Note To Readers:

The following error was identified after publication.

At the bottom of Table 3, the Health Canada's Food Directorate (2010) reference was published in 2007, not 2010. The correct citation is: Health Canada. 2007. Human Health Risk Assessment of Mercury in Fish and Health Benefits of Fish Consumption. Bureau of Chemical Safety.

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Part I:

Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0

Federal Contaminated Site Risk Assessment in Canada

Canada

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FEDERAL CONTAMINATED SITE RISK ASSESSMENT IN CANADA

PART I:

GUIDANCE ON HUMAN HEALTH PRELIMINARY QUANTITATIVE RISK ASSESSMENT (PQRA)

Version 2.0

September 2010
Prepared by:
Contaminated Sites Division
Safe Environments Directorate

TABLE OF CONTENTS

LIST OF TABLES

PREFACE

The Federal Contaminated Sites Action Plan (FCSAP) is a program of the Government of Canada designed to ensure improved and continuing federal environmental stewardship as it relates to contaminated sites located on federally owned or operated properties. Guidance documents on human health risk assessment (HHRA) prepared by the Contaminated Sites Division of Health Canada, in support of the FCSAP, are available on our website and may also be obtained by contacting the Contaminated Sites Division at cs-sc@hc-sc.gc.ca.

This guidance document *(Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0*) was prepared to provide guidance for custodial departments.

As is common with any national guidance, this document will not satisfy all of the requirements presented in every case by contaminated sites, custodial departments, or risk assessors. As the practice of HHRA advances, and as the FCSAP proceeds, new and updated information on various aspects of HHRA will be published. As a result, it is anticipated that revisions to this document will be necessary from time to time to reflect this new information. Health Canada should be consulted at the address below to confirm that the version of the document in your possession is the most recent edition and that the most recent assumptions, parameters, etc., are being used.

In addition, Health Canada requests that any questions, comments, criticisms, suggested additions, or revisions to this document be directed to: Contaminated Sites Division, Safe Environments Directorate, Health Canada, postal locator 4111A, 99 Metcalfe Street, 11th Floor, Ottawa, ON K1A 0K9. E-mail: cs-sc@hc-sc.gc.ca

See also: http://www.hc-sc.gc.ca/ewh-semt/contamsite/index_e.html.

SUMMARY OF REVISIONS

Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 reflects numerous revisions to text and tables, relative to Version 1.0. Significant technical revisions to this document include:

- a review of common problems encountered when peer reviewing preliminary quantitative risk assessment reports;
- information relevant to the assessment of risks posed by petroleum hydrocarbons;
- emphasis on the use of maximum concentrations only to characterize on-site contamination;
- a discussion of what constitutes surface soil;
- references to sources of data and information on background (natural) levels of elements and other substances in soil;
- a discussion of relevant soil particle-size ranges to consider for contaminated site risk assessment; and
- expanded guidance on the assessment of risks posed by mixtures:
  - potency equivalence factors for carcinogenic polycyclic aromatic hydrocarbons; and
  - toxic equivalence factors for polychlorinated dibenzo-*p*-dioxins, polychlorinated dibenzofurans, and dioxin-like polychlorinated biphenyls.

ABBREVIATIONS AND ACRONYMS

ADI	acceptable daily intake
BAF	bioaccumulation factor
BCF	bioconcentration factor
BTF	biotransfer factor
BTEX	benzene, toluene, ethylbenzene, and xylenes
CCME	Canadian Council of Ministers of the Environment
COPC	contaminant of potential concern
CWS	Canada-Wide Standard
DQRA	detailed quantitative risk assessment
$DQRA_{Chem}$	detailed quantitative risk assessment for chemicals
EDI	estimated daily intake
ESA	environmental site assessment
FCSAP	Federal Contaminated Sites Action Plan
GSC	Geological Survey of Canada
HHRA	human health risk assessment
HQ	hazard quotient
ILCR	incremental lifetime cancer risk
LADD	lifetime average daily dose
PAHs	polycyclic aromatic hydrocarbons
PCBs	polychlorinated biphenyls
PCDDs	polychlorinated dibenzo-*p*-dioxins
PCDFs	polychlorinated dibenzofurans
PEF	potency equivalence factor
PHCs	petroleum hydrocarbons
PQRA	preliminary quantitative risk assessment
QA/QC	quality assurance/quality control
RAF	relative absorption factor
RfD	reference dose (US EPA)
TCDD	tetrachlorodibenzo-*p*-dioxin
TDI	tolerable daily intake
TEF	toxic equivalence factor
TRV	toxicological reference value
US EPA	United States Environmental Protection Agency
VOCs	volatile organic compounds

1.0 INTRODUCTION

Risk assessment, whether at the screening (preliminary) level or a more complex one, involves professional judgment and requires scientific rationale. A wide variety of advice and direction is offered by international, national, and provincial/territorial environmental agencies regarding the conduct of human health risk assessments (HHRAs), and different risk assessors access and rely on the available regulatory advice and guidance differently. This results in variability in estimates of chemical exposure and risk. For example, in 1997, the Canada Mortgage and Housing Corporation (CMHC, 1997) published a study in which nine consulting firms were commissioned to estimate the risks posed by a contaminated residential property. The resulting estimates of exposure and risk produced by the different firms varied over nine orders of magnitude for non-cancer endpoints and over 10 orders of magnitude for cancer, despite being given the same site data. The large variability was related primarily to the differing receptors and exposure scenarios assumed by the different firms. Variability was also introduced by the selection of different toxicological reference values (TRVs) for risk characterization.

Likewise, a comparison of 10 preliminary quantitative risk assessments (PQRAs) conducted on behalf of Fisheries and Oceans Canada (RSSI, 2003) revealed widely differing approaches, assumptions, and risk-related conclusions, despite the fact that all 10 sites were similar in land use and public access. The TRV value selected for just one contaminant, evaluated at all 10 sites, varied by a factor of five among different consulting firms. Numerous other variables and assumptions also varied widely, both among consulting firms, and in one case within the same firm; this made it virtually impossible to rely on (at face value) and compare the conclusions among sites and reports with respect to the presence or absence of human health risk without further analysis and recalculation. A comparison of international approaches to HHRA (Jones-Otazo et al., 2005) confirmed that variations in the quantitative evaluation of risk also exist among international agencies.

Provincial regulatory agencies across Canada also offer differing guidance on many aspects of HHRA. For example, definitions of acceptable cancer risk vary, with British Columbia, Alberta, and the Atlantic provinces accepting an incremental lifetime cancer risk (ILCR) of 1 in 100,000 (10^{-5}), whereas Ontario and Quebec target 1 in 1million (10^{-6}). When characterizing the risks posed by exposure to non-carcinogenic substances, British Columbia accepts a hazard quotient (HQ) of 1.0 (exposure ≤ TRV), whereas Alberta and Ontario target 0.2 (exposure ≤ 1/5th TRV). Quebec accepts a HQ of 1.0, requiring however that background exposure is included in the calculation (MSSS, 2002). Provinces also differ in the preferred quantification of on-site contaminant concentration for exposure calculations, variably prescribing the maximum contaminant concentration, the 95% upper confidence limit of the mean concentration, or the 90th percentile or 95th percentile of the concentration data distribution.

A quantitative comparison of provincial methods was carried out on behalf of Health Canada (Dillon, 2004; Loney et al., 2007) for a single hypothetical site. Fortunately, despite observed quantitative differences in estimates of risk, the differing assessment approaches among the provinces did reach the same qualitative conclusions respecting the presence or absence of risk and the need for risk management action. However, differing quantitative estimates of cancer risk and HQs (for non-cancer endpoints) were observed, further confirming the need for standardized guidance to be applied nationally at sites under federal jurisdiction. This is particularly true for the Federal Contaminated Sites Action Plan where determinations of risk are used as a basis for funding and remediation priority.

Based on the above observations, it became apparent that standardized guidance was required at the federal level to assist with the consistent assessment of risks posed by contaminated sites under federal custodianship across the country.

1.1 Background

In 2003 the federal government established the Federal Contaminated Sites Accelerated Action Plan, an initiative to assist in identifying, assessing, and managing the risks at contaminated properties under the custodial care of Canadian federal government departments. In May 2005, this program was further enhanced and renamed the Federal Contaminated Sites Action Plan (FCSAP). Health Canada is designated to provide expert support to federal departments. Environment Canada, Fisheries and Oceans Canada, and Public Works and Government Services Canada are also designated as expert support departments in their areas of expertise. Further details of the FCSAP can be found at http://www.federalcontaminatedsites.gc.ca/fcsap_pascf/index-eng.aspx.

A major emphasis of the FCSAP is to ensure that remediation or risk management is applied to those sites and properties posing significant human health risks. The purpose of a PQRA is to quantify the degree of **potential** human health risk posed by the presence of contamination at a subject site. The results of a PQRA for federal sites/properties may be used within the FCSAP to rank and prioritize the subject site for remedial funding and priority for action.

The Contaminated Sites Division of Health Canada operates within the Healthy Environments and Consumer Safety Branch's Safe Environments Directorate. This Division provides expert advice, guidance, and training on HHRA, health risk communication, and public involvement to custodial departments that are remediating and/or risk managing their contaminated properties. The Contaminated Sites Division of Health Canada, through research and guidance documents, works to improve HHRA methods to

ensure a consistent, scientifically defensible approach to conducting HHRAs at federal contaminated properties across Canada.

Guidance on the evaluation of risks to ecological receptors is also available. Consultants and site proponents dealing with contaminated sites with potential ecological risks/impacts should contact the Contaminated Sites Division of Environment Canada.

PQRAs generally prescribe methods and assumptions that ensure that exposures and risks are not underestimated. In this way, if negligible or acceptable human health risks are indicated using these conservative methods, then actual site-use patterns and conditions will almost certainly present negligible or acceptable risks. However, the converse is not necessarily true; where PQRA suggests a potential for unacceptable human health risks, this does not immediately infer that actual site conditions are unacceptable. Often, further assessment may be necessary to resolve conservatism and uncertainty in the PQRA process before the actual extent of the human health risk can be fully quantified and defined.

When risk management strategies are implemented on the basis of the results of a PQRA, the remediated or managed site conditions will almost certainly achieve a reduction in human health risk that was greater than might have otherwise been necessary if the on-site risks had been more extensively and accurately ascertained. It becomes a question of cost and feasibility of risk management action when deciding whether to implement remediation on the basis of a PQRA or to further reduce risk assessment uncertainties at a given site, using more complex risk analysis methods, before defining the most suitable risk management strategy.

1.2 Purpose

The purpose of this guidance document is to prescribe, to the degree possible, standard exposure pathways, receptor characteristics, TRVs, and other parameters required to quantitatively and consistently assess the potential chemical exposures and human health risks at federal contaminated sites. As previously stated, a primary purpose for PQRA is to rank the potential human health risks posed by federal contaminated sites relative to one another (for decisions regarding funding, etc.) and, therefore, consistency across multiple provincial and territorial boundaries is essential for fair and equitable evaluation. At the same time, however, a PQRA may be employed as a basis for risk management decisions (if the inputs are appropriate for the site specific conditions) and, as a result, the methods must be well grounded in science.

The standard PQRA approach presented herein is designed specifically for the assessment of sites that are to remain the property of federal agencies. For properties being divested to a private party or to provincial or municipal government agencies, or for assessments that address human health risks from off-site migration of contamination (to an adjacent provincial water body or neighbouring private property, for example), HHRAs may have to be completed in accordance with provincial/territorial regulatory requirements. Local regulatory requirements may differ from the standardized methods described in this guidance document. When the methods being employed in such cases differ significantly from those presented in this document, risk assessors should identify those assumptions, methods, and interpretations required by provincial agencies that differ from this method, and discuss the cost and remedial implications for the federal custodial department of the subject site.

At first glance this guidance may seem overly demanding. However, the length of this document stems predominantly from the inclusion of explanatory text to ensure that the guidance is understood. In other words, an attempt has been made to describe **why** the methods are prescribed, not just **what** those methods are.

Although the guidance offered here is prescriptive in nature, it is not designed or intended as a substitute for the sound professional judgment of a qualified and experienced risk assessment practitioner. It is recognized that many sites will present unique situations that are not specifically addressed here. Risk assessors are encouraged to ensure that their HHRAs are complete and that they address all relevant risks. The methods delineated below should not be viewed as a "black box" of equations and assumptions that negate the need for sound professional judgment. However, where possible and appropriate, the guidance provided here should be used. Where alternate or unique approaches have been determined to be necessary, these approaches must be sufficiently documented and described to enable peer review.

The guidance that follows is organized according to subject areas that Health Canada suggests be included in the final report. However, it is recognized that different writing styles or corporate standard formats may differ somewhat from those outlined below. Alternate formats are acceptable as long as all of the requested information is presented.

During the preceding years of the FCSAP, Health Canada has noted a variety of issues in the conduct and reporting of PQRAs. These are summarized in Table A1 of Appendix A. Risk assessment practitioners and site managers are encouraged to review Table A1; these issues are the most common cause of delay in the PQRA peer review and approval process.

Health Canada's goals with respect to HHRA are to protect human health (i.e. reduction of health risks), and to have confidence that human health risks have been properly evaluated. Provided that PQRAs for federal contaminated sites have been conducted and reported according to the guidance presented herein, there will be departmental and public confidence that the PQRA is:

- **transparent –** It is readily obvious what was done and why
- **reproducible** – Peer reviewers can reproduce results based on the information contained in the report.
- **defensible –** The results can be defended scientifically and with confidence.
- **complete –** All relevant chemicals, receptors, pathways, and risks have been identified.

1.3 Preliminary Quantitative Risk Assessment versus Detailed Quantitative Risk Assessment

PQRAs and the more complex detailed quantitative risk assessments (DQRAs) are not independent but represent opposite ends of a continuum of complexity in risk assessment. The general characteristics of DQRAs versus PQRAs are outlined in Table 1. A PQRA is not intended as a substitute for a DQRA. A DQRA may be particularly appropriate in those situations where there is a large degree of variability across the site in terms of land use, contaminant types and concentrations, soil quality and other site characteristics, and receptors and their interaction with the site.

The increased detail and complexity of a DQRA will generally reduce the degree of uncertainty associated with a PQRA, resulting in the more accurate, precise, realistic, reliable, and defensible quantification of human health risks, as well as serving as a critical tool in the identification of complex remedial and risk management alternatives. When a PQRA determines that, for maximal exposures, potentially unacceptable human health risks may exist, it may be appropriate to undertake a DQRA prior to defining remedial or risk management options.

Guidance on conducting DQRAs for chemical contamination at federal sites has also been formulated by Health Canada. The following document is available by contacting the Contaminated Sites Division by E-mail at cs-sc@hc-sc.gc.ca:

- Federal Contaminated Site Risk Assessment in Canada, Part V: Detailed Human Health Quantitative Risk Assessment for Chemicals ($DQRA_{Chem}$)

1.4 Petroleum Hydrocarbons and Volatile Organic Compounds

The guidance presented herein is relevant to the assessment of risks posed by petroleum hydrocarbons (PHCs), but should be employed in conjunction with the Canada-Wide Standard (CWS) for PHCs in Soil, established and published by the Canadian Council of Ministers of the Environment (CCME) (CCME 2008a, 2008b, 2008c). Health Canada can be contacted at cs-sc@hc-sc.gc.ca for guidance that can be used for federal sites contaminated with PHCs. Further information on the assessment of risks posed by benzene, toluene, ethylbenzene, and xylenes (BTEX), and polycyclic aromatic hydrocarbons (PAHs) are presented later in this document.

For sites presenting vapour intrusion risks, the following guidance document should be consulted:

- Federal Contaminated Site Risk Assessment in Canada, Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites.

Information on the status of this publication may be obtained by contacting Health Canada at cs-sc@hc-sc.gc.ca.

1.5 Radioactive Contaminants

For sites presenting radiological risks, the following guidance document should be consulted:

- Federal Contaminated Site Risk Assessment in Canada, Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment ($DQRA_{Rad}$)

Information on the status of this publication may be obtained by contacting Health Canada at cs-sc@hc-sc.gc.ca.

1.6 Public Involvement and Federal Contaminated Sites

To further increase transparency in the manner in which a contaminated site is managed, Health Canada encourages custodial departments to implement public involvement strategies during all phases of contaminated site management (from the moment a site has been identified and through the site investigation, risk assessment, risk management, and remediation phases). To help custodial departments undertake public involvement activities, Health Canada has developed the following guidance materials:

- Improving Stakeholder Relationships: Public Involvement and the Federal Contaminated Sites Action Plan: A Guide for Site Managers
- Addressing Psychosocial Factors Through Capacity Building: A Guide for Managers of Contaminated Sites
- A Guide to Involving Aboriginal Peoples in Contaminated Sites Management

Fact sheets relating to public involvement and outreach may be found at http://www.hc-sc.gc.ca/ewh-semt/pubs/contamsite/index-eng.php.

1.7 Due-Diligence Issues at Federal Contaminated Sites

Due diligence is the level of judgement, care, prudence, determination, and activity that a person, company, or department would reasonably be expected to take under particular circumstances. When applied to contaminated sites, due diligence means that custodial departments shall take all

reasonable precautions, under the particular circumstances, to minimize potential adverse human health or environmental effects associated with the management and stewardship of the sites.

Some federal contaminated sites pose potential human health risks, as well as environmental risks to flora, fauna, and habitat. Where there is evidence, through environmental site assessment (ESA) or risk assessment, that a site poses significant potential human health or environmental risks, it is incumbent on the site custodian to ensure that actions are developed and implemented in a timely manner (commensurate with the seriousness of the risks) to prevent potential harm to humans or the environment.

Federal departments and consolidated Crown corporations should consult their particular agency's legal counsel concerning due-diligence responsibilities on a site-by-site basis.

1.8 Current versus Future Land Use

For PQRAs at federal contaminated sites, Health Canada prefers that the risk assessment be based on the conditions of current land use. This situation will best represent on-site risks for humans currently frequenting the site (for work, recreation, etc.), and/or in the event that the site will not be redeveloped.

Risks posed by current land use will be used within the FCSAP for ranking the site for funding and remedial priority. However, there is no reason why a PQRA cannot also be prepared for one or more scenarios of redevelopment. This is particularly appropriate if the risk management/remedial plan will include a future land use that is significantly different from current conditions.

1.9 Contaminated Sites versus Contaminated Properties

It is not uncommon for the terms **site** and **property** to be used interchangeably when referring to locations with soil contamination. However, numerous federal **properties** contain more than one contaminated **site** within their geographic boundaries. Readers are referred to policies of the Treasury Board of Canada (TBS, 2000, 2002) for a formal definition of these terms. Emphasis and focus within the FCSAP is placed on **sites** rather than **properties** as the unit of contaminated land. As a result, it will not be unusual for multiple PQRAs to be completed for multiple contaminated **sites** located on one federal **property**. By preparing PQRAs on sites rather than properties, complexities introduced by varying land use among sites, varying site occupation (frequency, duration), and varying access (remote versus near, open versus restricted, etc.) will be avoided, thus simplifying the PQRA for each **site**.

Table 1 Specific Characteristics of Preliminary Quantitative Risk Assessments versus Detailed Quantitative Risk Assessments

	PQRA	DQRA
ENVIRONMENTAL MEDIA SAMPLED	Generally, soil only; occasionally groundwater, if a concern	Generally, will include soil and groundwater, and may include vegetation, indoor air, outdoor air (volatiles and/or particulate), indoor dust, and other environmental media as required
QUANTITY OF DATA	Limited; generally restricted to data collected during ESA for confirmation of contamination and very limited delineation of hot spots	Extensive; generally includes a sampling plan designed to provide reliable and representative quantification of the contaminant(s) in each environmental medium/pathway
STATISTIC USED TO REPRESENT CONTAMINANTS OF POTENTIAL CONCERN (COPC) LEVEL(S)	Maximum measured concentration	Generally, the arithmetic mean or the upper 95% confidence limit on the arithmetic mean
USE OF MODELLING	Extensive, because COPC concentrations in all media but soil (and perhaps groundwater) are usually estimated with the use of models	Limited; generally, direct data will be collected for all environmental media expected to be contaminated and/or to contribute significantly to exposure
CHARACTERIZATION OF SITE	Limited to measurement of COPCs in soil (and perhaps groundwater)	Extensive; physical (soil grain size, depth to groundwater, etc.) and chemical (pH, organic carbon content, buffering capacity, etc.) characterization of on-site soils and groundwater; precise measurement of distance from on-site structures (house, etc.) to contamination sources (hot spots); other characteristics as required
CHARACTERIZATION OF RECEPTORS	Limited to standard, conservative assumptions available from published sources	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 conservatism
RISK CHARACTERIZATION	For non-carcinogens, based on 20% of the tolerable daily intake (TDI) because exposure from background sources (unrelated to the site) is not quantified For carcinogens, based on 100% of the acceptable risk value of 1×10^{-5} because the incremental lifetime cancer risk (ILCR) is independent of background sources	For non-carcinogens, can be based on 100% of the TDI because exposure from background sources is quantified For carcinogens, based on 100% of the acceptable risk value of 1×10^{-5} because the ILCR is independent of background sources

2.0 PRELIMINARY QUANTITATIVE RISK ASSESSMENT: REPORT CONTENT AND FORMAT

The human health PQRA report should include the chapters/sections listed below. It is important for health risk communication purposes that each PQRA report would be able to "stand alone." Therefore, all relevant equations, assumptions, models, etc. required for the PQRA must be presented in each report. Also, the report should be fully referenced, and all citations clearly and completely identified, to facilitate peer review and verification of assumptions.

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.

2.2 Introduction

This section should briefly and clearly identify the client department and the risk assessor undertaking the PQRA. The goal or purpose of the PQRA should be clearly defined. The goal may include one or more of the following:

- for ranking under FCSAP, considering current land use and conditions;
- to ascertain the need for site risk management or more complex risk assessment;
- to respond to concerns of the public or other interested parties regarding the human health risks associated with a particular site;
- to provide information on human health risks as part of an environmental assessment carried out for the *Canadian Environmental Assessment Act*;
- to establish site-specific remediation goals; and
- for proposed future land use(s), to ascertain the compliance of current site conditions with possible future redevelopment scenarios.

If site redevelopment is being considered or planned, the proposed future use should also be clearly described.

2.3 Description of the Site

A brief but complete description of the site should be provided, including all site characteristics that may be pertinent to the understanding and/or quantification of potential exposures and human health risks on site. Subsections may include but not necessarily be limited to:

- site identification;
- site owner;
- site location;
- current site use (and future use, if relevant);
- land-use history;
- topography;
- geology;
- hydrogeology, including the use of groundwater as a source of drinking water;
- identification of current land uses and potential receptors on neighbouring properties;
- distance to the nearest community (village, town, city, etc.); if the site is within municipal boundaries, this should be mentioned;
- an estimate of the size of the population of the nearest community;
- proximity to local surface water;
- summary of on-site contamination, including identification and description of any free product plumes, dense non-aqueous phase liquid, light non-aqueous phase liquid, etc.;
- local or regional background concentrations of contaminants (as available and appropriate); and
- reference to appropriate reports that provide a detailed description of the site, ESAs, and/or any other previous site investigations, sampling, analyses, or risk assessments of the site.

2.3.1 Identifying all relevant potential contaminants

A list of potential contaminants associated with various government and industry activities is presented in Appendix A (Section A.2 and Table A2). The list is not intended to be exhaustive, and professional judgment following review of historical and current site activities will ultimately dictate substances to be included in the sampling and analytical 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 is largely dependent on the adequacy of the site-sampling plan. Guidance on contaminated site-sampling plans is provided elsewhere (CCME, 1993a, 1993b, among others). Health Canada has prepared guidance on environmental sampling for federal contaminated sites that will ensure the collection of more reliable data for use in HHRAs. Information on the status of this publication may be obtained by contacting Health Canada at cs-sc@hc-sc.gc.ca.

The report should summarize all data regarding concentrations of chemicals in environmental media. This must include all previous sampling efforts, not only the most recent data collection survey. At the very least, for all sampled media (soil, groundwater, surface water, vegetation, etc.) the minimum, maximum, and arithmetic average concentrations (± standard deviation) should be reported, along with the number of samples analyzed, the detection limits, and the total number or proportion of non-detected measurements.

For soil samples, the depth at which samples were collected should be indicated, as should the soil particle-size range analyzed for chemical concentrations (<2mm, <250 μm, <65 μm, for example). A map depicting sampling locations should be included, as it is helpful in demonstrating or determining if the sampling plan has been adequate to reflect the distribution of chemicals across the site.

Direct exposure to soil contaminants (i.e. ingestion, dermal absorption, inhalation of suspended particulate matter) will relate predominantly to "surface" soil. The precise definition of surface soil will vary from site to site, depending on the depth of sample collection, and may be represented by depths ranging from ≤ 5 cm to 1.5 m. The CCME (2006) defines surface soil from "grade" to 1.5 m below grade. Barring consistent sampling from shallower depths, the CCME definition should be used to define surface versus subsurface soils. However, the surface layer of soil that will contribute to incidental exposures will typically be ≤ 5 cm, provided that the soils are not subject to gardening, tilling, excavation, etc. Therefore, the depth of the surface "layer" identified for the subject site must be clearly defined, and the site-characterization data must relate clearly and definitively to that same definition of surface soil. This does **not** imply that 5 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 surface soils at all sites. Rationale should be provided for site-specific depth of surface soil that differs from the CCME definition of grade to 1.5 m below grade.

The laboratory performing chemical analyses should be certified by the Canadian Association for Laboratory Accreditation or a similar organization like the Programme d'accréditation des laboratoires d'analyse in Quebec. Further information on sample collection, analysis, and data management is offered by the CCME (1993a, 1993b).

The particle-size range of soil is an important factor to control in sampling, chemical analysis, and HHRA. Soil adherence to skin (for dermal absorption and incidental soil ingestion via hand-to-mouth transfer) increases as soil particle size decreases (see Richardson et al., 2006; GlobalTox, 2005). Also, chemical concentrations are not uniform across all soil particle-size fractions (Bright et al., 2006), often increasing as particle size decreases. As a result, chemical concentrations for the < 65 μm fraction of soil may be considered for sampling and analysis, and these results can be employed for screening and HHRA. See Richardson et al. (2006) and Health Canada's guidance on detailed quantitative risk assessment for chemicals ($DQRA_{Chem}$) for more information.

2.4 Problem Formulation

It is essential that a brief but thorough problem formulation be provided. Specifically, report subsections will likely include but not necessarily be limited to:

- screening and identification of chemicals of potential concern (COPCs);
- identification and description of potential human receptors;
- identification of operable exposure pathways;
- a brief summary paragraph describing the COPCs, critical receptor(s), and exposure pathways;
- presentation of the Problem Formulation Checklist (see Section 2.4.4); and
- a conceptual site model indicating sources, pathways, and receptors.

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

2.4.1 Screening and identification of contaminants of potential concern

COPCs are defined as follows:

- those chemicals for which the maximum on-site concentration exceeds appropriate human health-based soil quality guidelines; and
- those chemicals for which the maximum on-site concentration exceeds local or regional background concentrations (discussed below); or
- those chemicals for which no such human health-based guidelines or background data exist.

This applies to sites where discrete (non-composited) samples have been collected and analyzed. In situations where only composite samples (≥2 samples combined as one) have been collected, the site proponent and/or risk assessor should consult Health Canada for further direction.

For soil-borne contaminants, COPCs should be identified (screened) by comparing the maximum measured on-site concentration to CCME *Environmental Quality Guidelines* (CCME, 1999, and subsequent updates) for protection of human health, where possible. Where CCME human health guidelines are not available, human health-based provincial guidelines may be used, provided those for non-carcinogens are derived on the basis of 20% of the TRV (as per CCME soil quality guidelines derivation procedures; see CCME, 2006). The CCME applies 20% of the residual tolerable daily intake (TDI), also termed a reference dose (RfD) or acceptable daily intake (ADI), when setting guidelines for soil and other media. Where no Canadian jurisdiction has established a human health-based environmental quality guideline for a particular chemical, the US Environmental Protection Agency's (US EPA) preliminary remediation goals (US EPA, 2004a) or risk-based concentrations (US EPA, 2006) may be used, again adjusting those for non-carcinogens to reflect 20% of the US EPA RfD. Health Canada can be contacted for advice on necessary adjustments to guidelines from the various provinces and the US EPA regions. Any adjustments made to guidelines from other jurisdictions should be clearly described and documented.

Where soil quality guidelines have been prescribed for more than one land-use category (agricultural, residential, industrial, etc.), the guidelines for the land use that is most consistent with current site use (and future land use where applicable) should be employed for identification of COPCs.

Where soil quality guidelines for a given land use have been formulated for more than one possible exposure scenario (direct ingestion, dermal exposure, indoor infiltration of volatile contaminants, etc.), such as done by CCME (1999), then the lowest (most appropriate for the current and future land use) soil quality guideline value should be employed for identification of COPCs.

In the event that a chemical has no corresponding human health-based soil quality guideline, the chemical should be included as a COPC for further risk assessment, unless the measured concentrations are consistent with natural or background concentrations (see below). Essential elements are often assumed to present no human health risk and are screened out without rationale or justification. However, essential elements can be toxic at doses exceeding the tolerable upper intake level as an essential nutrient. Therefore, essential elements must be retained if no guidelines are available for screening purposes, unless a detailed rationale can be provided to demonstrate that they are present at non-toxic levels.

For chemicals in groundwater, the *Health Canada Guidelines for Canadian Drinking Water Quality* can be used for screening of COPCs. However the application of *Health Canada Guidelines for Canadian Drinking Water Quality* would remain the choice of the custodian if the current groundwater use is non-potable. Screening of volatile substances in groundwater should ensure that the vapour migration to indoor air pathway has been considered in the screening criteria used, as applicable.

The following criteria may assist in determining if the groundwater is not potable:

- The most likely groundwater aquifer within 500 m of the site has a hydraulic conductivity of $< 1 \times 10^{-6}$ m/s or yield equal to or < 1.3 L/min.
- The natural total dissolved solids (TDS) concentration is > 4,000 mg/L.
- The "aquifer" is a peat deposit and/or muskeg.
- The province has provided a written statement that it concurs with the application of non-potable groundwater criteria to the site.

Before a site is considered contaminated, on-site concentrations of substances, particularly natural elements, should also be compared to data from local or regional surveys of background soil quality and groundwater quality (and surface water quality if relevant) in uncontaminated areas, if data are available. On-site levels would be considered to be consistent with background where the maximum measured concentration of a COPC is less than or equal to a representative background concentration for that element/contaminant (i.e. a representative statistic such as a mean, generally not the maximum).

The application of background soil concentrations in risk assessment and in guidelines set by various jurisdictions was reviewed by WESA (2005a) on behalf of Health Canada. Canadian sources of data on background soil concentrations of contaminants include (but may not be limited to) the following:

- British Columbia Ministry of Environment. 2010. Protocol for determining background soil quality, Table 1: Regional background soil quality estimates for inorganic substances;
- Ontario Ministry of the Environment, 2009. Rationale for the Development of Soil and Ground Water Standards for Use at Contaminated Sites in Ontario;
- Ministère du développement durable, de l'environnement et des parcs, Québec. 2002. Politique de protection des sols et de réhabilitation des terrains contaminés – Teneurs de fond (critères A) pour les métaux et métalloïdes;
- Geological Survey of Canada. *Canadian Geochemical Surveys.* See also: Spirito and Adcock (2009a, 2009b), Adcock (2009a, 2009b), Garrett and Chen (2007), Rencz et al. (2006), Spirito et al. (2006, 2004); and
- environmental site assessments and/or risk assessment reports for other sites in the same general vicinity, as and where available and appropriate (if the data in those reports have background information compiled, not affected by other anthropogenic activities).

If it is found that concentrations of COPCs at the site are representative of background levels, then the site may not be contaminated despite the fact that generic guidelines are exceeded. This can be due to natural geological conditions in the region. A further discussion of background levels is presented in Appendix B.

Petroleum hydrocarbons

PHCs are among the most common contaminants encountered at federal sites. The FCSAP requires the use of the most recent version of the CCME *Canada-Wide Standard (CWS) for Petroleum Hydrocarbons (PHCs) in Soil* for risk assessment at all federal contaminated sites. In cases where federal properties are to be divested to provincial jurisdiction, the appropriate provincial regulatory framework would also apply. Many Canadian provinces and territories have adopted the CCME CWS for PHCs, but some jurisdictions (British Columbia, Quebec, and the Atlantic provinces) have established alternative approaches for assessing PHC-contaminated sites. Where jurisdictional uncertainty exists, consultation with both federal and provincial authorities may be necessary to ensure that appropriate protocols have been followed and that relevant criteria have been satisfied.

2.4.2 Identification of potential human receptors

Exposure calculations should be performed for all potential human receptors/receptor age groups for which exposure is anticipated. Receptor groups likely to visit or inhabit a site will depend on land use. Due to the nature of federally owned and operated properties, human receptors will often include both employees of the custodial department and members of the general public. Members of specific population subgroups (Aboriginals, for example) may also access the site. Potential receptors may also include occupants of properties neighbouring the contaminated site, if off-site migration has occurred or is feasible. In these cases, the land use of the neighboring property, and not the federal site, will determine relevant off-site receptor groups. Critical receptors in all such subgroups should be identified and evaluated if it is anticipated that these groups could be exposed to on-site contaminants. Specified default receptors for use in PQRAs include:

- members of the general public
- employees (including maintenance workers)
- members of Aboriginal communities

Characteristics of these various receptor groups are discussed in Section 2.5.2.

Contaminated sites on agricultural land, residential land, and recreational lands are assessed for members of the general public. Institutional facilities (schools, hospitals, etc.) are assessed for members of the general public, with age groups, and frequency and duration of exposures commensurate with the type of facility. Commercial lands, industrial lands, and institutional facilities that are accessible to the public are assessed for both the general public and for employees because both receptor groups would have access to the sites. Commercial sites are differentiated between those with daycare facilities and those without. Commercial sites with daycare facilities address risks specific to infants, toddlers, and children that attend those facilities. For industrial or other work-related sites to which public access is controlled or restricted, the key receptor group is employees. Sites known to be frequented by members of Aboriginal communities, or that are in close proximity to such communities, should be evaluated for risks to that population group. All age groups that may frequent a site or consume foods from a site should be identified.

Within each receptor group, the age groups to be addressed are those specified by Health Canada (1994) and the CCME (2006): infants (0 to 6 months of age), toddlers (7 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 to 80 years of age inclusive). Employees are assumed to be adults only, unless jobs typically conducted by youths during summer employment are identified (tree planting, landscaping, etc.). A detailed justification should be provided for any receptor and/or age groups being excluded.

2.4.3 Identification of exposure scenarios and operable exposure pathways

Exposure to soil-borne contaminants is assumed to occur by one or more of the following means:

- direct ingestion of contaminated soil;
- dermal absorption from contaminated soil adhering to exposed skin surfaces;
- inhalation of suspended contaminated soil particles while outdoors;
- indoor inhalation of vapours infiltrating from contaminated soil or groundwater (particularly relevant for assessing exposures posed by volatile PHCs or other volatile substances), following indoor infiltration of vapours;
- outdoor inhalation of vapours emanating from contaminated soil; and
- ingestion of contaminated groundwater used as a source of drinking water.

One or more exposure pathways may not be functional at a given site. Operable and inoperable exposure pathways should be identified and a detailed rationale and justification provided for pathways deemed inoperable (i.e. to be excluded from exposure calculations) at the subject site.

Exposures may also conceivably occur by indirect means, such as:

- ingestion of contaminated produce/vegetation grown on contaminated soil;
- ingestion of contaminated livestock or wild game feeding/grazing on contaminated lands;
- ingestion of contaminated fish or shellfish due to surface runoff or subsurface recharge of water bodies adjacent to contaminated sites;
- inhalation of vapour and dermal absorption from contaminated groundwater or surface water while showering or bathing;
- ingestion or dermal contact and absorption from contaminated surface water while swimming;
- intake by the developing fetus via in utero exposure;
- ingestion of contaminated breast milk by infants; and
- ingestion of indoor dust or dermal contact with indoor dust that has been contaminated by tracking in contaminated soil.

In cases where risks are assessed due to ingestion of contaminated produce/vegetation or livestock/game, suitable screening methods are provided by CCME (2006), by the **produce check** and **livestock meat/milk check**. These checks are defined as a component of the process used to develop human health-based soil quality guidelines. It may be necessary to identify and select suitable values for the bioaccumulation factor (BAF), bioconcentration factor (BCF), and/or biotransfer factor (BTF), as the case may be, when assessing the uptake of contaminants into biota used as food.

Default chemical-specific values for these variables are not defined by Health Canada at this time. However, suitable relevant assumptions and information may be available, within the detailed scientific rationale documents created to support CCME soil quality guidelines, from published scientific literature or from other sources, such as Staven et al. (2003).

For these and other indirect exposure pathways, risk assessors are advised to determine the most suitable approach and suitable assumptions for variables such as BCF (as required), and to fully describe and rationalize the approach and assumptions selected. This description should be fully referenced to facilitate peer review.

It should also be noted that indirect exposure pathways may demand extensive 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 complex DQRA may be warranted.

2.4.4 Problem formulation checklist

Table 2 presents an example checklist to aid in, and summarize, the problem formulation for the subject site. It identifies land use, receptors, and operable/inoperable exposure pathways. This or a similar checklist should be included with the PQRA report as a health risk communication tool and to aid peer review of the PQRA.

Table 2 Problem Formulation Checklist

Land Uses (Check [√] As Appropriate)		Receptor Group(s) (Check [√] As Appropriate)		Critical Receptors (Check [√] As Appropriate)		Exposure Pathways (Check [√] As Appropriate)						
	[√]		[√]		[√]	Soil ingestion	Soil dermal contact	Particulate inhalation	Indoor vapour inhalation	Outdoor vapour inhalation	Ingestion of contaminated groundwater or surface water	Other (specify)
Agricultural		General public		Infant								
Residential		Employees		Toddler								
Commercial with daycare		Canadian Aboriginal communities		Child								
Commercial without daycare		Other (specify)		Teen								
Industrial		Other (specify)		Adult								
Urban recreational (e.g. city park)		Other (specify)		Other (specify)								
Remote wild lands (e.g. recreational, no camping)		Other (specify)		Other (specify)								
Remote wild lands, (e.g. hunting, fishing, camping)		Other (specify)		Other (specify)								
Construction or utility worker		Other (specify)		Other (specify)								
Other (specify)		Other (specify)		Other (specify)								

2.5 Exposure Assessment

This section should include all exposure equations, chemical-specific characteristics, receptor assumptions, the maximum concentration used to represent the concentrations of COPCs in applicable media (air, water, soil, vegetation, etc.), and the identification of and the results from the application of any methods or models required to estimate concentrations in one environmental medium based on those in another medium. Models may include those that employ measured soil-borne concentrations to estimate concentrations in groundwater, in surface water, in indoor air (volatile contaminants only), in ambient air, in vegetation consumed from the site or impacted by the site, and in wildlife or fish that serves as food, etc.

Examples of worked calculations should be included in the PQRA report, perhaps as an appendix, with at least one worked example for exposure (and risk) estimates for a non-carcinogen and one for a carcinogen, and should include any intermediate steps and all input parameters. Also, summary tables reporting all calculated exposures should be presented in the report. This will facilitate peer review, especially where alternative modelling has been used.

In some cases, risk assessors may believe that the assumptions and equations presented in this guidance document are inappropriate for the site in question. In these cases, the risk assessor should discuss concerns with the client department and Health Canada, and where appropriate, alternate assumptions and/or equations may be employed. However, the PQRA report should contain a clear description of the inadequacies of the guidance presented herein as it relates to the issue at hand, and present a rationale (with citations) to support the use of alternate methods or assumptions.

2.5.1 Characterization of on-site contaminant concentrations

For the PQRA of federal contaminated sites in Canada, the maximum on-site concentration of each COPC shall be employed to quantify potential risks posed to site occupants/visitors. Site proponents should be aware that the primary purpose of PQRA is to rank Canadian federal contaminated sites for priority access to limited remedial funds. Use of statistics other than the maximum concentration to estimate risks may prevent a fair and equitable comparison of multiple sites that are competing for access to those same limited resources.

A variety of methods are used to select sampling locations at the site for collection of samples of relevant contaminated environmental media; these could include soil, indoor dust, drinking water, indoor or ambient air, vegetation, and/or other biota. Sampling methods could include random, systematic (grid), targeted (at known or suspected "hot spots" or in locations of frequent/continuous receptor occupation), etc. In an initial ESA, the sampling is usually targeted at zones of known or suspected contamination, resulting in a data set that is biased to zones of elevated contamination/concentrations rather than being representative of the site as a whole. The soil sampling conducted at contaminated sites during a preliminary ESA that may be used in a PQRA is usually limited; it is not unusual for PQRA reports to be prepared on the basis of ≤ 20 samples (of soil or other contaminated environmental media). As a result of the biased and limited nature of the sampling plan for sites being subjected to a PQRA, only the maximum measured concentration for each COPC should be employed for purposes of estimating human health risks at the site. Where, in the opinion of the risk assessor, the data are sufficiently numerous and rigorous to warrant an alternate statistical treatment of on-site contamination data (such as the use of a mean concentration, or the use of an upper confidence limit on the mean), the risk assessor or site proponent is advised to contact Health Canada to discuss the use of $DQRA_{Chem}$ at the subject site.

2.5.2 Characterization of potential receptors

The physical characteristics (required for exposure calculations) for the variety of common receptor groups are presented in Table 3. With respect to rates of soil ingestion, data were recently reviewed on behalf of Health Canada (Wilson Scientific and Meridian, 2006). Available data support the continued use of the age group–specific soil ingestion rates employed by CCME (2006).

When considering exposure pathways and circumstances beyond those encompassed by the equations and assumptions outlined in this document, additional receptor characterization assumptions should be drawn, if available, from Richardson (1997). Where Canadian data on required receptor characteristics have not been published, alternate sources such as the *Exposure Factors Handbook* (US EPA, 1997) and *Child-Specific Exposure Factors Handbook* (US EPA, 2008) should be used. Where alternate data sources are consulted, they must be clearly cited and fully referenced.

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

2.5.3 Exposure frequency and duration

Most assumptions concerning exposure frequency and duration are arbitrary in nature, being based on best professional judgment. It is not the intent to question such professional judgment, however a less arbitrary basis for these assumptions is desirable for PQRAs used for ranking sites. For purposes of PQRAs, the frequency of site visits (e.g. days per year) and duration of such visits (e.g. hours per day) should be based on the guidance presented in Table 4 unless, in the opinion of the risk assessor, alternate assumptions are more defensible. Justification for alternate assumptions must be provided and fully referenced.

Developmental toxicants present a risk of harm that may not be related to either frequency or duration of exposure. In some cases a single exposure, or a short duration exposure during a specific developmental period, may present a risk to the fetus, depending on the amount of exposure to a substance. Health Canada has developed TRVs for substances based on protection against developmental effects (see *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors version, 2.0*), including, but not limited to the following: bis(2-ethyl-hexyl)phthalate, dibutyl phthalate, ethylbenzene, methylmercury, polychlorinated dibenzo-*p*-doxins (PCDDs), polychlorinated dibenzofurans (PCDFs), trichloroethylene, and xylenes.

Exposures to these or other developmental toxicants should be assessed assuming the hours per day and days per week as defined in Table 4, but assuming no exposure amortization (the exposure duration would be equivalent to the amortization period). This could be shown in equations as an exposure of 365 days per year amortized over 365 days per year.

In the case of substances like dioxins with TRVs based on a tolerable monthly intake, a less than monthly exposure may be averaged over 30 days to be consistent with the intent of the toxicity reference value. In all cases, the risk assessor is encouraged to confirm whether amortization of short-term exposure is appropriate based on the toxicological properties of the substance. If a risk assessor considers or suspects other COPCs at a subject site to be developmental toxicants, the risk assessor should consult with the Contaminated Sites Division of Health Canada for specific HHRA guidance and advice.

2.5.4 Exposure equations

The preferred exposure equations to be employed, for a limited number of exposure pathways, are presented in Table 5. Additional equations may also be included where the risk assessor determines that other exposure pathways, beyond those listed in Table 5, are required. In those cases, the Problem Formulation section of the PQRA report should provide an adequate explanation of the need to include those additional pathways. The source of any additional equations should be fully referenced.

A worked example for exposure of a toddler via direct soil ingestion is presented in Table 6.

Inhalation exposures will be derived on the basis of the time spent in the contaminated environment, e.g. 1.5 hours per day if outdoors, 22.5 hours per day if indoors (see tables 3 and 4). Soil ingestion exposures are considered to be independent of the time spent outdoors. Although it is unlikely that ingested soil would be delivered as a single bolus dose, it is equally unlikely that intake would be distributed uniformly throughout the day. Also, the available studies investigating soil ingestion rates do not provide sufficient resolution to distinguish intake rates among different times of the day or between indoor and outdoor environments. Therefore, for purposes of conservatism, 100% of the daily unintentional intake of contaminated soil should be assumed to arise from the site.

Table 3 Recommended Human Receptors and Their Characteristics for Preliminary Quantitative Risk Assessments

Canadian General Population							
Receptor Characteristic	**Infant**	**Toddler**	**Child**	**Teen**	**Adult**	**Construction/ Utility Worker**	**Source**
Age	0–6 mo.	7 mo.–4 yr.	5–11 yr.	12–19 yr.	≥ 20 yr.	≥ 20 yr.	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)	8.2	16.5	32.9	59.7	70.7	70.7	Richardson, 1997
Soil ingestion rate (kg/day)	0.00002	0.00008	0.00002	0.00002	0.00002	0.0001	CCME, 2006; Wilson Scientific and Meridian, 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
Time spent outdoors (h/day)	1.5†	1.5†	1.5†	1.5	1.5	_‡	Richardson, 1997
Skin surface area (cm^2) Hands Arms (upper and lower) Legs (upper and lower Total body	 320 550 910 3,620	 430 890 1,690 6,130	 590 1,480 3,070 10,140	 800 2,230 4,970 15,470	 890 2,500 5,720 17,640	 890 2500 5720 17,640	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
Food ingestion§ (kg/day) Root vegetables Other vegetables Fish§	 0.083 0.072	 0.105 0.067	 0.161 0.098	 0.227 0.120	 0.188 0.137	 Not available	 Richardson, 1997 Richardson, 1997
Canadian Aboriginal Populations (Characteristics Not Listed Should Be Assumed To Be Equivalent To Those For The General Population)							
Receptor Characteristic	**Infant**	**Toddler**	**Child**	**Teen**	**Adult**		**Source**
Age	0–6 mo.	7 mo.–4 yr.	5–11 yr.	12–19 yr.	≥ 20 yr.		Health Canada, 1994
Food ingestion§ (kg/day) Fish** Wild game	 0	 0.085	 0.125	 0.175	 0.270		 Richardson, 1997

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

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

‡ This should be site-specific, and any amortization should be applied on a chemical-specific basis with appropriate scientific rationale.

§ Data are for "eaters" only; those reporting 0 intake were excluded from the estimate.

** Health Canada's Food Directorate (2010) describes fish consumption values considered from various recent 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 not addressed in Health Canada's Food Directorate (2010), site-specific values should be provided with rationale.

Table 4 Exposure Duration and Frequency Assumptions for Preliminary Quantitative Risk Assessments

	Agricultural Land	Residential Land	Commercial Land	Industrial Land*	Urban Recreational Land†	Remote Wild Lands (Camping, Hunting, Fishing)†	Construction/ Utility Worker†
Hours per day on site	24	24	8	10	_	_	_
Days per week on site	7	7	5	5	_	_	_
Weeks per year on site	52	52	52	48	_	_	_
Dermal exposure events per day	1	1	1	1	_	_	_
Days per year of food ingested from the site	365	365	0	0	_	_	_
Total years exposed	80	80	35‡	35‡	_	_	_
Life expectancy (years)	80	80	80	80	_	_	_

* Receptor assumed to be adults only.
† These assumptions should be site-specific, and any amortization should be applied on a chemical-specific basis with appropriate scientific rationale.
‡ 35 years exposed based on assumption that employee, rather than member of the general public, will be the most repeatedly exposed.

2.5.5 Airborne respirable dust levels

It is anticipated that contaminant intake due to the inhalation of fugitive dust will be insignificant relative to the direct ingestion of soil and water, and to dermal contact. However, exposures corresponding to this pathway should be calculated if deemed appropriate by the risk assessor (e.g. unpaved site). When included, the concentration of a specific contaminant in the respirable airborne dust should be assumed to be equal to the (maximum) concentration in surface soil.

When this pathway is included in a PQRA, an average airborne concentration of respirable (≤10 µm aerodynamic diameter) particulate matter should be assumed to be 0.76 µg/m^3 (based on US EPA, 1992). For situations where significant vehicle traffic on contaminated unpaved surfaces is a concern, such traffic can generate considerably greater suspended dust levels than that on paved surfaces. 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). A reasonable dust level created by vehicle traffic on unpaved roads is 250 µg/m^3 (downwind side of the road; Claiborn et al., 1995).

Inhalation of particulate matter itself may pose a health risk in some situations and may need to be evaluated based on specific site conditions.

2.5.6 Models

Models may be necessary to estimate the concentrations of contaminants of potential concern in groundwater, surface water, indoor or ambient air, produce and vegetation, fish, wild game or other environmental media through which receptors may potentially be exposed. The review and recommendation of available models for a variety of environmental fate applications was conducted on behalf of Health Canada by Meridian Environmental Inc. (2006). Necessary modelling should be kept to a level of complexity consistent with the "screening" nature of the PQRA. Estimates of the concentrations of volatile COPCs in indoor air should be derived from the methods presented by Health Canada (see *Federal Contaminated Site Risk Assessment in Canada Part*

VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites). Guidance for estimating COPC concentrations in groundwater and in surface water may be obtained from the methods described by the CCME (2006). For estimating COPC concentrations in vegetation, methods presented by the CCME (2006) produce check or methods discussed by WESA (2005b) may be used. For estimating COPC concentrations in fish and wildlife, simple bioaccumulation/biomagnification factors may be employed where available on a chemical-by-chemical basis, or more sophisticated modelling may be used, as deemed appropriate by the risk assessor (see *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRA$_{Foods}$)*. The source of all models should be fully referenced.

Notwithstanding the guidance above, other modelling methods may be considered. It is recommended that these models be discussed with Health Canada prior to their application. Proponents and risk assessors must demonstrate that the models used are **generally accepted**. Any models employed should be fully referenced to permit peer review, including a rationale for the specific model selected.

Table 5 Recommended General Equations for Dose Estimation

Generalized equations are presented below; actual equations presented by individual contractors may vary according to the manner in which different variables are presented, the units used, and the precise presentation of exposure frequency, exposure duration, and averaging times. Abbreviations denoting variables have been harmonized through all equations; variables are not necessarily represented in every equation.

Inadvertent Ingestion of Contaminated Soil

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

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

Where:
C_S = concentration of contaminant in soil (mg/kg)
IR_S = receptor soil ingestion rate (kg/d)
RAF_{Oral} = relative absorption factor from the gastrointestinal tract (unitless)
D_2 = days per week exposed/7 days
D_3 = weeks per year exposed/52 weeks
D_4 = total years exposed to site (to be employed for assessment of carcinogens only)
BW = body weight (kg)
LE = life expectancy (years) (to be employed for assessment of carcinogens only)

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

Inhalation of Fugitive Dust

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

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

Where:
C_S = concentration of contaminant in soil (mg/kg)
P_{Air} = particulate concentration in air (kg/m^3)
IR_A = receptor air intake (inhalation) rate (m^3/day)
RAF_{Inh} = relative absorption factor by inhalation (unitless)
D1 = hours per day exposed/24 hours
D2 = days per week exposed/7 days
D3 = weeks per year exposed/52 weeks
D4 = total years exposed to site (to be employed for assessment of carcinogens only)
BW = body weight (kg)
LE = life expectancy (years) (to be employed for assessment of carcinogens only)

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

Inhalation of Volatile Substances

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

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

Where:
C_A = concentration of contaminant in air (mg/m^3)
IR_A = receptor air intake (inhalation) rate (m^3/day)
RAF_{Inh} = relative absorption factor 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
D_4 = total years exposed to site (to be employed for assessment of carcinogens only)
BW = body weight (kg)
LE = life expectancy (years) (to be employed for assessment of carcinogens only)

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

Ingestion of Contaminated Drinking Water

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

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

Where:
C_w = concentration of contaminant in drinking water (mg/L)
IR_w = receptor water intake rate (L/d)
RAF_{Oral} = relative absorption factor from the gastrointestinal tract (unitless)
D_2 = days per week exposed/7 days
D_3 = weeks per year exposed/52 weeks
D_4 = total years exposed to site (to be employed for assessment of carcinogens only)
BW = body weight (kg)
LE = life expectancy (years) (to be employed for assessment of carcinogens only)

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

Dermal Absorption from Contaminated Soil

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

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

Where:

C_S = concentration of contaminant in soil (mg/kg)
SA_H = surface area of hands exposed for soil loading (cm^2)
SA_O = surface area exposed other than hands (cm^2)
SL_H = soil loading rate to exposed skin of hands (kg/cm^2-event)
SL_O = soil loading rate to exposed skin other than hands (kg/cm^2-event)
RAF_{Derm} = relative dermal absorption factor (unitless)
D_2 = days per week exposed/7 days
D_3 = weeks per year exposed/52 weeks
D_4 = total years exposed to site (for assessment of carcinogens only)
BW = body weight (kg)
LE = life expectancy (years) (for assessment of carcinogens only)

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

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

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

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

Where:
C_{Foodi} = concentration of contaminant in food *i* (mg/kg)
IR_{Foodi} = receptor ingestion rate for food *i* (kg/day)
RAF_{Orali} = relative absorption factor from the gastrointestinal tract for contaminant *i* (unitless)
D_i = days per year during which consumption of food *i* will occur
D_4 = total years exposed to site (for assessment of carcinogens only)
BW = body weight (kg)
365 = total days per year (constant)
LE = life expectancy (years) (for assessment of carcinogens only)

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

Table 6 Worked Example for Exposure to Xylenes via Inadvertent Soil Ingestion by a Toddler

$$\text{Dose (mg/kg bw/day)} = \frac{C_s \times IR_s \times RAF_{Oral} \times D_2 \times D_3}{BW}$$

Where:
C_s = Concentration in soil = 9750 mg/kg
IR_s = Soil ingestion rate = 80 mg/day
Conversion factor from mg to kg, where 1 mg = 10^{-6} kg/mg
RAF_{Oral} = relative absorption factor (bioavailability) from the gastrointestinal tract = 100% (1.0)
D_2 = days per week/7 days = 5 days/7days = 0.71
D_3 = weeks exposed per year/52 weeks = 52 weeks/52 weeks = 1.0
BW = body weight = 16.5 kg

$$\text{Dose (mg/kg bw/day)} = \frac{9750 \text{ mg/kg} \times 80 \text{ mg/day} \times 10^{-6} \text{ kg/mg} \times 1.0 \times 0.71 \times 1.0}{16.5\text{kg}}$$

$$= \frac{0.5538 \text{ mg/day}}{16.5\text{kg bw}}$$

$$\text{Dose} = 0.03 \text{ mg/kg bw/day}$$

$$\text{Hazard Quotient (HQ)} = \frac{\text{Estimated Exposure (Dose) (mg/kg bw/day)}}{\text{Tolerable Daily Intake (TDI) (mg/kg bw/day)}}$$

Where:
TDI for xylenes = 1.5 mg/kg bw/day

$$\text{HQ} = \frac{0.03 \text{ mg/kg bw/day}}{1.5 \text{ mg/kg bw/day}}$$

$$\text{HQ} = 0.02$$

2.5.7 Relative absorption factors and exposure via multiple pathways

For some COPCs, separate TRVs are available for oral and inhalation exposures. In these cases, the exposures via these pathways should be determined separately for comparison to pathway-specific TRVs. Absorption following ingestion (oral) exposure will be assumed to be 100%, as oral TRVs are based on delivered, not absorbed, dose. Likewise, absorption following inhalation exposure will be assumed to be 100%, as inhalation TRVs are generally based on the measured airborne concentration, not absorbed dose.

Few TRVs exist specifically for the dermal exposure pathway. Therefore, dermal exposures will routinely be added to the oral dose, following adjustment for relative bioavailability or absorption, for subsequent comparison to the oral TRV. The exception to this rule will be carcinogenic PAHs, for which the Contaminated Sites Division has recently proposed a dermal slope factor (see *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors*; Version 2.0 see also EEI, 2006).

For COPCs where multiple exposure pathways will be summed for comparison to a single TRV, it will be necessary to apply relative absorption factors (RAFs) in exposure calculations. Oral exposures should always be assumed to have a relative absorption of 100% (RAF_{Oral} = 1). Where inhalation exposures are being summed with oral exposures, the inhalation RAF (RAF_{Inh}) will generally default to 1 unless there is good evidence that respiratory absorption is significantly less than 100%. Such evidence must be fully referenced in the event that a RAF_{Inh} < 1 is used. Also, published toxicological studies should be reviewed to confirm that using the oral TRV to characterize potential inhalation risks is defensible toxicologically.

Where dermal exposures are being summed with oral exposures, the RAF_{Derm} values presented in Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors should be applied, unless more appropriate information has been identified and justified (with proper citations). For contaminants not listed *in Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0* other sources such as US EPA (2004b), the Risk Assessment Information System (http://rais.ornl.gov/index.shtml), Toxicological Profiles published by the Agency for Toxic Substances and Disease Registry (http://www.atsdr.cdc.gov/toxpro2.html), or other authoritative sources should be consulted. Where alternate data sources are consulted, they must be clearly cited and fully referenced.

For other forms of dermal exposures, such as through submersion in water, dermal absorption factors in units of µg/cm^2/hour, may be required. The source of such equations and assumptions, if required, should be clearly cited and fully referenced.

2.5.8 Carcinogens

For carcinogenic substances, the lifetime average daily dose (LADD) should be derived employing the relevant (to the specific land use) life stages and their respective characteristics and durations as outlined in tables 4 and 5.

The validity and defensibility of exposure amortization for carcinogenic substances is under review by Health Canada. Until that review is complete and supplement guidance issued, cancer risks estimated within a PQRA should include scientific rationale for any amortization.

2.5.9 Assessment of risks posed by exposures of less-than-chronic duration

Guidance on assessing risks posed by exposures of less-than-chronic duration (i.e. acute, sub-chronic) is currently under development by Health Canada. The guidance presented herein is specific to chronic duration exposures. When sub-chronic exposures are considered to be relevant and significant at a federal contaminated site, risk assessors and site proponents are directed to consult the Contaminated Sites Division of Health Canada prior to initiating the risk assessment.

There are three situations where risks due to less-than-chronic duration exposures are relevant to discuss within a PQRA for federal contaminated sites in Canada:

- Short-term risks posed by chemicals that are especially acutely potent and the ingestion of soil by toddlers are major driving factors (e.g. the case for a site contaminated with cyanide).
- COPCs posing acute respiratory, gastrointestinal or skin irritation and inflammation. A screening level risk estimate should be completed by calculating the health risks without exposure amortization (i.e. omit exposure terms D_3 and D_4; see Table 5). If the screening level risks are elevated, the issue would need to be explored further with consideration of the use and/or derivation of acute or sub-chronic TRVs.
- For developmental toxicants, the estimated heath risk without exposure amortization (i.e. omit exposure terms D_3 and D_4; see Table 5) should be compared to a TRV that is based on developmental effects (see also Section 2.5.3).

2.6 Toxicity Assessment

A brief summary of the key health concern(s) associated with exposure to each COPC should be provided within the PQRA report, perhaps as an appendix. The summary should discuss both cancer and non-cancer endpoints, and should differentiate effects by exposure route (oral, dermal, inhalation), as and when appropriate.

For each COPC, the source (reference) of each TRV and the pathway(s) to which it is being applied should be identified. Health Canada TRVs should be employed where available, for the characterization of potential health risks. These TRVs are presented in a companion document entitled *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0*. For substances with no Health Canada TRVs, then alternate TRVs should be obtained from the following agencies, in order of preference:

- Other Health Canada TRVs
- US EPA Integrated Risk Information System: http://cfpub.epa.gov/ncea/iris/index.cfm
- World Health Organization – various sources including: http://www.inchem.org/ http://jecfa.ilsi.org/index.htm
- Netherlands National Institute of Public Health and the Environment: http://www.rivm.nl/bibliotheek/rapporten/711701025.pdf
- Agency for Toxic Substances and Disease Registry: http://www.atsdr.cdc.gov/toxpro2.html
- California Environmental Protection Agency: http://www.oehha.ca.gov/risk/ChemicalDB/index.asp

In some cases, risk assessors may prefer to apply an alternate TRV when a TRV is available from Health Canada. Alternate TRVs may be employed, but the PQRA report should contain a clear description of the inadequacies of the TRVs presented by Health Canada, along with a scientifically defensible rationale (with citations) to support the use of an alternate value.

2.7 Risk Characterization

2.7.1 Non-carcinogens: single-substance exposures

For substances presenting risks other than cancer, a HQ (analogous terms include "exposure ratio" and "hazard ratio") is derived as the ratio of the estimated exposure (for each critical receptor) to the TDI or tolerable concentration, as illustrated below.

HQs for individual exposure pathways should be presented where there are pathway-specific TRVs. Where exposures via multiple pathways are being summed for comparison to a single TRV (for example, it is common to sum oral and dermal exposures for comparison to the oral TDI), it is necessary only to display the HQ for the summed exposure.

For purposes of PQRA, on-site exposures (excluding background estimated daily intake [EDI]) for off-site sources including consumer products, food, air, and water) associated with a HQ $\leq$ 0.2 will be deemed negligible. This is consistent with the CCME (2006), and has become accepted common practice in Canada.

In some cases and jurisdictions, the risk assessor may choose to assess the risks associated with the site and the EDI from background sources combined, and compare the resulting HQ to a target value of 1.0. In the context of the PQRA, however, this information should be presented in addition to the calculation of the HQ for on-site exposures alone, and the target value of HQ $\leq$ 0.2 for on-site exposure would still apply.

For contaminants for which no data exist regarding background exposures, on-site exposures must be evaluated on the basis of HQ ≤ 0.2. An estimated background daily intake value of 0.0 mg/kg/day and subsequent application of HQ $\leq$ 1.0 would require extensive evidence and citations.

$$\text{Hazard Quotient} = \frac{\text{Estimated Exposure } (\mu g/kg \text{ bw/day})}{\text{Tolerable Daily Intake } (\mu g/kg \text{ bw/day})}$$

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

$$\text{Hazard Quotient} = \frac{\text{Air Concentration } (\mu g/m^3) \times \text{Fraction of Time Exposed}}{\text{Tolerable Air Concentration } (\mu g/m^3)}$$

2.7.2 Carcinogens: single-substance exposures

For substances deemed to be carcinogenic, the estimated LADD will be multiplied by the appropriate slope factor or unit risk to derive a conservative estimate of the potential ILCR associated with that exposure. The ILCR is derived as illustrated below.

Where pathway-specific slope factors or unit risks exist, the risks via inhalation, oral intake, and dermal absorption should be estimated separately. In cases where route-specific slope factors do not exist for all of these exposure routes, the cancer risks posed by simultaneous oral + dermal exposure, or inhalation + oral + dermal exposure will be estimated for risk characterization by a single (possible oral or inhalation) slope-factor value. However, published toxicological studies should be reviewed to confirm that using the oral TRV to characterize potential inhalation cancer risks, or use of 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 minimus) where the estimated ILCR is ≤ 1 in 100,000 (≤ 1 x 10^{-5}). The rationale for this essentially negligible risk level is presented in Appendix C.

2.7.3 Exposure to mixtures

Exposures to mixtures of carcinogenic PAHs should be assessed according to the potency equivalence factor (PEF) scheme presented in Table 7, in which carcinogenic PAHs are adjusted to their carcinogenic potency relative to benzo[a]pyrene, and the potency equivalents are then summed. These PEFs are equivalent to those recommended by CCME (2008d) and/or Equilibrium Environmental Inc. (EEI 2006). Not all PAHs on this list are required to be assessed at every contaminated site. Note that non-carcinogenic PAHs should be evaluated individually using non-carcinogenic endpoints (see *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0*).

Potential risks posed by exposure to carcinogenic PAHs are subsequently characterized by estimation of cancer risk employing the cancer slope factors or unit risks for benzo[a]pyrene . Cancer risks are determined separately for ingestion, inhalation, and dermal contact (for prescribed slope factors and unit risks, see *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0*).

Likewise, exposures to mixtures of (PCDDs, PCDFs, and certain dioxin-like polychlorinated biphenyls (PCBs) should be assessed according to the recently revised toxic equivalence factor (TEF) scheme of the World Health Organization (Table 8; see van den Berg et al., 2006). PCDDs, PCDFs, and certain PCBs are adjusted to their toxic potency relative to 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (TCDD), and the TEFs are summed. Risk is subsequently characterized by employing the TRV for TCDD presented in *Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0*.

For simultaneous exposure to other multiple COPCs, determined to have similar target tissues and mechanisms of action as identified in consultation with Health Canada, non-cancer HQs should be assumed to be additive, and should be summed for those substances. Health Canada should be consulted as necessary regarding similarity of mechanism of action and the need to sum HQs. For the purposes of PQRAs, exposures associated with a total HQ ≤ 0.2 will be deemed negligible for on-site exposures or total HQ ≤ 1.0 when background (off-site) exposures have also been considered. All other COPCs with unique mechanisms of action and/or target organs should be assessed individually.

For carcinogens determined to have similar target tissues and mechanisms of action, the risks should be assumed to be additive and thus summed. Health Canada may be consulted as necessary regarding similarity of mechanism of action and the need to sum risks. The total cancer risk in such cases will be deemed to be "essentially negligible" where the estimated total ILCR is ≤ 1 in 100,000 (1 x 10^{-5}). All other carcinogens with unique mechanisms of action, target organs, and/or forms of cancer should be assessed individually.

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

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

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

Table 7 Potency Equivalence Factors for Carcinogenic Polycyclic Aromatic Hydrocarbons

Polycyclic Aromatic Hydrocarbon	Potency Equivalence Factors Relative to Benzo[a]pyrene
Anthanthracene (Aant)	0.1
Benzo[a]pyrene (B[a]P)	1
Benzo[a]anthracene (B[a]A)	0.1
Benzo[b]fluoranthene (B[b]F)	0.1
Benzo[j]fluoranthene (B[j]F)	0.1
Benzo[g,h,i]perylene (B[g,h,i]P)	0.01
Benzo[k]fluoranthene (B[k]F)*	0.1
Chrysene (Chry)	0.01
Cyclopenta[c,d]pyrene (CP[c,d]P)	0.1
Dibenzo[a,e]fluoranthene (DB[ae]F)	1
Dibenzo[a,h]anthracene (DB[a,h]A)	1
Dibenzo[a,e]pyrene (DB[a,e]P)	1.0
Dibenzo[a,h]pyrene (DB[a,h]P)	1.0
Dibenzo[a,i]pyrene (DB[a,i]P)	1.0
Dibenzo[a,l]pyrene (DB[a,l]P)	100
7,12-dimethylbenzo[a]anthracene (7,12-DMB[a]A)	10
Fluoranthene (Fanth)	0.001
Indeno[1,2,3-cd]pyrene (I[123cd]P)	0.1
5-methylchrysene (5-mChry)	1.0
Phenanthrene (Phen)	0.001
1,4-dimethylphenanthrene	0.01
4,10-dimethylphenanthrene	0.001
9,10-dimethylanthracene	0.01
2,9,10-trimethylanthracene	0.01
2,3,9,10-trimethylanthracene	0.01
Benzo[c]phenanthrene	0.01

* The potency equivalence factor agrees with recent recommendations of CCME (2008d); others are as recommended by EEI (2006)

Table 7 Potency Equivalence Factors for Carcinogenic Polycyclic Aromatic Hydrocarbons (Continued)

Polycyclic Aromatic Hydrocarbon	Potency Equivalence Factors Relative to Benzo[a]pyrene
11-methylbenzo[b]fluorene	0.01
6-, 7-, 8-, 9- , and 10-methylchrysenes	0.1
5-ethylchrysene	0.1
5,9- and 5,11-dimethylchrysene	1.0
5,6-, 5,7-, and 5,8-dimethylchrysene	0.1
7-methylbenzo[a]anthracene	1.0
8-methylbenzo[a]anthracene	1.0
9-methylbenzo[a]anthracene	0.1
12-methylbenzo[a]anthracene	0.1
7,12-dimethylbenzo[a]anthracene	10
2-methylfluoranthene	0.001
3-methylfluoranthene	0
Benzo[c]chrysene	0.01
Benzo[g]chrysene	0.1
1-, 2-, 3-, 4-, 11-, and 12-methylB[a]P	1.0
5- and 6-methylB[a]P	0.1
1,2-, 3,6-, and 4,5-dimethylB[a]P	1.0
1,6-dimethylB[a]P	0.1

Table 8 Toxic Equivalence Factors for Dioxins, Furans, and Certain Polychlorinated Biphenyls*

Compound	World Health Organization (2005) Toxic Equivalence Factor
Chlorinated dibenzo-*p*-dioxins	
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	0.1
1,2,3,7,8,9-HxCDD	0.1
1,2,3,4,6,7,8-HpCDD	0.01
OCDD	0.0003
Chlorinated dibenzofurans	
2,3,7,8-TCDF	0.1
1,2,3,7,8-PeCDF	0.03
2,3,4,7,8-PeCDF	0.3
1,2,3,4,7,8-HxCDF	0.1
1,2,3,6,7,8-HxCDF	0.1
1,2,3,7,8,9-HxCDF	0.1
2,3,4,6,7,8-HxCDF	0.1
1,2,3,4,6,7,8-HpCDF	0.01
1,2,3,4,7,8,9-HpCDF	0.01
OCDF	0.0003
Non-ortho substituted PCBs	
PCB 77	0.0001
PCB 81	0.0003
PCB 126	0.1
PCB 169	0.03
Mono-ortho substituted PCBs	
105	0.00003
114	0.00003
118	0.00003
123	0.00003
156	0.00003
157	0.00003
167	0.00003
189	0.00003

*** See van den Berg et al. (2006)**

2.8 Non-standard Assumptions and Non-Standard Toxicological Reference Values

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

- Were exposures increased, decreased, or essentially unchanged compared to the prescribed procedures?
- Were the resulting risks increased, decreased, or essentially unchanged compared to the prescribed procedures?
- Do the prescribed methods predict negligible risks whereas the alternate methods suggest that a risk exists, or vice versa?
- Were prescribed methods insufficient, or do not exist, to adequately estimate risk?

2.9 Uncertainties

The uncertainties in the exposure and risk estimates should be discussed. Issues to be addressed should include, but not be limited to:

- identification of COPCs based on historical and current activities;
- environmental characterization (number and location of samples per media);
- laboratory analyses and quality assurance/quality control (QA/QC);
- the overall quality and quantity of data;
- use of maximum COPC concentrations (where possible and appropriate to discuss);
- toxicological information for each COPC;
- factors, assumptions, and models that would likely lead to an overestimation of exposures and risks; and
- factors, assumptions, and models that might lead to an underestimation of risks.

2.10 Conclusions and Discussion

The overall conclusions with respect to the 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 may impact risk management of the site, should also be included here and also presented in the executive summary.

2.11 Recommendations

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

- the need for additional site investigation to better delineate the contamination or address any critical data gaps;
- any measures that need to be taken immediately to protect human receptors that may be accessing the site (e.g. employees, remediation workers, etc);
- the requirement for a DQRA to reduce uncertainty and to provide input to risk management measures;
- any recommended remedial and/or risk management measures; and
- the need for any ongoing monitoring of environmental media.

2.12 References and Citations

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

3.0 REFERENCES

The references cited in this document are listed below. Contractor reports prepared on behalf of Health Canada and cited herein may be obtained by contacting Health Canada at cs-sc@hc-sc.gc.ca.

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APPENDIX A

Important Preliminary Quantitative Risk Assessment Considerations

A1.0 Common Issues to Consider in Preliminary Quantitative Risk Assessment

Table A1 Summary of Common Issues in the Conduct and Reporting of Preliminary Quantitative Risk Assessments

Report Topic	Problem or Issue	Resolution
Problem formulation	Objectives of PQRA not clear	Explain how the PQRA will be used in the overall contaminated site management process: • If site is to be remediated to guidelines, then PQRA may be used only for ranking • If site is to be risk managed, then PQRA may be used to: o direct additional site assessment o determine need for more detailed risk assessment o develop site-specific remediation levels
	Ownership of site not clear	Provide clarification of ownership. If site is not federally owned or operated, Health Canada involvement (and PQRA) may not be necessary.
	Is divestiture planned?	If divestiture is planned, provincial risk assessment guidance may be more relevant than Health Canada guidance.
	Contaminants selected do not always reflecthistorical use of the site	COPC screening should note historical activities and confirmation that all COPCs were considered.
	Chemicals may be “screened out” if detected but lacking CCME screening guidelines. Screening criteria not appropriate for media, chemical analyses. or land use for the site	Check other jurisdictions for human health–based screening criteria and use for screening. If no guidelines, screen against background concentrations or provide rationale for why the chemical is not a concern (e.g. essential nutrient such as Ca, Mg) and is not present at toxic levels.
	Screening criteria not transcribed correctly or properly referenced	
	Use of statistics other than maximum concentration for screening	Use of maximum on-site concentrations for screening
Site Description	Insufficient detail on background information	Include detailed site map(s), content and information on:
	Inadequate site maps	• site description (i.e. topography, geology, hydrogeology etc.), • location for source of drinking water • locations of buildings, surface water • description of adjacent land use

Report Topic	Problem or Issue	Resolution
	Inadequate description of current and historical land use and activities Inadequate description of adjacent land use(s), including distance to nearest residence/community, size of population, water use, etc.	Sufficient detail is required for identification of all COPCs based on historical activities. Potential receptors on adjacent properties need to be considered when COPCs are environmentally mobile or if people access the site.
Site Characterization	Quality of sampling data: • little information provided on sampling or analytical methodologies • method dtection limits not provided • description of QA/QC procedures for laboratory analyses or field sampling techniques not included Quantity of samples: • insufficient samples collected to be confident that (even) maximum concentration has been measured • insufficient samples to delineate the extent of contamination	Describe magnitude and extent of contamination in environmental media Summarize data in table format (minimum, maximum, detection limits, number of non-detects, etc.) Provide reference to standard sampling and analytical procedures including QA/QC (refer to other documents if required) Include a map depicting sample locations to include but not limited to: • sampling locations • delineation of zone(s) of contamination • presence of free product
Exposure Assessment	Each receptor and each associated exposure pathway not clearly defined Receptor exposure characteristics not from accepted sources Maximum concentrations not used as exposure point concentrations Worked calculations not included Calculations cannot be reproduced; equations not dimensionally consistent or units of equations not correct Exposure pathway exclusions not justified	Ensure that the problem formulation checklist is completed, and that each receptor and pathway in the checklist is addressed. Use Health Canada receptor characteristics when available. Where required, reference, describe, and justify each alternate source of receptor characteristics employed in the PQRA. The use of alternate statistics indicates that sufficient data exist, or some other condition exists, that would indicate that a $DQRA_{Chem}$ should be completed. Risk assessors should check for mathematical, dimensional and/or unit conversion errors, and confirm that calculations are correct and reproducible before submitting a PQRA for peer review. Potentially operable exposure pathway exclusions should be fully and adequately justified.

Report Topic	Problem or Issue	Resolution
Toxicity Assessment	TRVs from alternate source when (more conservative) Health Canada TRVs are available When used correctly, alternate TRVs not referenced or transcribed correctly Health effects associated with each COPC and the basis of the TRVS not described	Health Canada TRVs, when available, should be applied even if for comparison when an alternate TRV is preferred. When sources for TRVs other than Health Canada are used, the following should be included: justification, description, basis and reference, method of derivation, level of protection, uncertainty or confidence level, any modifications made. Potential health effects associated with the COPCs should be described.
Uncertainty (and Data Gaps)	Uncertainty associated with risk assessment and data gaps that require consideration are frequently not discussed	Considerations include (but not limited to): • data quantity (sufficiency of sampling), • data quality (QA/QC, analytical detection limits relative to screening criteria) • seasonal effects on sampling • selection of COPCs relative to historical use, • modelling versus measurement of COPC concentrations in secondary media etc.

A.2 Contaminants Associated with Various Governmental and Industrial Activities

On occasion, it has been observed that sampling and analytical plans do not recognize or address all potential contaminants that may be present at a contaminated site due to current and historical activities. ESAs should ensure that all relevant contaminants are considered. For example, it should be noted that any contaminated site at which PHCs were used as fuels or lubricants may also contain BTEX and/or PAHs. Depending on the time frame when contamination occurred, lead, and/or methyl tert-butyl ether may also be present on site where gasoline was identified based on site use.

Contaminants associated with various governmental and industrial operations/activities are listed in Table A2. The list is not intended to be exhaustive of either all industrial and governmental operations/activities or the contaminants present at contaminated sites. Historical and current activities and operations at a site will necessarily 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 and specific contaminants that could potentially 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.

Older buildings at a site may contain asbestos-containing material (insulation, tiles, wall board, etc.), lead (old paint), and mercury (old paint, electrical switches, and lights). Historically, lead was commonly used as a paint pigment, whereas mercury was added as a fungicide (preservative).

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

Additional sources of information include:

US National Library of Medicine (2007). *HazMap: Occupational Exposures to Hazardous Agents*: http://hazmap.nlm.nih.gov/index.html

United Kingdom Environment Agency. *DoE Industry Profiles*: http://www.environment-agency.gov.uk/research/planning/33708.aspx

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Table A2 Contaminants Commonly Associated with Various Governmental and Industrial Activities*

Industrial facility/operation	Potential contaminants
Abandoned laboratory/chemical facilities	Metals, cyanide, ACM, pH changes, VOCs, 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), microbiologicals, nitrates
Airstrips/hangars operations	PHCs, BTEX, PAHs, ethylene glycol, VOCs (notably degreasing solvents), metals
Antifreeze bulk storage or recycling	Glycols
Ash from incinerators or other thermal facilities	Metals, pH change, PAHs, PCBs, dioxins/furans (depending on feedstock)
Asbestos mining, milling, wholesale bulk storage, or shipping	ACM
Automotive repair, maintenance, autobody shops	Metals (notably aluminium, cadmium, chromium, lead, mercury), VOCs, 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 aluminium, chromium, iron, lead, nickel), pH changes
Drum and barrel recycling	Cyanide, pH changes, pesticides, PHCs, BTEX, PAHs, solvents
Dry cleaning	PCE and degradation products; some new dry cleaners employed 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
Explosives or ammunition manufacturing	Metals, nitrates
Electroplating	Metals (notably cadmium, chromium, copper, nickel, zinc), cyanide, TCE and degradation products, TCA, pH changes
Electronic/computer equipment manufacturing	Solvents, TCE, TCA and degradation products, PHCs, metals
Fertilizer manufacturing and storage	Nitrate, chloride, sulphur, metals
Fire training areas	PHCs, PAHs, VOCs (notably, solvents), lead, MTBE, PFOS, PFOAs
Fire retardant manufacturing	Metals (notably antimony and brominated compounds such polybrominated diphenyl ether), PFOS, PFOA
Firing range	PAHs, metals (notably arsenic, antimony, lead), possible ordnance (see “ordnance sites”), herbicides
Foundries and scrap metal smelting	Metals
Glass manufacturing	Metals (notably arsenic, cobalt, thorium, uranium and zinc), radioactive material, PHCs, BTEX, PAHs
Ink manufacturing	PHCs, BTEX, metals
Landfills	Metals (including iron, mercury, lead, zinc), PHCs, BTEX, PAHs, VOCs, phenols, cyanide, PCBs, PCDDs/DFs, pesticides, gases (including methane, carbon dioxide)
Machine maintenance shops, metal fabrication	Metals, VOCs, TCE and degradation products

Industrial facility/operation	Potential contaminants
Mining, smelting, ore processing, tailings	Metals, pH changes, ACM, cyanide
Mining of coal	Metals, pH changes, sulphur, PAHs
Ordnance sites	Metals, nitro substituted phenols and benzenes, trinitrotoluene (TNT), nitroaromatics, cyclotrimethylene trinitramine (RDX), hexahydro-1,3,5-trinitro-1,3,5-triazine, nitroglycerin, VOCs and SVOCs (including formaldehyde), toluene, herbicides, perchlorate, cyclic nitramine explosive HMX (octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine), and unexploded ordnance (UXO)
Paint industry	Benzene, toluene, xylene, metals (notably cadmium, chromium, lead, mercury, zinc), herbicides/fungicides, VOCs
Pesticide production and use	Benzene, xylene, carbon tetrachloride, cyanide, metals (notably arsenic, cadmium, lead, mercury), CCA, VOCs, pesticides
Oil and gas – downstream petroleum facilities (service stations, tank farms, cardlots)	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 – oil refineries	PHCs (F1 to F2), BTEX, VOCs, 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 – 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
Photographic facilities	Metals (notably chromium, lead, mercury), TCA
Plastic manufacturing	PHCs, BTEX, styrene, isocyanites, PBDEs
Print shops	Metals, VOCs, toluene, xylene, pH changes
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, ACM, cyanide, PCBs, PHCs, BTEX, PAHs
Scrap metal	Metals, ACM, BTEX, halogenated solvents (notably TCE, TCA 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).

Abbreviations:

ACM	asbestos containing material
BTEX	benzene, toluene, ethylbenzene, xylenes
CCA	chromated copper arsenate, copper chromium arsenate,
CFCs	chlorofluorocarbons;
PAHs	polycyclic aromatic hydrocarbons
PBDE	polybrominated diphenyl ethers
PCBs	polychlorinated biphenyls
PCDDs/DFs	polychlorinated dibenzodioxins/furans
PCE	tetrachloroethylene
PFOAs	perflurooctanoic acids
PFOS	perfluorooctane sulfonate
PHCs	petroleum hydrocarbons compounds
MTBE	methyl tertiary butyl ether
SVOCs	semi-volatile organic compounds
TBT	tributyltin
TCA	trichloroethane
TCE	trichloroethylene
TNT	trinitrotoluene
UXO	unexploded ordnance
VOCs	volatile organic compounds

REFERENCE

United States Environmental Protection Agency (US EPA). 2007; *Industry Profile Fact Sheets. Region 3 Brownfields: Regional Initiatives*. Accessed on Sept 1, 2010, at http://www.epa.gov/reg3hwmd/bf-lr/industryprofilefs.htm.

APPENDIX B

Screening Contaminants of Potential Concern for Local or Regional Background (Natural) Soil, Groundwater, and Surface Water Concentrations

Before a site is considered contaminated, on-site concentrations of contaminants, particularly natural elements, can be compared to data from local or regional surveys of soil quality, groundwater quality, or surface water quality in areas unaffected by the site or anthropogenic activities. If possible, such surveys should be conducted at the time of the site environmental assessment. However, the results of many regional soil surveys are available in the open scientific literature. Soil survey data for inorganic elements are available from various provincial ministries of natural resources and from the Geological Survey of Canada (GSC); these have conducted surveys and compiled soil survey data for purposes 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 the FCSAP, the GSC has now compiled the majority of available federal and provincial geological mineral surveys (see http://gdr.nrcan.gc.ca/geochem/). See also the citations presented in Section 2.4.1 of this guidance document.

If COPCs at the site are found to be are representative of background levels, the site may not be considered contaminated despite the fact that generic guidelines are exceeded.

Many contaminants, particularly metals, are naturally occurring, and natural levels can exceed CCME guidelines and other generic guidelines without representing anthropogenic contamination. One example is arsenic. The CCME soil quality guideline for arsenic is 12 ppm. This guideline was derived on the basis of a "national" natural background concentration of 10 ppm arsenic in agricultural soils from southern Ontario and the Prairies, with an additional 2 ppm that represented the additional contamination (above background) associated with a 1 in 1 million incremental cancer risk (Health Canada, 1995). Although natural levels of arsenic in those agricultural soils are only 10 ppm, the regional background of arsenic established for Ontario is 17 ppm (OMEE, 1997), and in various regions of British Columbia it ranges up to 25 ppm (BCMWLAP, 2010). In Sydney, Nova Scotia, local sampling determined that the local urban background concentration of arsenic ranged up to 200 ppm (JDAC Environment Ltd., 2002). In Yellowknife, NWT, the natural soil-borne levels of arsenic average approximately 150 ppm, with natural levels occasionally exceeding 1,500 ppm (RSSI, 2002).

Yellowknife is situated on a geologic anomaly known as a greenstone belt. Greenstone belts and other geologic deposits are rich in mineral deposits of which arsenic is a natural contaminant. Soils derived from such geologic deposits will have naturally high concentrations of this element. In fact, prospecting for mineral deposits is often accomplished by surveying soils for anomalously high arsenic levels (see RSSI, 2002). Therefore, arsenic and other metals can be present in soils at levels far in excess of national or provincial guideline values, and may not represent anthropogenic pollution.

When setting national guidelines, the CCME derives guideline values by determining the tolerable or essentially negligible concentration of a contaminant above the background (natural) level (CCME, 2006). The CCME also recognizes that natural levels in soil vary spatially, and 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 in the derivation of the national generic guideline for a particular contaminant (CCME, 1996).

In some cases, it may be appropriate to use "urban" background concentrations, rather than those associated with more rural areas. This may be particularly true for carcinogens where risk assessment and risk management are targeted at **incremental** risks above background levels. If the local urban environment and/or adjacent properties 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 judgment will be required to determine the most suitable basis for defining background concentrations.

The Ontario Ministry of Environment and Energy presents the main elements of a background approach and Ontario-specific criteria (OMEE, 1997, Table F). Similar guidance is also provided by the British Columbia Ministry of Water, Land and Air Protection (BCMWLAP, 2010).

REFERENCES

BCMWLAP (British Columbia Ministry of Water, Land and Air Protection). 2010. *Protocol 4: Determining Background Soil Quality*. Section 53, Contaminated Sites Regulation, Environmental Management Act. Government of British Columbia, Victoria, BC. Accessed on Sept 1, 2010, at http://www.env.gov.bc.ca/epd/remediation/

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APPENDIX C

Essentially Negligible Cancer Risk for Contaminated Site Risk Assessment

When assessing risks posed by exposure to genotoxic carcinogenic substances, regulatory agencies such as Health Canada and the US EPA assume that any level of exposure (other than zero) is 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 million (10^{-6}) as the incremental cancer risk for carcinogenic residues in foods that was considered to be "essentially zero" (Kelly, 1991). The origin of this "essentially zero" risk level was purely arbitrary. Since then, the 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 10^{-6} as its primary risk benchmark for "acceptable" exposure to carcinogens within the general population.

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

In contrast, many industrial standards for workplace environments (e.g. ACGIH, 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 technologically or financially infeasible 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).

In establishing generic Canadian soil quality guidelines, the CCME (2006) prescribed the 10^{-6} level of risk as being essentially negligible. This was established as the lowest common denominator amongst provincial and federal agencies participating in the CCME guidelines derivation process. CCME has maintained this same philosophy since the inception of its guidelines derivation procedures in 1996.

However, the CCME (2006) acknowledged that the designation of negligible cancer risk is an issue of policy rather than of science, allowing different agencies to establish such a policy consistent with their respective environmental regulatory agendas. To that end, Health Canada, when publishing human health soil quality guidelines in support of the CCME process, applied the concentration of carcinogenic substances in soil associated with risks ranging from 1 in 10,000 (10^{-4}) to 1 in 10,000,000 (10^{-7}) (see Health Canada, 1995, for example).

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 in 100,000 (10^{-5}) to 1 in 1,000,000 (10^{-6}) is "essentially negligible" for carcinogenic substances in drinking water. Although published Health Canada advice on this issue has been restricted to exposures via drinking water, the 10^{-5} risk level has been widely accepted by federal agencies and others involved with contaminated site risk assessment. This level of risk was deemed essentially negligible for risk assessments being conducted in Sydney, Nova Scotia, for soil-borne carcinogenic contaminants associated with the Sydney Tar Ponds, for example (JDAC Environment Ltd., 2002).

The Atlantic provinces (Nova Scotia, New Brunswick, Prince Edward Island, and Newfoundland and Labrador) have implemented a common approach to contaminated site risk assessment known as Atlantic Risk-Based Corrective Action (Atlantic RBCA, 2003). Within that common risk assessment/risk management framework, an acceptable or essentially negligible cancer risk level of 10^{-5} has been adopted.

The background incidence of cancer in Canada and the US is high, relative to a 10^{-5} or 10^{-6} risk level. The lifetime probability of developing cancer in the US and Canada is approximately 0.4, or 40% (NCIC, 2001; NCI, 1999)). Thus, an excess or incremental cancer risk of 1×10^{-5} increases a person's lifetime cancer risk from 0.40000 to 0.40001.

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

Hypothetical incremental cancer rates associated with carcinogenic substances 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 (Crump, 1996), low-dose extrapolation is achieved through application of the linearized multistage model; 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. Health Canada often applies 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 (see Health Canada, 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). Health Canada 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 slope factors or unit risks employed for the estimation of hypothetical cancer rates. As such, it is believed (but not proven) that the slope factor or unit risk for carcinogenic substances will overestimate the true cancer incidence associated with low-dose exposure to environmental pollutants, such as from 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 in 100,000 incremental risk level for contaminated site exposures, a cancer risk level of 1 in 100,000 (1×10^{-5}) is recommended for the purposes of assessing and managing federal sites contaminated with carcinogenic substances.

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