumulation metrics, where applicable and available, on a chemical-specific basis. More sophisticated modelling may be used, as deemed appropriate by a risk assessment professional (see HC, 2010e).

2.6.2 HUMAN RECEPTOR CHARACTERIZATION

The physical and behavioural characteristics of human receptors required for exposure calculations are quantified at this stage.

Physical characteristics (e.g., body weight, soil, water and sediment ingestion rates, inhalation rate) for the common receptor groups are presented in **Appendix E**.

Inhalation exposures are based on the time spent at the site (hours per day). On the other hand, soil and drinking water ingestion, and dermal exposures are considered to be independent of the time spent daily on the site (i.e., no adjustment for number of hours spent on the site). Although it is unlikely that the daily soil ingestion rate may be a single bolus dose, it is equally unlikely that intake would be distributed uniformly throughout the day. Moreover, for the purpose of conservatism, 100% of the daily unintentional intake of soil is generally assumed to arise from the contaminated site. Sediment ingestion rates on the other hand, may be determined as a function of the time spent at the aquatic site (HC, 2017b).

Typically, studies investigating soil ingestion rates do not provide sufficient resolution to distinguish between intake rates associated with the indoor and outdoor environments. Rates of incidental soil ingestion recommended for the characterization of risks at federal contaminated sites (which may include both soil and indoor dust ingestion), based on CCME (2006), are indicated in **Appendix E**. For further information on the evaluation of indoor settled dust (including indoor dust ingestion rates), please consult HC (2018).

No recommendations are provided for the amount of food (e.g., produce, vegetation, livestock, wild game, fish) from a contaminated site that could be consumed, as this will depend on the nature of the site. Please refer to HC (2010e) for additional information. Additionally, HC (2007) describes fish consumption values considered from various studies and surveys on fish consumption in Canada. Please refer to this document for consumption values of fish for the general population. For subsistence users and populations, it is recommended that site-specific values be provided along with scientific rationale.

Most assumptions concerning exposure frequency and duration at contaminated sites are based on best professional judgment. However, when site-specific exposure frequency and duration assumptions are not available, the assumptions presented in **Table 2** may be used and documented. If, in the opinion of the risk assessor, other assumptions are more defensible and/or more representative of actual site conditions these may be used, with full justification and references.

The complexity of HHRA for short-duration exposure may not be consistent with the simpler screening-level PQRA. As a result, more detailed risk assessment is typically warranted (as described in HC's DQRA guidance [HC, 2010a]). Dose averaging is not recommended unless supported by a chemical-specific rationale. If short-duration or intermittent exposure is assumed at a site, please consult **Appendix D** of this guidance, the DQRA guidance (HC, 2010a), and the guidance related to the assessment of carcinogens (HC, 2013) for additional information.

When exposure pathways and circumstances beyond those encompassed by the equations and assumptions outlined in this document are considered, additional receptor characterization assumptions should be identified from relevant, recent scientific literature (including the references provided in this document and other Canadian sources of receptor characteristics which are currently published or are published subsequent to this guidance). When Canadian data on required receptor characteristics have not been published, other sources may be consulted. If alternative data sources are used, they must be clearly justified and referenced.

A table of the specific values for receptor characteristics employed in the exposure assessment should be included in the PQRA report to allow for technical review.

2.6.3 EXPOSURE ESTIMATION

Exposure is estimated for each chemical, human receptor/age group (or critical receptors only) and exposure pathway identified as being of concern. Depending on the circumstances, the exposures from multiple pathways and/or chemicals may be summed to derive a total exposure dose (as described further in Section 2.6.3.1). Background exposures may also be assessed in some circumstances.

General exposure estimation equations for chemicals associated with a threshold response are provided in **Box 1**. Additional equations for the estimation of exposure (e.g., from radiation, consumption of country foods, non-threshold carcinogenic effects, air, indoor dust and sediments, and for the incorporation of the oral bioavailability of substances in soil) are found in other HC guidance documents (HC 2010c, 2010e, 2013, 2017a-c, 2018).

For non-threshold carcinogenic effects, derivation of the lifetime average daily dose (LADD) should employ the life stages relevant to the specific land use and their respective characteristics and durations. The reader is referred to HC (2013) for guidance on assessment of carcinogens.

A worked example for exposure of a toddler to "Chemical A" in soil (threshold effects) via direct soil ingestion is presented in **Box 2**.

Table 2: Exposure Duration and Frequency Assumptions for Preliminary Quantitative Risk Assessments*

	Agricultural Land	Residential Land	Commercial Land	Industrial Land**
Hours per day on site	24	24	10	10
Days per week on site	7	7	5	5
Weeks per year on site	52	52	48	48
Dermal exposure events per day	1	1	1	1
Days per year of consumption of food from the site†	site-specific	site-specific	site-specific	site-specific
Total years exposed	80	80	35§	35§
Life expectancy (years)	80	80	80	80

* No assumptions are provided for other land uses or remote sites where activities such as camping, hunting/fishing, military exercises, etc. may occur. Rather, site-specific assumptions are requested and a short duration exposure should be evaluated on a chemical-specific basis with appropriate scientific rationale.

** Receptors are assumed to be adults only for industrial land use.

† Food consumption rates should be site-specific and any short duration exposure should be evaluated on a chemical-specific basis with appropriate scientific rationale.

§ 35 years' exposure based on the assumption that an employee, rather than member of the general public, will be the most exposed.

Box 1: Recommended General Equations for Exposure Dose Estimation – Threshold Effects

General equations are presented below for exposure dose estimation of chemicals associated with a threshold response. Abbreviations denoting variables have been harmonized through all equations.

For non-threshold carcinogenic effects, the reader is referred to HC (2013) guidance on assessment of carcinogens.

Inadvertent Ingestion of Contaminated Soil

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

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

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
BW = body weight (kg_{BW})

Notes: Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures to chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_2 and D_3 should be 1 (i.e., 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_2 and D_3 values are preferred.

Inhalation of Suspended Particulate Matter in Air From Contaminated Soils – with TRV Expressed as an Oral Tolerable Daily Intake (TDI)

If the oral TRV is the only TRV available for the substance (i.e., if there are no data available to derive an inhalation TRV and if the toxicological effects are expected to be similar for ingestion and inhalation exposure routes), the predicted intake of COPCs via inhalation of particulate matter in air is calculated as follows:

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

Where:
C_S = concentration of contaminant in soil (mg/kg)
P_{Air} = particulate concentration in air (kg/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
BW = body weight (kg_{BW})

Notes: (1) Where the TRV is in mg/m^3, there is no need to convert the concentration to a dose rate in mg/kg_{BW}-day (refer to alternative equation below). (2) P_{Air} may be directly measured or may be estimated using the methods discussed in the text. Alternatively, C_A = airborne concentration of contaminant (mg/m^3) may be directly measured, and would replace the terms C_S and P_{Air} in the above equation. (3) Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures to chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_1, D_2 and D_3 should be 1 (i.e., 24 hours per day, 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_1 should be not less than 0.42 (i.e., 10 hours per day), D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_1, D_2 and D_3 values are preferred.

Inhalation of Volatile Substances – with TRV Expressed as an Oral Tolerable Daily Intake (TDI)

If the oral TRV is the only TRV available for the substance (i.e., if there are no data available to derive an inhalation TRV and if the toxicological effects are expected to be similar for ingestion and inhalation exposure routes), the predicted intake of COPCs via inhalation of vapours is calculated as follows:

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

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 for 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
BW = body weight (kg_{BW})

Notes: (1) Where the TRV is in mg/m^3, there is no need to convert the concentration to a dose rate in mg/kg_{BW}-day (refer to alternative equation below). (2) C_A may be directly measured or may be estimated from concentrations of volatile COPCs in soil, groundwater or soil vapour. (3) Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures to chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_1, D_2 and D_3 should be 1 (i.e., 24 hours per day, 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_1 should be not less than 0.42 (i.e., 10 hours per day), D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_1, D_2 and D_3 values are preferred.

Inhalation of Volatile Substances or Suspended Particulate Matter – with TRV Expressed as a Tolerable Concentration (TC)

It is typical to estimate the time-adjusted average daily air concentration (TDC_A) rather than an exposure dose for COPCs with TRVs expressed as TCs (i.e., threshold response with TCs in µg/m^3 or mg/m^3). The exposure can be estimated according to the following equation:

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

Where:
TDC_A = time-adjusted average daily air concentration (mg/m^3)
C_A = concentration of contaminant in air (mg/m^3); in the case of suspended particulate matter C_A may be measured, or estimated by $C_A = C_S \times P_{Air}$ (where C_S = concentration of contaminant in soil [mg/kg], P_{air} = particulate concentration in air [kg/m^3])
RAF_{Inh} = relative absorption factor for 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

Notes: (1) The TDC_A represents the average daily air concentration that a receptor may be exposed to as a result of frequenting the site. Often this may be the daily average concentration for any 1-year period for systemically acting COPCs. However, care should be taken so that the use of such a long averaging period does not "mask" possible short-term effects, such as irritation. For example, the TDC_A for a chemical that may cause irritation during a 15-minute exposure period should not be averaged over a 24-hour period. Instead, exposure periods need to "match" the exposure period for the short-term toxicological effect as much as possible. Refer to HC's Supplemental Guidance on Human Health Risk Assessment of Air Quality (2017a) for additional equations and information. (2) Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures to chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_1, D_2 and D_3 should be 1 (i.e., 24 hours per day, 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_1 should be not less than 0.42 (i.e., 10 hours per day), D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_1, D_2 and D_3 values are preferred.

Ingestion of Contaminated Drinking Water

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

$$\text{Dose (mg/kg}_{BW}\text{-day)} = \frac{C_W \times IR_W \times RAF_{Oral} \times D_2 \times D_3}{BW}$$

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
BW = body weight (kg_{BW})

Notes: (1) The calculation of a site-specific drinking water guideline is not recommended for substances with existing Guidelines for Canadian Drinking Water Quality or Health Canada interim screening values. The predicted intake of COPCs via contaminated drinking water should be included in the total dose estimate. (2) C_W may be directly measured or may be estimated using methods described by CCME (2006) or other validated models, with references provided. (3) Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures to chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_2 and D_3 should be 1 (i.e., 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_2 and D_3 values are preferred. (4) Select Drinking Water Screening Values are available for some substances (on request), in cases where no Canadian Drinking Water Guidelines exist. Please contact HC by email at **hc.cs-sc.sc@canada.ca**.

Dermal Absorption from Contaminated Soil

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

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

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)
nEv = number of dermal exposure events/day (assumed to be 1 event/day)
RAF_{Derm} = relative dermal absorption factor (unitless)
D_2 = days per week exposed/7 days
D_3 = weeks per year exposed/52 weeks
BW = body weight (kg_{BW})

Notes: Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures to chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_2 and D_3 should be 1 (i.e., 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_2 and D_3 values are preferred.

Ingestion of Contaminated Foods (Produce, Fish, Game, etc.)

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

$$\text{Dose (mg/kg}_{BW}\text{-day)} = \frac{\sum [C_{Food_i} \times IR_{Food_i} \times RAF_{Food_i} \times D_2 \times D_3]}{BW}$$

Where:
C_{Food_i} = concentration of contaminant in food type *i* (mg/kg)
IR_{Food_i} = ingestion rate for food type *i* (kg/day)*
RAF_{Food_i} = relative absorption factor from the gastrointestinal tract for contaminant in food type *i* (unitless)
D_2 = days per week food type *i* is consumed/7days
D_3 = weeks per year food type *i* is consumed/52 weeks
BW = body weight (kg_{BW})

Notes: (1) Concentrations of contaminants in foods can be measured directly or can be predicted using models. (2) Dose averaging should be evaluated on a chemical-specific basis. This is particularly important when considering exposures posed by chemicals with developmental (fetal) effects, as these effects may result from exposures during a particular window of susceptibility. In a PQRA for residential, parkland or agricultural land use, D_2 and D_3 should be 1 (i.e., 7 days per week, 52 weeks per year). In a PQRA for commercial or industrial land use, D_2 should be not less than 0.71 (i.e., 5 days per week) and D_3 should be not less than 0.92 (i.e., 48 weeks per year). A DQRA is recommended for scenarios where alternate D_2 and D_3 values are preferred.

* Site-specific ingestion rates are recommended for foods, and it should be noted in the HHRA whether elevated consumption of some foods may occur in specific seasons.

Box 2: Worked Example of Exposure to Chemical A via Inadvertent Soil Ingestion by a Toddler at a Contaminated Site

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

Where:
C_S = concentration of contaminant in soil (mg/kg) = 9750 mg/kg
IR_S = receptor soil ingestion rate (kg/d) = 0.000080 kg/d
RAF_{Oral} = relative absorption factor from the gastrointestinal tract (unitless) = 100% (1.0)
D_2 = days per week exposed/7 days = 5 days/7 days = 0.71 (commercial land use)
D_3 = weeks per year exposed/52 weeks = 48 weeks/52 weeks = 0.92 (commercial land use)
BW = body weight (kg_{BW})

$$\text{Dose (mg/kg}_{BW}\text{-day)} = \frac{9750 \text{ mg/kg} \times 0.000080 \text{ kg/day} \times 1.0 \times 0.71 \times 0.92}{16.5 \text{ kg}_{BW}}$$

$$= \frac{0.51 \text{ mg/day}}{16.5 \text{ kg}_{BW}}$$

$$= 0.031 \text{ mg/kg}_{BW}\text{-day}$$

2.6.3.1 RELATIVE ABSORPTION FACTORS AND EXPOSURE VIA MULTIPLE PATHWAYS

In a risk assessment, chemical-specific exposure should be assessed for each exposure pathway and for each human receptor age or group (or critical receptor) that may be impacted by the site contamination. As appropriate, the exposures from various potential pathways may be further combined by exposure route (e.g., estimates of soil, water, and food ingestion exposure summed for the oral route).

Estimates of exposure are calculated separately for each exposure route (e.g., ingestion, dermal contact, and inhalation) for comparison with pathway-specific TRVs. Typically, absorption following ingestion exposure is assumed to be 100% (i.e., the oral bioavailability of a COPC at the site is assumed to be identical to the one in the study used to derive the TRV), as oral TRVs are based on the administered (not absorbed) dose. Oral exposures should always be assumed to have a relative absorption of 100% (oral relative absorption factor or RAF_{Oral} = 1) in a PQRA. Likewise, absorption following inhalation exposure will be assumed to be 100%, as inhalation TRVs are generally based on the measured airborne concentration, not the absorbed dose (i.e., the bioavailability of the COPC at the site is assumed to be the same as the bioavailability of the COPC in the inhalation study used to derive the TRV).

If the oral bioavailability for site-specific soils relative to the critical study used to derive the TRV is known, the reader is referred to HC guidance (2017c) on oral bioavailability for possible application of another value in a DQRA. Such data are typically used in a DQRA and are often beyond the scope of a PQRA.

In the case of COPCs for which exposure estimates from multiple exposure routes will be summed for comparison with a single TRV, it may be necessary to apply RAFs (one route relative to another) in exposure calculations. When inhalation exposures are being summed with ingestion exposures (e.g., because there is no separate inhalation TRV), the inhalation RAF (RAF_{Inh}) will generally default to 1, unless there is good evidence that respiratory absorption is significantly less than oral absorption. Such evidence must be fully referenced if an $RAF_{Inh} < 1$ is used. Published toxicological studies should also be reviewed to confirm that using the oral TRV to characterize potential inhalation risks is toxicologically defensible.

Few TRVs exist specifically for the dermal exposure pathway. Therefore, dermal exposures are routinely added to the oral exposure, following adjustment for relative bioavailability or absorption, for subsequent comparison with the oral TRV. When dermal exposures are summed with oral exposures, the dermal RAF (RAF_{Derm}) values presented in HC guidance (HC, 2021) should be applied, unless more appropriate information has been identified and justified (with proper citations). For contaminants not listed in that document, other authoritative sources, such as the US EPA's Risk Assessment Information System (**http://rais.ornl.gov**) and the Toxicological Profiles published by the Agency for Toxic Substances and Disease Registry (**www.atsdr.cdc.gov/toxprofiledocs/index.html**) should be consulted. If alternative data sources are used, they should be clearly cited and fully referenced.

For other forms of dermal exposures, such as while swimming, dermal absorption factors in units of $\mu g/cm^2$-hour may be required. The source of the equations for these types of dermal exposure (and the related assumptions) should be clearly cited and fully referenced.

2.6.3.2 ASSESSMENT OF RISKS POSED BY EXPOSURES OF LESS-THAN-CHRONIC DURATION

Some sites are not accessed on an ongoing basis, unlike residential or commercial/industrial settings, as defined by CCME (2006). For sites that are not accessed frequently, please consult Appendix D, DQRA guidance (HC, 2010a), guidance on assessment of exposure to carcinogens (HC, 2013), as well as published literature (e.g., Haber et al., 2016) for information related to assessment of less than chronic exposure. Dose averaging is not recommended unless supported by a chemical-specific rationale. The complexity of short-duration exposure assessment is not consistent with a PQRA and a more detailed risk assessment is typically warranted, as described in HC (2010a).

2.7 RISK CHARACTERIZATION

Risk characterization is the estimation of the potential risks that may result from exposure to chemicals at a contaminated site. Risks are quantified by comparing the estimated exposures to chemicals from the site (**Section 2.6**) with the appropriate TRVs (**Section 2.5**).

2.7.1 THRESHOLD EFFECTS: SINGLE-CHEMICAL EXPOSURES

For threshold effects, a hazard quotient (HQ) (analogous terms include "exposure ratio" and "hazard ratio") is derived as the ratio of the estimated exposure to the TDI or TC, as indicated below. The HQ is not an actual indicator of health risks (probability and/or level of effect), but rather indicates the potential for adverse effects.

Box 3: Hazard quotient (HQ) equations

In the case of oral, dermal, or summed exposures being compared with a tolerable daily intake (TDI) (or similar TRV such as an RfD, etc.) in units of mg/kg$_{BW}$-day:

$$\text{Hazard Quotient} = \frac{\text{Estimated Dose (mg/kg}_{BW}\text{-d)}}{\text{Tolerable Daily Intake (mg/kg}_{BW}\text{-d)}}$$

In the case of airborne contaminants with TRVs expressed as tolerable air concentrations (TCs) in units of µg/m^3:

$$\text{Hazard Quotient} = \frac{\text{Time-Adjusted Average Daily Air Concentration (µg/m}^3\text{)}}{\text{Tolerable Air Concentration (µg/m}^3\text{)}}$$

HQs for ingestion, dermal contact, and inhalation exposures should be presented separately when there are pathway-specific TRVs. When exposures via multiple exposure pathways or routes are being summed for comparison with a single TRV (for example, it is common to sum oral and dermal exposures for comparison with the oral TDI), it is recommended that the report provide the HQs for the summed exposures as well as HQs for the individual exposure pathways. Where a TC is used to assess potential risk via inhalation exposure, the report should provide a rationale as to whether the HQ for inhalation exposure needs to be summed with the HQ for the oral and dermal pathways if effects are anticipated on the same target organ.

For purposes of the PQRA, exposures arising from the site (excluding background exposures) associated with an HQ ≤ 0.2 will be deemed negligible. This is consistent with CCME (2006). For some substances, such as PHCs, a target other than 0.2 may be used (CCME, 2008a), with rationale.

In some cases, the risk assessor may choose to assess the combined risks associated with the site and background sources (including exposures from use of consumer products as well as from food, air, and water that are not related to the site) and compare the resulting HQ with a target value of 1.0, as per HC (2010a) guidance.

2.7.2 NON-THRESHOLD CARCINOGENIC EFFECTS: SINGLE-CHEMICAL EXPOSURES

For substances with non-threshold carcinogenic effects, the estimated exposure is multiplied by an appropriate TRV (e.g., slope factor [SF] or unit risk [UR]) to derive a conservative estimate of the potential incremental lifetime cancer risk (ILCR) associated with that exposure. The ILCR for oral exposure is derived as indicated in the equation below. For more details and for an equation for inhalation exposure, refer to HC (2013).

Box 4: Incremental lifetime cancer risk (ILCR) equations

In the case of oral, dermal or summed exposures, the estimated ILCR can be based on the oral cancer slope factor (SF) $(mg/kg_{BW}\text{-}day)^{-1}$ using the following equation:

$$ILCR = \sum_{i=1}^{n} (SF \times ADAF_i \times LADD_i)$$

Where:
i varies between 1 and n, which is the number of life stages for which there are specific ADAFs and LADDs
ILCR = incremental lifetime cancer risk
SF_{oral} = oral cancer slope factor for adults $(mg/kg_{BW}\text{-}day)^{-1}$
$ADAF_i$ = age-dependent adjustment factor for lifestage i
$LADD_i$ = dose received during lifestage i averaged over a lifetime $(mg/kg_{BW}\text{-}day)$

In the case of airborne contaminants with TRVs expressed as a unit risk (UR) in units of $(mg/m^3)^{-1}$:

$$ILCR = \sum_{i=1}^{n} (C_{ai} * TR_i * UR * ADAF_i)$$

Where:
i varies between 1 and n, which is the number of life stages for which there are specific ADAFs
C_{ai} = concentration in air during lifestage i (mg/m^3)
TR_i = fraction of time exposed for lifestage i (yr/80 yr)
UR = adult inhalation cancer unit risk $(mg/m^3)^{-1}$
$ADAF_i$ = age-dependent adjustment factor for lifestage i

Refer to HC (2013) for more details and other ILCR equations.

The ILCR can be estimated by summing the risk of each discrete life stage or exposure period. The receptor that is exposed throughout all life stages is often referred to as a "composite" receptor. This approach takes into consideration potential varying sensitivity of the different life stages.

Cancer SFs and URs derived for non-threshold carcinogens are usually based on adult cancer data (i.e., from adult animal bioassays or adult human epidemiological studies). Hence, to account for the varying sensitivities of the age-specific exposure periods to non-threshold carcinogens acting through a mutagenic mode of action, it is recommended that age-dependent adjustment factors (ADAFs) be applied to the adult cancer SF (or inhalation UR). This approach is illustrated by the ILCR equations presented above. Exposure received during each age-specific exposure period "i" is averaged over a lifetime. In HC (2013), default ADAFs were developed by adjusting the US EPA's ADAFs to be consistent with the age groups recommended in **Appendix E**. These default factors can be applied when age-specific cancer oral SF (or inhalation UR) 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, non-threshold approach to cancer risk estimation is applied. In these cases, a default age-specific adjustment is not recommended (i.e., ADAF = 1 for all life stages). However, for all carcinogenic effects, adjustments to the TRV can be made on a chemical-specific basis if supported by experimental data.

When pathway-specific TRVs exist, the risks via inhalation, ingestion, and dermal contact exposures should be estimated separately. If route-specific TRVs do not exist for all of these exposure routes, the cancer risks posed by simultaneous oral + dermal exposure or inhalation + ingestion + dermal contact exposure may be estimated, in some cases, by a single (possible ingestion or inhalation) TRV. However, published toxicological studies should be reviewed to confirm that using the oral TRV to characterize potential inhalation cancer risks or using an inhalation TRV to characterize ingestion cancer risks (as the case may be) is defensible toxicologically.

Cancer risks will be deemed to be "essentially negligible" (*de minimis*) at federal contaminated sites when the estimated ILCR is ≤ 1 in 100 000 (≤ 1×10^{-5}). The rationale for this essentially negligible risk level is presented in **Appendix C**.

2.7.3 COMBINED EXPOSURE TO MULTIPLE CHEMICALS

Concurrent exposure to a number of chemicals present at a contaminated site is common. HHRA of combined exposure to multiple chemicals is generally conducted with the assumption of additivity where there are similar effects on the same target organ. The World Health Organization (WHO, 2017) has developed a tiered framework for the risk assessment of combined exposure to multiple chemicals. The framework puts chemicals into assessment groups based on similar effects on a common target organ as well as co-exposures.

In a PQRA, considered to be a lower-tiered assessment, an approach based on dose/concentration additivity is the recommended default for chemical groups that induce similar effects on a common target organ. In a higher-tiered assessment, as in a DQRA, the definition of an assessment group is further refined taking into consideration other information such as the mode of action. A DQRA applies additivity to chemical groups that elicit similar effects on a common target organ through a similar mode of action. The approach recommended for a PQRA is deemed conservative, based on analysis of empirical results for the effects of combined exposure, including for chemicals that have different modes of action (Meek et al., 2011).

For simultaneous exposure to COPCs found to have similar threshold effects on common target organs, HQs should be assumed to be additive for those substances. Threshold health effects due to exposure to such COPCs will be deemed negligible if the total HQ is ≤ 0.2 or, when background exposures have also been considered, if the total HQ is ≤ 1.0. All other COPCs that affect different target organs may be assessed individually.

WHO (2017) has summarized additional approaches that can be used to evaluate mixtures of chemicals with dissimilar modes of action, and approaches for evaluating mixtures of chemicals that are interactive (i.e., non-additive effect). Risk assessors can consider the use of these methods.

For non-threshold carcinogenic effects, the ILCRs due to exposure to multiple substances should be added if they elicit similar effects on the same target organ. Carcinogens acting on different target organs may be assessed individually. At federal contaminated sites, the cancer risk in such cases will be deemed "essentially negligible" when the estimated total ILCR is ≤ 1 in 100 000 (1×10^{-5}). P/T guidance should be consulted where a target of 1 in 1 000 000 (1×10^{-6}) may apply.

Methods have been developed to assess the risks from mixtures consisting of a single class of structurally similar chemicals, where extensive toxicological information is available for one chemical (the index chemical) but less is known about the others. These methods rely on the use of scaling factors (e.g., relative potency or toxic equivalency factors) to express the estimated compound-specific toxicity relative to the toxicity of the index chemical.

For example, mixtures of carcinogenic PAHs are assessed using relative potency factors (RPFs), also referred to as potency equivalence factors. An RPF is the ratio of carcinogenic potential of an individual PAH relative to benzo[a]pyrene (B[a]P). For a given mixture, the concentration of each carcinogenic PAH is multiplied by its RPF, and the resulting concentrations are summed to estimate a B[a]P equivalent concentration. Potential cancer risks posed by exposure to carcinogenic PAHs are subsequently characterized by employing the cancer oral SF or inhalation UR for B[a]P.

Likewise, exposures to mixtures of PCDDs/PCDFs and dioxin-like polychlorinated biphenyls (PCBs) are assessed using the World Health Organization's toxic equivalency factors (TEFs) (see van den Berg et al., 2006). For a given mixture, the concentration of each PCDD, PCDF and PCB is multiplied by its respective TEF, and the resulting

concentrations are summed to estimate a 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) toxic equivalent (TEQ) concentration. Risk is subsequently characterized by employing the TRV for 2,3,7,8-TCDD.

2.8 NON-STANDARD ASSUMPTIONS AND NON-STANDARD TOXICOLOGICAL REFERENCE VALUES

If risk assessors have introduced exposure pathways, equations, assumptions and/or TRVs that are different from, or in addition to, those prescribed in this and other HC guidance documents, the implications for exposure and risk estimates should be explained. For example:

- Are the estimated exposures and/or risks higher, lower or of the same order of magnitude as those estimated by means of the prescribed procedures?
- Do the prescribed methods predict negligible risks, whereas the alternative methods suggest that potentially unacceptable risks exist, or vice versa?
- Were the prescribed methods insufficient (or non-existent) to adequately estimate risks?

2.9 VARIABILITIES AND UNCERTAINTIES

Variabilities and uncertainties in exposure and risk estimates should be discussed in order to (1) put into context the conclusions drawn from the risk assessment findings and (2) indicate whether additional work is warranted to reduce variabilities and/or uncertainties in the assessment and/or to allow for site management decisions to be made in a manner that is protective of human health. Issues to be addressed should include, but not be limited to, the following:

- Identification of COPCs based on historical and current activities and the screening criteria used;
- Environmental characterization (number and location of samples, sampling methods, seasonal effects on sampling, analytical methods, quality assurance/quality control [QA/QC], etc.);
- The overall quality and quantity of data;
- Models used (and associated assumptions) to estimate COPC concentrations in secondary media;
- Statistics used to estimate exposure to COPCs (maximum concentrations or other statistic);
- Human receptor characteristics (exposure frequency and duration, ingestion/inhalation rates, etc.);
- Toxicological information for each COPC; and
- Other factors, assumptions, and models that could lead to an overestimation or underestimation of exposures and risks.

2.10 CONCLUSIONS AND DISCUSSION

The overall conclusions with respect to the potential human health risks posed by the contaminated site should be summarized in this section of the PQRA report. Any other issues that, in the opinion of the risk assessor, require discussion or that may affect risk management of the site should be included here and also presented in the executive summary. Key assumptions made in the risk assessment (e.g., assumptions about site conditions and human activities, of time spent at the site) should be noted. The conclusions and discussion should also identify whether additional sampling or modelling and/or a DQRA should be completed in order to more adequately characterize potential health risks at the site or for off-site receptors.

2.11 RECOMMENDATIONS

List all recommendations that may stem from the results of the PQRA, including, but not limited to, the following:

- Details of any additional site investigation study required to further delineate and characterize the contamination or to address critical data gaps in order to better assess health risks;
- Any measures that need to be taken as quickly as possible to protect people who may be affected by site contamination;
- The scope and details for a DQRA, if it is required to reduce uncertainty and to support decisions on remediation or risk management measures;
- Any proposed remedial and/or risk management measures;
- Any site use restriction or risk management measure that must be in place so that assumptions made in the assessment remain valid (e.g., assumption of paved areas that negate direct exposure to soils, building characteristics assumed for vapour intrusion assessment, etc.); and
- The need for any ongoing monitoring.

2.12 REFERENCES AND CITATIONS

The report should be thoroughly referenced to enable technical reviewers to identify and obtain all documents and authoritative sources cited. A complete list of those references is required.

3.0 REFERENCES

HC documents, as well as contractor reports prepared on behalf of HC and cited herein, may be obtained by contacting HC at **hc.cs-sc.sc@canada.ca**.

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Environment Canada. 2016. *Federal Contaminated Sites Action Plan (FCSAP) – Guidance Document on Federal Interim Groundwater Quality Guidelines for Federal Contaminated Sites.* June 2016 (Version 4).

Haber LT, Sandhu R, Li-Muller A, Mohapatra A, Petrovic S, Meek ME. 2016. Framework for human health risk assessment of noncancer effects resulting from short-duration and intermittent exposures to chemicals. *J Appl Toxicol* 36 (9): 1077–1089.

Health Canada (HC). 1994. *Human Health Risk Assessment for Priority Substances: Canadian Environmental Protection Act.* Environmental Substances Division, Environmental Health Directorate, Health Canada, Ottawa.

HC. 2007. *Human Health Risk Assessment of Mercury in Fish and Health Benefits of Fish Consumption.* Bureau of Chemical Safety, Food Directorate. Health Products and Food Branch. Cat.: H164-54/2007E-PDF. ISBN: 978-0-662-47023-6. Available at: **www.canada.ca/en/health-canada/services/food-nutrition/reports-publications/human-health-risk-assessment-mercury-fish-health-benefits-fish-consumption.html**

HC. 2010a. *Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals ($DQRA_{Chem}$).* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

HC. 2010b. *Federal Contaminated Site Risk Assessment in Canada, Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0.* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

HC. 2010c. *Federal Contaminated Site Risk Assessment in Canada, Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment ($DQRA_{RAD}$).* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

HC. 2010d. *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Developing a Contract Statement of Work (SOW) for Human Health Preliminary Quantitative Risk Assessment (PQRA) and Detailed Quantitative Risk Assessment (DQRA).* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

HC. 2010e. *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods ($HHRA_{Foods}$).* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

HC. 2010f. *Federal Contaminated Site Risk Assessment in Canada, Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessments (HHRA).* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

HC. 2010g. *Federal Contaminated Site Risk Assessment in Canada, Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites.* Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

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World Health Organization. 2017. *Chemical Mixtures in Source Water and Drinking-Water.* Geneva, Switzerland, WHO. Available at: **www.who.int/water_sanitation_health/publications/chemical-mixtures-in-water/en**

APPENDIX A: IMPORTANT HUMAN HEALTH RISK ASSESSMENT CONSIDERATIONS

A-1 COMMON ISSUES TO CONSIDER IN HUMAN HEALTH RISK ASSESSMENT

Table A1: Summary of Common Issues in the Conduct and Reporting of Human Health Risk Assessments

Report Topic	Problem or Issue	Resolution
Site Description	Ownership of site not clear.	Provide clarification of ownership.
	Is divestiture planned?	If divestiture is planned, P/T risk assessment guidance (or other P/T requirements) may need to be considered along with HC guidance.
	Insufficient detail on background information. Inadequate site maps.	Include detailed site map(s), content and information on: • Site description (e.g., topography, geology, hydrogeology); • Location of source of drinking water (both on- and off-site, as warranted); • Locations of buildings, surface water (both on- and off-site, as warranted); and • Other (see **Section 2.3**, bulleted list).
	Inadequate description of current and historical land use and activities.	Sufficient detail should be presented in the HHRA to allow a technical reviewer to confirm identification of all potential contaminants based on historical activities (i.e., to identify whether all potential contaminants were analyzed).
	Inadequate description of adjacent land use(s), including distance to nearest residence/ community, size of population, water use, etc.	Consider potential receptors on adjacent properties when contaminants are environmentally mobile (e.g., in groundwater or air) or if people access the site.
Site Characterization	Quality of sampling data: • Little information provided on sampling or analytical methodologies; • Method detection limits not provided; • Description of QA/QC procedures for laboratory analyses and/or field sampling techniques, as well as QA/QC results, not included.	The document should provide reference to standard sampling and analytical procedures, including QA/QC procedures and results (refer to other documents if required). Detection limits should be provided and be compatible with screening criteria. The quality of the data from the site assessment should be assessed for each medium.

Report Topic	Problem or Issue	Resolution
Site Characterization	Quantity of samples: • Insufficient samples collected for a reasonable maximum concentration to be confidently measured or a representative concentration of exposure estimated; and • Insufficient samples collected to delineate (horizontally and vertically) the extent of contamination.	The HHRA report should identify whether additional sampling is required and where samples would be relevant so that the maximum or near maximum contaminant concentration and a representative concentration of exposure may be estimated (and whether a DQRA may be completed to include the additional information). The HHRA should provide a map depicting recent and previous sample locations, and may also include (as applicable): • Delineation of zone(s) of contamination; • Presence and spatial extent of free product; and • Other elements (see **Section 2.3**).
Problem Formulation	Objectives of HHRA not clear.	Explain how the HHRA will be used in the overall contaminated site management process. If the site is to be risk managed, then a PQRA may be used to: • Direct additional site assessment; • Determine the need for more detailed risk assessment; and • Determine the need to identify risk management measures and/or site-specific remediation goals and whether a DQRA would be required for this.
	Contaminants analyzed in the ESA do not reflect historical and current land use.	Identify potential contaminants associated with historical and current land use activities and confirm that they are analyzed in the appropriate environmental media and areas of the site, and that data are available to adequately assess the site and meet the needs of the HHRA.
	Chemicals that lack CCME screening guidelines/standards are inappropriately "screened out". Screening criteria not appropriate for media, chemical analyses or land use for the site. Screening criteria not transcribed correctly or properly referenced.	When CCME guidelines for the protection of human health are not available for a particular substance, human health-based screening criteria from other jurisdiction may be used. If no human health-based criteria exist, the chemical is retained as a COPC and carried forward for further risk assessment, unless measured concentrations are below background concentrations for that area. Otherwise, the report needs to include a rationale for substances not considered to be present at toxic levels (e.g., as may be the case for some essential nutrients such as Ca, Mg). CCME guidelines/standards or other criteria should be used appropriately (i.e., human health-based, relevant land use/pathways, site-specific conditions), referenced and reviewed for transcription errors.

Report Topic	Problem or Issue	Resolution
Problem Formulation	Use of a statistical value other than maximum concentration for COPC screening.	Use **maximum** measured concentrations for screening COPCs into an HHRA. Statistics may be used to estimate an exposure point concentration in the exposure assessment, but not for screening against criteria to identify COPCs. Maximum concentrations of substances in environmental media are used to screen COPCs into the HHRA so that areas of potential environmental concern are not missed and to identify chemicals that may pose risks to human health.
	Receptors and associated exposure pathways not clearly defined.	A detailed rationale should be provided for exposure pathways deemed operable and those deemed inoperable. Also, provide a detailed justification for any receptor/age groups being excluded from the risk assessment.
Exposure Assessment	Receptor exposure characteristics not from accepted sources.	Use receptor characteristics identified by HC when available and applicable. Reference, describe and justify each alternative source of receptor characteristics employed in the HHRA.
	Maximum concentrations or other statistics that represent reasonable maximum exposure not used as exposure point concentrations.	If maximum concentrations or other statistics representing reasonable maximum exposure are not used as exposure point concentrations in the PQRA, provide sufficient data and rationale for the use of alternative statistics. Exposure point concentrations should reflect the data available from the site assessment (e.g., if there are few data points, the maximum concentration should be used), and exposure areas and patterns should be considered. In estimating exposure point concentrations, confirm that areas of potential environmental concern are not missed or "underestimated" by the use of statistics that include data from uncontaminated areas. Statistics should not include data from different sampling pools (e.g., different statistics may be required for soils at depth and at the surface, or for different aquifers).
	Worked calculations not included.	Examples of worked calculations for exposure and risk estimates should be included, with all input parameters.
	Calculations cannot be reproduced; incorrect units in equations.	Risk assessors should check for mathematical errors and confirm the accuracy of unit conversion factors and of calculations. Calculations should be reproducible.

Report Topic	Problem or Issue	Resolution
Toxicity Assessment	TRVs from alternative source used when HC TRVs are available.	Health Canada TRVs, when available, should be applied unless a detailed, scientifically defensible rationale to support the use of an alternative value is provided (e.g., if more recent toxicological information is available from a different agency).
	Inadequate rationale provided for use of alternative TRVs, lack of reference or incorrect transcription.	When sources of TRVs other than HC are used, the following should be included: the basis, method of derivation, level of protection, uncertainty or confidence level, any modifications made to the TRV, and references.
	Health effects associated with each COPC not included.	Potential health effects associated with the COPCs (for both cancer and non-cancer endpoints) should be described. The effects should be differentiated by exposure route (ingestion, dermal contact, inhalation) when appropriate.
Risk Characterization	Risks not calculated for all chemicals, receptors and exposure pathways identified as being of concern in the problem formulation.	Risks associated with all chemicals, receptors, exposure pathways/routes identified as being of concern should be determined. Otherwise, an appropriate rationale should be provided (e.g., where risk estimates are provided solely for critical receptors).
	Quantitative risk estimates for chemicals that elicit similar effects on the same target organ are not summed.	Quantitative risk estimates for chemicals that elicit similar effects on the same target organ should be summed.
	Results of the risk assessment and key assumptions not presented clearly.	Results should be presented so that it is clear which COPCs are associated with unacceptable risks, in which media and for which exposure pathways, including a clear summary of key assumptions. Worked examples should be provided.
Variabilities and Uncertainties (and Data Gaps)	The variabilities and uncertainties in the various components of HHRA (e.g., environmental data, assumptions and models, toxicological information) and their impact on risk assessment results, together with any data gaps that require consideration are not addressed.	Considerations should include (but are not limited to): • Data quantity (sufficiency and location of sampling); • Data quality (sampling and analytical methods, seasonal effects, QA/QC, analytical detection limits relative to screening criteria, etc.); • Selection of COPCs relative to historical and current land uses and screening criteria used; • Models used (and associated assumptions) to estimate COPC concentrations in secondary media; • Statistics used to estimate COPCs exposure point concentrations; • Human receptor characteristics assumed; • Toxicological information for each COPC; and • Other key factors.

A-2 CONTAMINANTS ASSOCIATED WITH VARIOUS GOVERNMENT AND INDUSTRY SECTORS

On occasion, it has been observed that sampling and analytical plans do not address all potential contaminants that may be present at a contaminated site as a result of current and/or historical activities. ESAs should consider all contaminants that may be relevant at a federal contaminated site. For example, any contaminated site at which PHCs were used as fuels or lubricants may also contain benzene, toluene, ethylbenzene, and xylenes (BTEX) and/or PAHs. Depending on the time frame when contamination occurred, lead and/or methyl tert-butyl ether may also be present on sites where gasoline was identified according to site use information.

Contaminants associated with various government and industrial operations/activities are listed in **Table A2**. The list is not intended to be exhaustive of all industrial and government operations/activities or of the contaminants that may be present. Historical and current activities and operations at a site will dictate potential contaminants, and there is no substitute for a thorough examination of past activities and operations.

Table A2 provides an initial starting point to identify both broad classes of contaminants and specific ones that could be associated with the operations and activities at a site.

Contaminated sites at which pH changes are more likely to be observed are also noted in **Table A2**. While not always posing a direct risk to human health, pH changes resulting from the use of strong acids and bases may influence the environmental fate, transport, and biological uptake of metals and ionogenic compounds.

Older buildings at a site may incorporate asbestos-containing material (ACM; insulation, tiles, wall board, etc.), lead (old paint) and mercury (old paint, electrical switches and lights) that may have impacted soils.

Any site where combustion activities (including wood fires) or a fire occurred may contain PAHs and dioxins/furans.

Additional sources of information include the following:

CCME. 2016. *Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment Volume 1*. CCME, Winnipeg.

United Kingdom Environment Agency. *DoE Industry Profiles.* Available at: **http://webarchive.nationalarchives.gov.uk/20140328091253** | **www.environment-agency.gov.uk/research/planning/33708.aspx**

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Table A2: Contaminants Commonly Associated with Government and Industry Sectors*

Facility/operation	Potential contaminants
Abandoned laboratory/chemical facilities	Metals, cyanide, ACM, pH changes, VOCs, 1,4-dioxane, PAHs, PCBs, solvents, site-specific chemicals used, stored or manufactured on site
Adhesives manufacturing and storage	Variable depending on type: water-based, solvent-based, epoxy resin based, natural adhesives (e.g., rubber), solvents, PHCs, isocyanate or cyanocrylates
Agricultural operations	Pesticides, metals (as components of pesticides), 1,4-dioxane, microbiological parameters, nitrates
Airstrip/hangar operations	PHCs, BTEX, PAHs, ethylene glycol, VOCs (notably degreasing solvents), 1,4-dioxane, metals
Antifreeze bulk storage and recovery installations	Glycols
Asbestos mining, milling, wholesale bulk storage or shipping	ACM
Ash from incinerators or other thermal facilities	Metals, pH changes, PAHs, PCBs, dioxins/furans (depending on feedstock)
Automotive repair, maintenance, autobody shops	Metals (notably aluminum, cadmium, chromium, lead, mercury), VOCs, 1,4-dioxane, PHCs, BTEX, PAHs, acetone, carbon tetrachloride, PCE and degradation products, TCE and degradation products, ethylene glycol, CFCs, pH changes
Battery recycling, disposal	Metals (notably arsenic, cadmium, chromium, copper, lead, mercury, nickel, zinc), pH changes
Coal gasification plants/coal tar sites	PAHs, BTEX, cyanide, phenols, ammonia, metals (notably aluminum, chromium, iron, lead, nickel), pH changes
Drum and barrel recycling	Cyanide, pH changes, pesticides, PHCs, BTEX, PAHs, solvents
Dry cleaning	TCE, PCE and degradation products; some dry cleaners employ hydrocarbon-based cleaners
Dye facilities	PAHs, benzene, toluene, metals (notably cadmium, chromium, copper, lead, mercury, nickel, zinc), anilines, amines, quinolines, pH changes
Electrical equipment/transformers	PCBs, PHCs (mineral oils), possibly PAHs and metals
Electronic/computer equipment manufacturing	Solvents, TCE, trichloroethane and degradation products, PHCs, metals
Electroplating	Metals (notably cadmium, chromium, copper, nickel, zinc), cyanide, TCE and trichloroethane and degradation products, pH changes
Fertilizer manufacturing and storage	Nitrate, chloride, sulphur, metals
Firefighting training areas	PHCs, PAHs, VOCs (notably, solvents), lead, MTBE, PFOS, PFOA, PFAS

Facility/operation	Potential contaminants
Fire retardant manufacturing	Metals (notably antimony), brominated compounds such polybrominated diphenyl ether, PFOS, PFOA
Firing range, military training ranges	PAHs, metals (notably arsenic, antimony, lead), possible ordnance (see "Ordnance sites", below), herbicides, energetics
Foundries and scrap metal smelting	Metals
Glass manufacturing	Metals (notably arsenic, cobalt, thorium, uranium, zinc), radioactive materials, PHC, BTEX, PAH
Ink manufacturing	PHC, BTEX, metals
Landfills	Metals (including iron, mercury, lead, zinc), PHCs, BTEX, PAHs, VOCs, 1,4-dioxane, PFAS, phenols, cyanide, PCBs, PCDDs/DFs, pesticides, gases (including methane, carbon dioxide)
Machine maintenance shops, metal fabrication	Metals, VOCs, 1,4-dioxane, TCE and degradation products
Mining, smelting, ore processing, tailings	Metals, pH changes, ACM, cyanide
Mining of coal	Metals, pH changes, sulphur, PAHs
Oil and gas – downstream petroleum facilities (service stations, tank farms)	PHCs (notably F1 and F2), BTEX, PAHs (notably naphthalene), MTBE, organic lead compounds, glycols, other additives, redox changes (possible mobilization of certain metals)
Oil and gas – drilling and exploration sites (well-heads, sumps, flare pits)	Crude oil (PHCs [F1 to F4]), PAHs, BTEX, metals), produced water (salinity, sodicity, chlorides, sulphates, soluble inorganics), workover fluids (pH, salinity, methanol, glycol, Brocide®), chemical additives (pH, sodium, potassium, salinity, chloride, sulphates), halogenated solvents
Oil and gas – oil refineries	PHCs (F1 to F2), BTEX, VOCs, metals
Oil and gas – pipelines (transfer stations, pipeline leaks, cleanouts)	Crude oil and condensate (PHCs [F1 to F4]), PAHs, BTEX, metals), waxes (F3 and F4), halogenated solvents to clear lines
Oil and gas – waste oil (reprocessing, recycling or bulk storage)	PHC, VOCs, BTEX, metals
Ordnance sites	Metals, nitro substituted phenols and benzenes, nitroaromatics, cyclic nitramine explosives (e.g., HMX and RDX), VOCs and SVOCs (including formaldehyde and toluene), herbicides, pesticides and insecticides, UXO, nitroglycerin, perchlorate, other energetic substances (i.e., DNAN, 2,4- and 2,6-DNT, NTO, PETN, TNT)
Paint industry	Benzene, toluene, xylene, metals (notably cadmium, chromium, lead, mercury, zinc), herbicides/fungicides, VOCs
Photographic facilities	Metals (notably chromium, lead, mercury), trichloroethane and degradation products
Print shops	Metals, VOCs, toluene, xylene, pH changes

Facility/operation	Potential contaminants
Pulp and paper mills	Metals (notably boron, cadmium, chromium, mercury, lead, zinc, silver, titanium), VOCs, phenols, dioxins/furans, PCBs, pH changes, cyanide
Quarry sites	Metals, VOCs
Rail yards, maintenance and tracks	PHCs, BTEX, PAHs, VOCs (including solvents and degreasing agents), phenols, PCBs, metals (notably arsenic, cadmium, lead, mercury)
Road salt storage	Chloride, sodium
Salvage/junk yards	Metals, VOCs, 1,4-dioxane, ACM, cyanide, PCBs, PHCs, BTEX, PAHs
Scrap metal	Metals, ACM, BTEX, halogenated solvents (notably TCE, trichloroethane and degradation products), PCBs
Snow from street removal dumping	Metals, chloride, sodium
Steel manufacturing/coke ovens	Metals, BTEX, PAHs, PHCs, phenol
Tanneries	Metals, benzene, cyanide, VOCs, phenols, formaldehyde, pH changes, tannins and lignins
Wharves and docks	Chlorophenols, PAHs, PHCs, TBT
Wood/lumber treatment/preservation	Chlorophenols, phenols, PAHs, PHCs, BTEX, metals (CCA)

* Adapted in part from information presented by the US EPA. 2007. *Industry Profile Fact Sheets. Region 3 Brownfields: Regional Initiatives.*

ABBREVIATIONS

ACM	asbestos-containing material
BTEX	benzene, toluene, ethylbenzene, xylene
CCA	chromated copper arsenate, copper chromium arsenate
CFCs	chlorofluorocarbons
HMX	High Melting eXplosive (octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine)
PAHs	polycyclic aromatic hydrocarbons
PCBs	polychlorinated biphenyls
PCDDs/DFs	polychlorinated dibenzo-*p*-dioxins/dibenzofurans
PCE	perchloroethylene (tetrachloroethylene)
PFAS	poly- and perfluoroalkyl substances
PFOA	perflurooctanoic acid
PFOS	perfluorooctane sulfonate
PHCs	petroleum hydrocarbon compounds
MTBE	methyl tertiary-butyl ether
RDX	Royal Demolition eXplosive (cyclotrimethylene trinitramine)
SVOCs	semi-volatile organic compounds
TBT	tributyltin
TCE	trichloroethylene
TNT	trinitrotoluene
UXO	unexploded ordnance
VOCs	volatile organic compounds

APPENDIX B: SCREENING CONTAMINANTS OF POTENTIAL CONCERN AGAINST LOCAL OR REGIONAL BACKGROUND SOIL, GROUNDWATER, AND SURFACE WATER CONCENTRATIONS

Before a site is considered contaminated, on-site concentrations of substances, particularly natural elements and widely distributed chemicals, can be compared with data from local or regional surveys of soil quality, groundwater quality, or surface water quality in areas unaffected by the site or local anthropogenic activities. They can also be compared with measurements from appropriate reference sites free of any possible anthropogenic point source influence. If possible, such surveys should be conducted at the time of the ESA.

The results of many regional soil surveys are available in the open scientific literature. Soil survey data for inorganic elements are available from various P/T ministries of natural resources and from the Geological Survey of Canada (GSC); these have conducted surveys and compiled soil survey data for the purpose of mineral exploration and mineral mapping. The GSC surveys are publicly available as GSC Open Files, which can be searched and reviewed with the assistance of the local GSC office or library. In support of FCSAP, the GSC has now compiled the majority of available federal and P/T regional geochemical surveys (see **http://geochem.nrcan.gc.ca/cdogs/content/main/home_en.htm**).

If concentrations of substances at the site are found to be representative of background levels, these substances may not be considered contaminants, despite the fact that generic guidelines are exceeded. Metals speciation may be pertinent in this determination.

Many substances, particularly metals, are naturally occurring, and natural levels can exceed CCME guidelines without representing anthropogenic contamination, as the background concentration identified in setting CCME guidelines may be variable across Canada and may not be reflective of natural regional background concentrations.

The CCME national soil quality guidelines are derived considering background levels in soil in Canada (CCME, 2006). CCME (1996) recommends that local soil quality objectives be established to incorporate local or regional background concentrations if they are significantly different from the background value used to derive the national generic guideline for a particular contaminant.

In some cases, it may be appropriate to use urban background concentrations, rather than those associated with more rural areas, if the site is in an urban environment. If the local or regional urban environments have elevated concentrations from sources other than the subject site, and those elevated concentrations are accepted and not slated for remediation or risk management, then these urban background levels may constitute the appropriate background concentrations for risk assessment and risk management purposes. However, professional judgement will be required to determine the most suitable basis for defining background concentrations.

The British Columbia Ministry of Environment and Climate Change Strategy (2019) provides procedures for establishing local background concentrations in soil and also provides some specific regional background estimates in soil. Ontario-specific background data are reported in Ontario Ministry of the Environment, Conservation and Parks (MECP, 2011) (formerly Ontario Ministry of the Environment).

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APPENDIX C: ESSENTIALLY NEGLIGIBLE CANCER RISK FOR CONTAMINATED SITE RISK ASSESSMENT

When assessing the potential risks posed by exposure to substances eliciting non-threshold carcinogenic effects, regulatory agencies such as HC assume that any level of exposure (other than zero) may be associated with some hypothetical cancer risk. As a result, it is necessary for regulatory agencies to specify a level of carcinogenic risk that is considered acceptable, tolerable or essentially negligible.

In the 1970s, the US Food and Drug Agency was the first agency to address this issue, adopting a risk level of 1 in 1 000 000 (1×10^{-6}) as the incremental cancer risk considered to be "essentially zero" for carcinogenic residues in foods (Kelly, 1991). Since then, the 1×10^{-6} risk level has become commonplace in the regulation and management of environmental contaminants, with the strongest endorsement coming from the US EPA, which employs 1×10^{-6} as its primary risk benchmark for "acceptable" exposure to carcinogens eliciting non-threshold carcinogenic effects within the general population.

Although a 1×10^{-6} additional *de minimis* cancer risk is frequently used for the management of risks posed by environmental (including soil) contamination, many agencies and provinces, including the US EPA, identify an acceptable risk range, generally from 1 in 10 000 (or 1×10^{-4}) to 1 in 1 000 000 (or 1×10^{-6}), depending on the situation and circumstances of exposure (Graham, 1993; Kelly, 1991; Lohner, 1997; Travis et al., 1987; US EPA, 1991).

In contrast, many industrial standards for workplace environments (e.g., American Conference of Government Industrial Hygienists, 2002) offer a protection to only the 1×10^{-3} level or higher of risk (e.g., a risk of 1×10^{-2}, or 1 in 100, is a 1% chance). This higher cancer risk is "accepted" in workplace environments because it is often not technologically or financially feasible to reduce exposures to even lower levels, and the nature of exposure is generally deemed to be informed and "voluntary" in the workplace. The US Supreme Court has upheld the industry basis for such standards (Graham, 1993).

Health Canada (formerly Health and Welfare Canada) (HWC, 1989), as the federal advisor on environmental health issues, has established that a cancer risk in the range of 1×10^{-5} to 1×10^{-6} is "essentially negligible" for carcinogenic substances in drinking water. Although published HC advice on this issue has been restricted to exposures via drinking water, the 1×10^{-5} risk level has been widely accepted by federal agencies and others involved with contaminated site risk assessment.

The background incidence of cancer in Canada and the US is high relative to a 1×10^{-5} or 1×10^{-6} risk level. In Canada, 50% of Canadians will develop cancer in their lifetime (Canadian Cancer Statistics Advisory Committee, 2018). Thus, an excess or incremental cancer risk of 1×10^{-5} increases a Canadian's lifetime cancer risk from 0.50000 to 0.50001.

Some unknown proportion of this "background" cancer incidence is believed to be associated with exposure to environmental pollutants. However, a 1×10^{-5} incremental (i.e., over and above background) cancer risk represents only a 0.0025% increase over background cancer incidence. This marginal increase is very unlikely to be detectable with available epidemiological data and statistical methods, particularly in smaller populations that may reside near contaminated sites.

Hypothetical incremental cancer rates associated with substances eliciting non-threshold carcinogenic effects at contaminated sites are estimated from cancer slope factors or unit risks derived from human epidemiological studies and animal cancer bioassays. Generally, the incidence of cancer for occupationally exposed adults or laboratory animals (both of which are exposed to dose levels generally greater than exposure levels in the general population or in populations residing near contaminated sites) is plotted against the exposure dose (often standardized for exposure duration, particularly for occupational studies), and a dose–response curve is fitted to those data. This dose–response curve is then extrapolated from the study exposure range down to a dose of zero, with the assumption that there is no threshold below which cancer will not occur.

In the US, low-dose extrapolation is achieved through application of the linearized multistage model (Crump, 1996); this statistical model can describe both linear and non-linear dose–response patterns, and produces an upper confidence bound on the linear low-dose slope of the dose–response curve. HC applied this same methodology for the derivation of the tumourigenic concentration 05 (TC_{05}) (the concentration in air or water found to induce a 5% increase in the incidence of, or deaths due to, tumours considered to be associated with exposure [HC, 1996]) or the tumourigenic dose 05 (TD_{05}) (the dose found to induce a 5% increase in the incidence of, or deaths due to, tumours considered to be associated with exposure).

HC may also apply a model-free low-dose extrapolation method (Krewski et al., 1991), making no *a priori* judgments regarding the shape of the dose–response curve in the low-dose range. The model-free approach can also provide an upper bound estimate on the slope of the dose–response curve in the low-dose range. These upper bounds on the dose–response curve become the cancer slope factors or unit risks employed for the estimation of hypothetical cancer rates. As such, the slope factor or unit risk for non-threshold carcinogenic effects is believed to overestimate the true cancer incidence associated with low-dose exposure to environmental pollutants, such as those at contaminated sites (Kelly, 1991).

Given the conservative (safety) margin associated with the derivation of cancer slope factors and unit risks, and the negligible impact of a 1×10^{-5} incremental risk level for contaminated site exposures, a cancer risk level of 1×10^{-5} is recommended for the purposes of assessing and managing federal sites contaminated with substances eliciting non-threshold carcinogenic effects.

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APPENDIX D: EVALUATING HUMAN HEALTH RISK AT CONTAMINATED SITES FOR CHRONIC AND LESS-THAN-CHRONIC EXPOSURES TO CHEMICALS

D-1 INTRODUCTION

This appendix highlights the fundamentals of HC's current advice regarding the evaluation of cancer and non-cancer health risks from exposure to chemicals present at a contaminated site related to (1) chronic (e.g., lifetime) and (2) less-than-chronic (e.g., less-than-lifetime or short-duration) exposures. Other guidance documents on HHRA in support of FCSAP are listed on the HC website (**www.canada.ca/en/health-canada/services/environmental-workplace-health/contaminated-sites.html**) and may be obtained by contacting HC at **hc.cs-sc.sc@canada.ca**.

D-1.1 PURPOSE

The main purpose of this appendix is to provide additional guidance to custodians of federal contaminated sites where human access to the site is infrequent and/or for short periods of time. Although assessment of short duration exposures is typically addressed in a DQRA, this appendix provides information that requires consideration where short-duration exposures are assessed for risk within the context of a PQRA. It is important that short-term exposures in a PQRA are not amortized over a longer period without consideration of the following information.

Short-duration exposure at contaminated sites may be associated with activities that occur over a relatively short period of time, such as seasonal activities (e.g., gardening and camping), and with certain occupational activities (e.g., construction and underground service installation, or rare site visits to remote locations). Health risks from short-duration exposure often need to be addressed at federal contaminated sites.

Health effects due to less-than-chronic (or less-than-lifetime) exposure may differ from the effects of chronic (or lifetime) exposure and thus may need to be evaluated using different approaches. The present document and HC's (2010) DQRA guidance on human health risk assessment mainly address chronic or lifetime exposures. The *Interim Guidance on Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites* (HC, 2013) presents an updated cancer risk assessment approach that is applicable to both lifetime and less-than-lifetime exposures.

This appendix provides supplemental information related to evaluating potential cancer and non-cancer health effects resulting from exposure to chemicals at contaminated sites under both chronic and less-than-chronic (single, repeated or intermittent) exposure scenarios. For other HHRA issues related to federal contaminated sites, please refer to relevant HC guidance documents.

D-1.2 BACKGROUND

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

TRVs for carcinogens are often based on the results of animal studies in which the animals were exposed on a daily basis throughout their adult lifespan. Exposures of people at a contaminated site 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 *in utero* or during childhood, which are life stages not represented in standard cancer bioassays. In the case of non-carcinogenic effects, most of the TRVs are for chronic exposure and are derived from studies involving long-duration exposure of at least 1 year. An uncertainty factor is applied for those that are based on subchronic studies (i.e., at least 10% of the life span, 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 exposures of people are of a much shorter duration.

It is recommended that dose averaging not be used to characterize health risks associated with short-duration exposures which 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 of non-exposure). One reason is that dose averaging assumes toxicity to be linearly proportional to the magnitude and duration of exposure. For example, it assumes an exposure of 365 mg/kg_{BW}-day for 1 day, 36.5 mg/kg_{BW}-day for 10 days and 1 mg/kg_{BW}-day for 365 days to be toxicologically equivalent, which could be untrue.

The following additional issues related to dose averaging (sometimes referred to as dose amortization) have been raised (HC, 2013):

- There is the potential to underestimate chronic health risks because of the practice of time averaging of exposures. This issue arises for both cancer and non-cancer risk assessments.
- The possibilities 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, prenatal, neonatal, childhood, adolescent, 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.

D-2 NON-CARCINOGENIC EFFECTS

This section provides HC's current guidance on approaches to contaminated sites risk assessment associated with non-cancer effects from chronic and less-than-chronic exposures. It is suggested that the reader be familiar with the general concepts and approach to contaminated sites HHRA presented in HC (2010) *Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA)*.

D-2.1 CHRONIC EXPOSURE

For guidance on evaluation of non-cancer effects from chronic exposures, please refer to HC's (2010) *Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA)*.

D-2.2 LESS-THAN-CHRONIC EXPOSURE

Non-cancer effects from less-than-chronic exposures can be evaluated for the most critical receptors accessing a site. 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 (i.e., where the potential effect on human health is not cancer), 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") with a chronic TRV (which is based on the most sensitive endpoint and life stage, including developmental toxicity). Limited dose averaging is permissible if supported with a chemical-specific rationale, i.e., for chemicals with tolerable weekly intakes (TWIs) or tolerable monthly intakes (TMIs). For chemicals with existing CCME human health based guidelines, dose averaging of 5 days/7 days (plus 10 hours/24 hours in the case of inhalation exposure) and 48 weeks/52 weeks in a year are allowed in the initial screening for commercial and industrial land uses. For these substances, 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 substances that do not require further consideration. This tiered approach is desirable in order to minimize costs associated with HHRAs and so that appropriate attention is given to the substances that may be of concern and that may require additional work.

Higher-tiered assessments compare exposure with 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 HC's DQRA guidance (2010). 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 an appropriate, scientifically based rationale is provided in the assessment report. Higher-tiered assessments may also involve physiologically based pharmacokinetic (PBPK) modelling, which is not typically conducted in contaminated site risk assessments, with the exception of very large and complex sites. For example, when a multimedia DQRA that exceeds the target risk level is deemed overly conservative on the basis of evidence from the scientific literature, the risk assessment can be further refined to reduce uncertainty. Like bioavailability testing, PBPK modelling is one of the potential tools that can be used to further reduce uncertainty.

It is important that any dose averaging conducted does not underestimate the potential for threshold effects. The HHRA practitioner should not mathematically spread out a daily short-duration exposure rate over a longer period and conclude 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 with the appropriate TRV.

When dose averaging is being considered, HC's DQRA guidance (2010) recommends that it be supported by an 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. First, the TRV should match as closely as possible the duration of exposure at the site; the TRVs must be developed for the same (or longer) duration as the exposure of interest. Second, 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, for example:
  - › If toxicity is primarily driven by contaminant concentration (c), or
  - › If toxicity is primarily driven by time-integrated exposure (concentration or dose multiplied by time [c * t] or expressed as the area under the concentration-time curve) or

    - If toxicity is primarily driven by both the contaminant concentration and the time-integrated exposure;
- The duration of effects (i.e., the reversibility of the effect 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 metabolite(s).

For some chemicals, sufficient toxicokinetic and/or toxicodynamic data may not be available to satisfy the data 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, if 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 that this exposure would not exceed a TRV for this endpoint, even for one day.

Sections D-2.2.1 and **D-2.2.2** provide a brief description of the higher-tiered assessments that would be most applicable to federal contaminated sites.

D-2.2.1 SINGLE EXPOSURE

Short-duration TRVs with comparable exposure periods can be used for short-duration exposures, but the TRVs must be developed for a similar (or longer) duration as the exposure scenario of interest. These less-than-chronic duration TRVs can either be obtained from other regulatory agencies or derived from literature values as per HC's DQRA guidance (HC, 2010). If short-duration TRVs are not available, an analysis can be conducted on the basis of 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 whether earlier biological key events might progress to these health effects.

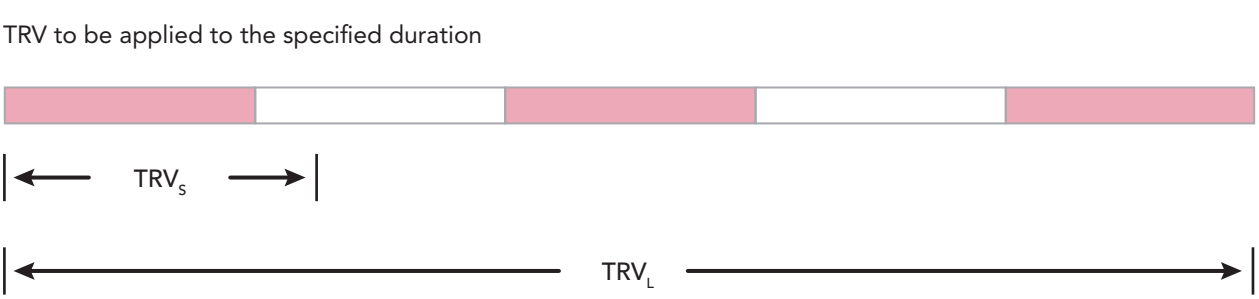
D-2.2.2 REPEATED AND INTERMITTENT EXPOSURES

It is important to note that most TRVs intended for short-duration exposure are derived assuming one-time exposure and not repeated intermittent exposure events. Intermittent exposure can happen at contaminated sites where people access the site multiple times, but each time is only for a short period. Repeated exposures may result in different health effects than those from a single exposure, particularly if the substance 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 with a suitable longer-duration TRV. A suitable longer-duration TRV would be one that has been developed for 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, particularly if the chemicals (or their active metabolite[s]) have long elimination half-lives. When 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 a rationale from a toxicologist to support the TRV and anticipated exposure. As above, in a tiered approach, 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 with the intervals between exposure, if the effects are reversible and recovery from them is rapid (i.e., recovery time shorter than the interval between exposures), it may be adequate to apply a short-duration TRV to each discrete exposure period. The rationale should be provided in the HHRA, with references. 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[s]) has been virtually eliminated before re-exposure occurs, with repeated exposures biological changes will likely progress 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 should include a discussion of uncertainties and the potential for over- or under-estimation of risk.

The analysis to be conducted for intermittent exposure is illustrated in **Figure D1**, which highlights that a short-duration TRV should be selected that is consistent with the (repeated or intermittent) discrete exposure episode.

Figure D1: Analysis Required for the Selection of Appropriate TRVs for Assessing Non-Carcinogenic Effects Associated with Intermittent Exposures



D-2.3 EXAMPLES OF SHORT-DURATION EXPOSURE

The following examples illustrate an assessment of non-cancer effects for short-duration exposures. Whether dose averaging is appropriate 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.

- If the chemical (or active metabolite[s]) cannot be eliminated entirely before the next exposure, no dose averaging is supported.
- If the chemical is eliminated entirely but the effect persists beyond the non-exposure interval, the mode of action determines whether dose averaging can be supported, as follows:
  - No dose averaging can be supported if toxicity is primarily driven by contaminant concentration (c).
  - Dose averaging may be appropriate if toxicity is primarily driven by time-integrated exposure (t) (i.e., c × t or area under the concentration–time curve).
  - Dose averaging may not be appropriate if toxicity is primarily driven by both the contaminant concentration and time-integrated exposure.

Life stage sensitivity to the action of the chemical is also chemical-specific and has to be factored into the considerations. All considerations need to be provided and fully referenced in the HHRA report.

A screening assessment is usually recommended at the outset, comparing the exposure (usually without dose averaging) with an appropriate chronic TRV. A TRV based on developmental effects can be considered a chronic TRV. If the HQ is above the target value (refer to HC's (2010) DQRA guidance), then further assessment is required.

D-2.3.1 SCENARIO 1

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

This scenario involves an exposure episode of 5 days, which is not repeated until the following year. 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[s]) cannot be eliminated entirely before the next exposure occurs (i.e., 1 year later) or the effect accumulates (and does not reverse) within the 1-year no-exposure interval. Generally, provided that elimination mechanisms are not saturated, approximately 97% of the chemical present in the body would have been eliminated (often considered "complete removal") after a period of five whole-body elimination half-lives has elapsed since exposure ceases. Since this exposure is repeated for 35 years, the additional assessment would involve a chronic TRV. Whether dose averaging is appropriate will depend on the factors indicated in **Section D-2.2.2**.

D-2.3.2 SCENARIO 2

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

This scenario involves a 1-day exposure and no exposure until 2 weeks later. It is necessary to evaluate whether there are potential risks resulting from the 1-day exposure. Additional assessment is needed if the chemical (or active metabolite[s]) cannot be eliminated entirely before the next exposure occurs (i.e., 2 weeks later) or the effect accumulates (and does not reverse) within the 2-week non-exposure interval. Generally, a chemical can be considered completely eliminated from the body if the non-exposure interval is ≥ 5 × whole body elimination half-life. Since this exposure is repeated for 60 years, the additional assessment would involve a chronic TRV. Whether dose averaging is appropriate will depend on the factors indicated in **Section D-2.2.2**.

D-3 CARCINOGENIC EFFECTS

This section summarizes HC current guidance on approaches to the contaminated sites cancer risk assessment resulting from lifetime and less-than-lifetime exposures to chemical carcinogens at contaminated sites. These approaches (with supporting scientific analysis) are described in HC's *Interim Guidance on Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites* (HC, 2013). For detailed guidance, equations, worked examples, and an analysis of dose-averaging issues in less-than-lifetime exposures for cancer effects, please refer to the HC (2013) document.

D-3.1 LIFETIME EXPOSURE

D-3.1.1 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 TRV, expressed as the cancer slope factor (or inhalation unit risk).

The US Environmental Protection Agency approach (US EPA, 2005 a,b) has been adapted as the interim default recommendation for contaminated site risk assessments, and is discussed further in HC (2013). The ILCR can be estimated by summing the risk 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 the potential varying sensitivity of the different life stages to the carcinogenic agent. **Equation D1** summaries the recommended approach to cancer risk assessment associated with oral exposure. Readers can refer to HC (2013) for relevant equations.

Equation D1

$$ILCR = \sum_{i=1}^{n} (SF_{oral} \times ADAF_i \times LADD_i)$$

Where:
i varies between 1 and n, which is the number of life stages for which there are specific ADAFs and LADDs
ILCR = incremental lifetime cancer risk
SF_{oral} = oral cancer slope factor for adults $(mg/kg_{BW}\text{-}day)^{-1}$
$ADAF_i$ = age-dependent adjustment factor for life stage i
$LADD_i$ = dose received during life stage i averaged over a lifetime $(mg/kg_{BW}\text{-}day)$

For non-threshold carcinogens acting through a mutagenic mode of action, it is recommended that ADAFs be applied to the cancer slope factor (or inhalation unit risk) for adults with exposure averaged over a lifetime (LADD*i*), to account for the varying sensitivities of the age-specific exposure periods. In HC (2013), default ADAFs were developed by adjusting the US EPA's ADAFs to be consistent with the age groups recommended in **Appendix E**. 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, a non-threshold approach to cancer risk estimation is recommended; 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.

D-3.1.2 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 TDIs or TCs, i.e., the intakes or concentrations to which it is believed that a person can be exposed daily over a lifetime without deleterious effects (for further information please consult HC's DQRA guidance [2010]). PCDDs (commonly known as dioxins) provide an example of chemicals that are associated with threshold carcinogenic effect(s) when exposures are high, whereas lower environmental concentrations are associated with threshold non-carcinogenic response(s). Human exposure is compared with these TRVs, where appropriate, to determine health risks.

D-3.2 LESS-THAN-LIFETIME EXPOSURE

D-3.2.1 NON-THRESHOLD CARCINOGENIC EFFECTS

The same risk equations (e.g., **Equation D1**) and ADAFs apply to estimation of cancer risk from less-than-lifetime exposure to a chemical that elicits a non-threshold carcinogenic effect.

D-3.2.2 THRESHOLD CARCINOGENIC EFFECTS

Dose averaging of short-duration exposure (i.e., intermittent, seasonal activities, occasional visits or certain occupational activities) for threshold carcinogenic effects is performed in the same way as for substances with threshold non-carcinogenic effects, see **Section D-2.2**. The carcinogenic short-duration TRV should match the duration of exposure at the site as closely as possible; 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.

D-3.2.3 OTHER (NON-CARCINOGENIC) CONSIDERATIONS

It should be noted that short-duration exposure 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 needs to be evaluated, in addition to risk from the carcinogenic endpoint. Please refer to **Section D-2.2** for basic principles related to assessment of the potential for non-cancer health effects from short-duration exposure.

D-3.3 EXAMPLE OF SHORT-DURATION EXPOSURE

Daily exposure for 4 months in a lifetime

This scenario involves exposure to a carcinogenic substance for a period of 4 months in a lifetime (e.g., during remediation of a contaminated site). HC (2013) provides further detail on the required assessment for this type of exposure scenario but, briefly, it is necessary to evaluate whether there is a risk of cancer developing above the target ILCR resulting from the 4-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 it. In this case, a short-duration TRV may be identified, and additional assessment is needed.

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APPENDIX E: RECOMMENDED RECEPTOR CHARACTERISTICS FOR HHRAs

Canadian General Population							
Receptor Characteristic*	**Infant**	**Toddler**	**Child**	**Teen**	**Adult**	**Construction/ Utility Worker**	**Source**
Age	0 to <6 mo	6 mo to <5 yrs	5 to <12 yrs	12 to <20 yrs	≥20 yrs	≥20 yrs	Health Canada (1994)
Age group duration	0.5 yr	4.5 yr	7 yr	8 yr	60 yr	60 yr	Based on an 80-year lifespan
Body weight (kg_{BW})	8.2	16.5	32.9	59.7	70.7	70.7	Richardson (1997)
Soil ingestion rate (mg/day)	20	80	20	20	20	100	CCME (2006) MassDEP (2002)
Inhalation rate (m^3/day)	2.2	8.3	14.5	15.6	16.6	1.4 m^3/hr**	Allan et al. (2008) Allan et al. (2009)
Water ingestion rate (L/day)	0.3	0.6	0.8	1.0	1.5	1.5	Richardson (1997)
Sediment ingestion rate (mg/h) due to hand-to-mouth transfer	N/A	72	57	18	20	N/A	Wilson et al. (2015)
Sediment ingestion rate† due to surface water intake (mg/h)	N/A	7.7	7.7	7.7	7.7	7.7	Wilson et al. (2015)
Skin surface area (cm^2) Hands	320	430	590	800	890	890	Richardson (1997)
Skin surface area (cm^2) Arms (upper and lower)	550	890	1480	2230	2500	2500	Richardson (1997)
Skin surface area (cm^2) Legs (upper and lower)	910	1690	3070	4970	5720	5720	Richardson (1997)
Skin surface area (cm^2) Feet	250	430	720	1080	1190	N/A	Richardson (1997)
Skin surface area (cm^2) Total body	3620	6130	10 140	15 470	17 640	1 640	Richardson (1997)
Soil loading to exposed skin (kg/cm^2-event) Hands Surfaces other than hands	1×10^{-7} 1×10^{-8}	1×10^{-7} 1×10^{-8}	1×10^{-7} 1×10^{-8}	1×10^{-7} 1×10^{-8}	1×10^{-7} 1×10^{-8}	1×10^{-6} 1×10^{-7}	Kissel et al. (1996, 1998)
Sediment dermal adherence factor	site-specific	site-specific	site-specific	site-specific	site-specific	site-specific	HC (2017)§

* The measure of central tendency is the arithmetic mean (log normal probability density functions) for inhalation rate (Allan et al., 2009) and for multiple exposure factors from Richardson et al. (1997) (i.e., body weight, water ingestion rate, skin surface area). For skin loading to exposed skin, the measure of central tendency is the geometric mean (Kissel et al., 1996; 1998).

** Allan et al. (2009) reported an inhalation rate of 1.4 m^3/hr for male and 1.25 m^3/hr for female construction workers. Please note that the inhalation rate is applicable to the number of hours worked at the site, which differs from that presented for the general population, given per day.

† Applicable to near-shore in-water activities; does not consider high-energy environments (refer to Wilson et al., 2015).

§ See HC (2017) for guidance on sediment dermal adherence.

NA = not applicable.

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