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Part III:

Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0

Federal Contaminated Site Risk Assessment in Canada

Canada

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Health Canada
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Tel.: 613-954-5995
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FEDERAL CONTAMINATED SITE RISK ASSESSMENT IN CANADA

PART III:

GUIDANCE ON PEER REVIEW OF HUMAN HEALTH RISK ASSESSMENTS FOR FEDERAL CONTAMINATED SITES IN CANADA

Version 2.0

September 2010
Prepared by:
Contaminated Sites Division
Safe Environments Directorate

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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 publishing division at cs-sc@hc-sc.gc.ca.

This guidance document (*Federal Contaminated Site Risk Assessment in Canada, Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0*) 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 by contaminated sites, custodial departments, or risk assessors in every case. As the practice of HHRA advances and 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, 99 Metcalfe Street, 11th Floor, Address Locator: 4111A, Ottawa, ON, K1A 0K9. E-mail: cs-sc@hc-sc.gc.ca.

See also: http://www.hc-sc.gc.ca/ewh-semt/contamsite/index-eng.php.

ABBREVIATIONS AND ACRONYMS

CALA	Canadian Association for Laboratory Accreditation
CCME	Canadian Council of Ministers of the Environment
COPCs	chemicals of potential concern
CSM	conceptual site model
EDI	estimated daily intake
DQRA	detailed quantitative risk assessment
FCSAP	Federal Contaminated Sites Action Plan
HHRA	human health risk assessment
HQ	hazard quotient
PAHs	polycyclic aromatic hydrocarbons
PCBs	polychlorinated biphenyls
PCDDs/PCDFs	polychlorinated dibenzo-*p*-dioxins/polychlorinated dibenzofurans
PEF	potency equivalent factor
PQRA	preliminary quantitative risk assessment
QA/QC	quality assurance/quality control
TEF	toxic equivalent factor
TRV	toxicological reference value
U.S. EPA	United States Environmental Protection Agency

1.0 INTRODUCTION

The objective of this document is to provide guidance to federal custodial departments on Health Canada's peer-review process for human health risk assessments (HHRAs) of federal contaminated sites. A checklist, Health Canada's Checklist for Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada (i.e. the Checklist), has been formulated to assist in conducting peer reviews of HHRAs of federal contaminated sites submitted to Health Canada for review. The Checklist (see Section 3.0.) can be used directly for peer review of preliminary quantitative risk assessments (e.g. PQRA; HC, 2010a). The Checklist can also be applied to the peer review of detailed quantitative risk assessments (e.g. $DQRA_{Chem}$; HC, 2010c) with the understanding that the more complex components of a DQRA may not be addressed in the Checklist, and that some of the recommendations for a PQRA may not apply to a DQRA (e.g. use of maximum exposure site concentrations). Section 2.0, Guidance on the Checklist for Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, is intended to supplement the Checklist by providing explanations of some of the key checklist questions and items, as well as cross-references to other Health Canada guidance documents for further explanations. An electronic version of the Checklist can be obtained by request from Health Canada at cs-sc@hc-sc.gc.ca.

Health Canada recommends that the Checklist be reviewed by the authors of risk assessments, prior to report submission, to ensure that all issues likely to trigger comments from a peer reviewer are identified and addressed beforehand. The Checklist is designed for a response of "yes," "no," or "not applicable" for each question or set of questions. Generally, where Health Canada is conducting the peer review, the department will seek or suggest clarifications, revisions, corrections, or additional information when the response to a question is "no."

The Checklist is not intended as a regulatory or approval tool or instrument by Health Canada. Under the FCSAP, Health Canada has no regulatory role; rather, our role is to provide expert guidance and advice in the identification, assessment, and management of federal contaminated sites in Canada. The primary purpose of the Checklist is to aid Health Canada staff and others who may undertake the peer review of contaminated site risk assessment reports. This document also provides transparency to federal custodial departments and consultants with respect to the issues within, and components of, HHRAs that Health Canada often finds missing, incomplete, or confusing. The ultimate goal is to promote the preparation of HHRA reports that are complete, clearly understandable, transparent, and as close as possible to a stand-alone document.

When reviewing submitted PQRAs, Health Canada will complete the Checklist, and where major gaps or questions exist, will request clarifications, revisions, and/or additional information to ensure that the final PQRA report can be used for ranking the relative risks of all federal contaminated sites in Canada—a ranking required by the FCSAP. When reviewing more complex DQRAs, the Checklist is used only by Health Canada as general guidance, owing to the unique conditions, situations, and data associated with individual contaminated sites.

2.0 GUIDANCE ON THE CHECKLIST FOR PEER REVIEW OF HUMAN HEALTH RISK ASSESSMENTS FOR FEDERAL CONTAMINATED SITES IN CANADA

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

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
2.1. Background and Objectives				
Is the purpose of the risk assessment clear? (i.e. Why is the risk assessment being conducted?)	Explain how the PQRA will be used in the overall contaminated site management process: • If site is to be remediated to Canadian Council of Ministers of the Environment (CCME) guidelines, then PQRA may be used only for ranking purposes. • 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 (i.e. identification of data gaps, significant exposure pathways); o develop site-specific target levels for remediation; o on-site versus off-site impacts; o current versus future land use; o types and age of receptors; and o exposure pathways considered.			
Is the scope of the risk assessment clear?	The conditions of current land use are a requirement for FCSAP in terms of ranking for funding and remedial priority. However, in cases of divesture or changes in future land use, if they are significantly different from the current land use, future land use can be considered. If off-site migration of contaminants is a possibility, then the off-site land use should be included.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Does the report indicate who currently owns the site, or whether there are plans for divestiture of the site and to whom? If the site is not federally owned, does the report indicate the scope of federal responsibility for management of the site?	The requirements of another regulatory jurisdiction (e.g. provincial) may need to be addressed in addition to those of Health Canada if: • there is potential for off-site migration of contaminants and therefore off-site effects; or • the site is being divested by a federal department.			
2.1.1 Site description				
Have previous site investigations been conducted, and have they been adequately summarized?	The results of previous site investigations should be summarized in the text and the data provided in an appendix. They should include, but should not be restricted to the following: • a brief description of the sampling protocols and design (e.g. number, location, media, and depth of the samples collected); • chemical analyzed; • guidelines used (and referenced) for screening; • results from screening; assessments; and • previous site remediation activities. A site plan, presenting all sample locations, should be included in the risk assessment report.			
Are all relevant site characteristics documented?	Relevant site characteristics include, but are not restricted to: • soil type and classification (i.e. coarse or fine); • depth to groundwater; • direction of groundwater flow; • distance to nearest surface water body; • current and historic buildings, etc.; and • regional information concerning the topography, geology, and hydrogeology of the area briefly summarized.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Has the site been adequately described in terms of physical setting by maps and site plans?	A site-location map(s) should include key on-site and off-site features such as: • buildings (current and historic) • drinking water wells • surface water • groundwater flow • topography • residences • communities • recreational areas/parkland • roads • vegetation, etc.			
Does the report include a description of both current and historical land uses of the site and surrounding land?	Current and historical land use information should be used to assess whether all potential chemicals of concern have been analyzed and considered in the site investigations and risk assessment. Surrounding land use can be used to determine potential receptors.			
If there was potable groundwater on the site, or in the vicinity of the site (within 500 m), was it tested?	The source of potable water for the site, 500 m off site and the surrounding area should be documented. Groundwater should be tested if used as a source of drinking water.			
2.2 Problem Formulation				
2.2.1 Site characterization				
Have all relevant media been tested?	Based on the historical land use information, COPCs are identified and tested in relevant media such as soil, groundwater, surface water, sediment, soil gas, indoor air, outdoor air, vegetation and/or other biota.			
Have contaminant concentrations been adequately summarized for the site?	Preferably in tabular form, contaminant concentrations should be summarized and include, but not be restricted to, the following: • number of samples • detection limits • depth of sample • media • location • minimum and maximum • date sampled • proportion or number of samples data below the detection limit • definition of surface and subsurface soil (in cm), etc.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Were sufficient samples collected from known/suspected locations at the site that the likely maximum concentration was measured?	A variety of methods can be used to select sampling locations, including random, systematic (grid), targeted (at known or suspected "hot spots" or in locations of frequent/continuous receptor occupation), etc. Professional judgment and characteristics of the site will determine the most appropriate sampling protocol. Rationale for the sampling program (e.g. number of samples, locations of samples, etc.) should be provided. Generally, targeted sampling in zones of known or suspected contamination is the most commonly used sampling protocol for preliminary site investigation. In such cases, sampling will not be random. Areas with elevated concentrations will typically receive more frequent sampling than areas without contamination; therefore, likelihood of measuring the maximum concentration is increased.			
Have areas of contamination been delineated horizontally and vertically?	This is an important consideration for risk management or remediation as well as exposure pathways. It is necessary that the site be sampled in areas where the contamination is likely to be present and where receptors are likely to contact the contaminants.			
Does the list of contaminants that were selected for analysis include all those typically associated with the historical uses of the site or their potential degradation products?	The risk assessment report should include analyses for contaminants expected to be present in association with the current or previous land use. Appendix A of *Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA)* (HC, 2010a) lists contaminants typically associated with a variety of land uses and industrial operations. In many cases, particularly for trichloroethylene, the degradation products can be as toxic as, or more toxic than, the parent compound. It is important that degradation products be investigated when appropriate. In general for sites where tetrachloroethylene and/or trichloroethylene are identified, their degradation products (even if not detected) should be included as COPCs when future land use is being evaluated in the risk assessment because they may be produced in the future. When current land use is the focus of the risk assessment, but it is anticipated that the land use will not change for the foreseeable future, then consideration of degradation products may also be relevant.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Were samples of media discrete (i.e. not composite)?	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.			
If the report refers to groundwater monitoring wells, are borehole logs and details of the monitoring well installations provided?	If there are potential exposure pathways due to affected groundwater or due to volatilization of organic chemicals from soil or groundwater, then the risk assessment report should include information from the site investigation reports, including the borehole logs (with descriptions of monitoring well installations), measurements of the depth to groundwater, a contour of groundwater flow direction, etc.			
Does the report include a description of the sampling quality assurance and quality control measures employed?	The risk assessment should provide a description of quality control and quality assurance measures employed in sampling. For example: • duplicate samples • field blanks, etc. The details can be included in appendices to the risk assessment report.			
Are sampling methodologies and chemical analysis protocols described and do they follow a standard method?	Standard methods have been published by CCME, United States Environmental Protection Agency (U.S. EPA) and various provincial governments (e.g. Ontario). Proper sampling techniques are important: • to make sure the sample is representative of the medium sampled, • to reduce the likelihood of chemical loss during sampling (for volatile organic chemicals), and • to prevent contamination of samples. If field-screening methods were used during the sample collection (e.g. headspace vapour measurements), then these methods should also be described in the risk assessment report or reference made to the appropriate section in the relevant environmental site investigation report.			
Were the chemical analyses completed by a laboratory that was certified by the Canadian Association for Laboratory Accreditation (CALA) or other organization for the analyses?	CALA certifies laboratories for specific analytical methods. The risk assessment should state whether or not the samples were analyzed by a laboratory certified for the tests conducted.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Does the report include laboratory Certificates of Analysis?	These can be included in appendices in the risk assessment report or reference made to the appropriate section in the relevant environmental site investigation report.			
Does the report include a description of laboratory quality assurance and quality control (QA/QC) measures employed?	The risk assessment should provide a description of quality control and quality assurance measures employed in chemical analysis. For example: • laboratory duplicates spiked samples, etc. • Were sufficient duplicates tested? • Were the results of the QA/QC acceptable?			
2.2.2 Identification of chemicals of potential concern				
Were all COPCs screened using CCME guidelines, or if guidelines other than CCME were used, was their use appropriate?	CCME guidelines should be used appropriately (i.e. human health-based, relevant land use) and can be restricted to a relevant pathway or pathways, if applicable (direct ingestion, dermal exposure, indoor infiltration of volatile contaminants, etc.). For example, Canadian Water Quality Guidelines for the Protection of Agricultural Water Uses does not protect human consumers of agricultural products; the guidelines were developed to protect crops and livestock from contaminants in irrigation and livestock water. In addition, they are based on unfiltered water samples unless otherwise specified. The most protective value that applies to the site use should be used for screening (e.g. protection of drinking water). Preference is given to soil quality guidelines derived for human health (not generic). The CCME website should be checked to ensure that their latest guidelines are being used for screening. If a CCME guideline exists for a particular chemical and guidelines from another jurisdiction were used instead, justification with appropriate references should be provided See Section 2.4.1 and Appendix B, Part I (HC, 2010a). List the agencies from which other human health-based screening guidelines were used (e.g. provincial, U.S. EPA). Adjustments may be required for guidelines other than those from CCME if they were based on a hazard quotient (HQ) of 1.0 rather than 0.2. See Appendix B, Part I (HC, 2010a).			
Were COPCs screened using the maximum measured on-site concentrations?	Maximum concentrations should be used for screening of COPCs in a PQRA.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Was the screening process transparent and were screening guidelines used correctly?	The text should summarize the screening process including which chemicals will be carried forward in the risk assessment and why, as well as those that were screened out. All guidelines should be fully referenced and reviewed for transcription errors. Detection limits of chemicals should not exceed guideline values. Sample concentrations with their appropriate detection limits should be listed in tabular form with appropriate screening guidelines. Units for sample concentrations should be the same as those of the guideline values. Concentrations that exceed guideline values should be highlighted in the appendix and summarized in a table which should include sample number, date of sampling, depth (if applicable), units of measurement, and media.			
If chemicals were screened out in previous site investigations, was there sufficient information provided in the HHRA to evaluate whether the screening was conducted appropriately and correctly?	Historical data should be screened in the same manner as current data and against current guidelines (see above). In some cases, historical data have been screened against guidelines that were current at the time, but are no longer valid. In those cases, screening should be conducted for all data with the most current guidelines.			
If chemicals were screened out for reasons other than comparison to screening guidelines, were the reasons for exclusion adequately justified and referenced?	If no guidelines are available for a particular chemical in the media of interest, the chemical should be carried forward in the risk assessment. Exceptions are: 1) A chemical is considered not a human health concern; then, a detailed justification with references should be provided (e.g. calcium as an essential nutrient and found at non-toxic levels at the site). 2) Some chemicals may also be screened against site-specific background concentrations. See Appendix B, Part I (HC, 2010a). Essential elements are toxic at doses exceeding the 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.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
If chemicals were screened out because their concentrations fell within background levels, were background concentrations calculated appropriately and used correctly?	If concentrations of COPCs at the site are equal or below background concentrations **and** there is no suspected source on site, then COPCs may be screened out even if generic guidelines have been exceeded. Full rationale should be provided. See Part I (HC, 2010a) for a list of Canadian sources on background concentrations and further guidance. See Section 2.4.1 and Appendix A, Part I (HC, 2010a). The source of background data for that site should be referenced			
2.2.3 Receptors and pathways				
Have all relevant receptor age groups been identified (e.g. infant, toddler, child, adolescent, adult)?	Receptor age groups should follow those defined by Health Canada. See Section 2.5.2 and Table 3, Part I (HC, 2010a). In some cases, a risk assessment will focus only on what has been defined as the most sensitive age group or receptor group. For example, toddlers are often considered the most sensitive age group due to having the greatest intake per unit of body weight of any age group. Other sensitive age groups may be identified for toxicological reasons. For example, exposure to methyl mercury is a concern for women of child-bearing age, to protect against teratogenic effects.			
If relevant, have all potentially sensitive receptor population groups been identified (e.g. the elderly, First Nations communities)?	The risk assessment should also identify the presence of any potentially sensitive population groups. For example, exposure to methyl mercury or other bioaccumulative substance is a concern for subsistence fishing populations (First Nations communities, sports fishers who consume their catch) because of high-intake rates relative to the general population.			
Have all relevant exposure pathways been considered? For those pathways that were excluded, was their exclusion adequately justified?	See Section 2.4.3, Part I (HC, 2010a) for a list of direct and indirect exposure pathways. Justification for any pathways that are considered incomplete, and therefore eliminated from consideration, should be provided. For example, if a pathway is excluded for any reason, this should be restated in the final conclusions and recommendations. If risk management options are required to ensure future site use is consistent with the assumptions in the risk assessment, this should also be identified.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Was a conceptual site model (CSM) provided, summarizing land use, receptor groups, critical receptors, and potential exposure pathways?	A CSM for each land use at the site should: • describe all of the known or suspected sources of contamination, • consider how and where the contaminants are likely to move (pathways), and • identify who (receptors) is most likely to be affected by the contaminants. A CSM may be in text or graphical form. A useful aid may be completion of Table 2, Problem Formulation Checklist, Part I (HC, 2010a). Additional guidance can be found in Section 2.4.4, Part I (HC, 2010a).			
2.3 Exposure Assessment				
2.3.1 Chemicals of potential concern: exposure estimation				
Was an appropriate exposure site concentration used (i.e. maximum for a PQRA)? If a statistic other than the maximum concentration was used for exposure site concentrations in a DQRA, is a statistical analysis of the data presented and is the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given sample size and other factors?	For PQRAs, the **maximum** concentrations must be used for site concentrations. In DQRAs where sufficient data exist, some other statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) may be applied, at the discretion of the risk assessor. Both rationale and statistical evaluation must be fully documented to ensure that the statistic used is appropriate.			
2.3.2 Fate and transport modelling				
If models were used to predict the environmental fate and transport of a contaminant from one environmental medium to another, was their use appropriate?	Environmental fate models commonly used include those that: • estimate the groundwater concentration from the soil concentration; • predict the rate of migration (down-gradient concentrations) of a COPC in groundwater; • predict the indoor air concentration of a volatile substance from the concentration in soil or groundwater; or • predict concentrations in produce, meat, or milk that are consumed from concentrations in soil or water. In general, a simple model is more appropriate for application in a PQRA. The application of a complex model and/or complex treatment of data is generally associated with complex site-specific assessments (i.e. DQRAs).			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
	If a model is used for calculation of chemical concentrations in one medium from measured concentrations in another medium, the following questions should be answered: • Has the model been referenced and peer reviewed? • Is it readily available? • Is the complexity of the model appropriate for the situation, number of samples, and risk assessment complexity? • Why was this particular model selected? • Is a complex model applied to a preliminary quantitative (simple) risk assessment? • Does the model attempt to make too much out of very limited input data? (i.e. Does it suggest greater precision in the model results than the input data could conceivably deliver?) • Are model results given with more significant digits than the available data can justify? • Is the model intended for use for the type of chemicals considered in the risk assessment? (e.g. Many models are intended only to be applied to non-ionizing organic chemicals and extrapolation to other chemicals may not be appropriate.)			
If a unique model was created from first principles, was comment and assistance provided by an appropriate expert to determine its validity and applicability?	Provide name, date, position, and company/government agency and some justification of expertise.			
Are all model assumptions and equations explained? Are intermediate results included (e.g. predicted concentrations at relevant locations) and do they make sense?	All model assumptions should be fully documented and equations with units provided. Intermediate calculations (e.g. concentrations at specific locations) should be presented so that, even if the calculations are not readily reproduced by hand, the sensibility of the calculations may be evaluated.			
2.3.3 Receptor characterization				
Were all receptor exposure characteristics drawn from Health Canada guidance? If an alternate source of receptor characteristics was used, was this because no Canadian data or value has been published? Was the source/citation for alternate source(s) for exposure characteristics clearly documented?	Receptor exposure characteristics include, but are not limited to, body weight, inhalation rate, etc. The physical and behavioural characteristics of each receptor group should be documented, with references, in the risk assessment. Health Canada guidance on receptor characteristics can be found in Section 2.5.2 and Table 3, Part I (HC, 2010a). All alternate sources for exposure characteristics should be referenced and their use justified.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Were the assumptions used appropriate and adequately justified for the alternate source(s) of exposure characteristics?	For characteristics not included in Health Canada guidance, the U.S. EPA *Exposure Factors Handbook* (U.S. EPA, 1997) and the U.S. EPA *Child-Specific Exposure Factors Handbook* (U.S. EPA, 2008) are suitable reference sources.			
Were assumptions regarding exposure duration and exposure frequency appropriate and adequately justified?	Often the exposure frequency and duration must be assumed; these assumptions should be clearly noted in the risk assessment to assess their validity. Typical assumptions for a PQRA are provided in Table 4, Part I (HC, 2010a). However, in many cases the risk assessor will have to apply professional judgment in defining such assumptions. The peer reviewer should consider whether such assumptions are reasonable and protective of human health. Where possible, assumptions associated with exposure duration and frequency should be fully documented and referenced. When the values used are not directly quoted in the reference, then methodology and calculations used should be fully documented.			
If exposures of less-than-chronic duration were considered for non-carcinogens, was their use appropriate and justified with references?	Contact Health Canada for further guidance.			
2.3.4 Exposure estimation				
Were Health Canada equations used to estimate dose (i.e. exposure)? If no, were alternate equations fully justified, referenced, and all assumptions explained?	Section 2.5.3 and Table 5, Part 1(HC, 2010a) presents the equations for estimating the dose via each pathway. Equations presented in the risk assessment should have the same units as those used by Health Canada to avoid mistakes due to errors in unit conversion. Unit-related problems are one of the most common mistakes in risk assessments.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Does the report include sample calculations for estimating the dose via each exposure pathway? Can those calculations be reproduced? (i.e. Check the math.) Are all equations dimensionally consistent and are all units correct?	An example sample calculation can be found in Table 6, Part I (HC, 2010a). It is important for peer reviewers to confirm the accuracy of mathematical calculations. Dimensionally consistent means that the dimensions (and units) are the same on both sides of the "equal" sign (e.g. a dose in mg/kg/d on one side and a concentration in mg/kg on the other side are not dimensionally consistent). This serves as a quick check that the equations are correct, and that the equation actually produces the units indicated for the equation product.			
Has 100% oral bioavailability been assumed? (If a variable representing bioavailability is not included, then 100% is implicitly assumed.) If no, then were the values based on tests of on-site soil? If no, was the value based on scientific literature and properly referenced?	Absorption factors for ingestion are usually assumed to be 100% in PQRAs. In complex risk assessments, assays of contaminant bioaccessibility may be conducted to directly measure potential bioavailability. Therefore, if a value for oral bioavailability of less than 100% is used, ideally it is based on site-specific measurements of bioaccessibility. If estimates of oral bioaccessibility were obtained from the literature, Health Canada should be consulted as to the study's applicability to the site under assessment. All absorption factors < 100% must be fully explained and referenced.			
If dermal absorption was a pathway evaluated, were dermal absorption factors drawn from Health Canada advice? If no, were the sources of dermal absorption factors referenced?	These factors are listed in *Federal Contaminated Site Risk Assessment, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors* (HC, 2010b).			
If inhalation was a pathway evaluated, was absorption by this pathway assumed to be 100%? (If a variable representing inhalation bioavailability is not included, then 100% is implicitly assumed.) If no, was the value based on scientific literature and properly referenced?	Absorption factors for inhalation are usually 100% because inhalation toxicological reference values (TRVs) are generally based on measured airborne concentration, not absorbed dose. All absorption factors < 100% must be fully explained and referenced.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
In calculating lifetime average daily dose for cancer risks, was the assumption of lifetime exposure included?	In a PQRA, cancer risks should not be amortized over a shorter-than-lifetime exposure. See Section 2.5.8, Part I (HC, 2010a). When shorter-than-lifetime carcinogenic exposures are considered appropriate, chemical-specific rationale should be provided.			
If exposures of less-than-chronic duration are considered for non-carcinogens, was their use appropriate and justified with references?	See Section 2.5.9, Part I (HC, 2010a) for further guidance on this issue. Health Canada may also be contacted to provide guidance on a case-by-case basis. Health Canada is planning to provide supplemental guidance on amortization.			
2.4 Toxicity Assessment				
Were all TRVs drawn from Health Canada? If no, was it because Health Canada had no TRV for the particular COPC?	All TRVs used should be properly referenced and double-checked to ensure correct transcription. Part II (HC, 2010b) provides a list of TRVs for a large number of chemicals and is the preferred source for risk assessments prepared for Health Canada. For chemicals not listed in Part II (HC, 2010b), TRVs may be obtained from another peer-reviewed source If alternate values are used in the risk assessment when a Health Canada TRV is available, the following should be provided: • justification (i.e. why the Heath Canada TRV is inadequate) • description, basis, and reference • method of derivation • level of protection • uncertainty or confidence level • any modification made for consistency with Health Canada			
Are the selected TRVs clearly stated, with references, for each chemical and for each pathway?				

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Are the health effects associated with each COPC and the basis for the TRV described?	The risk assessment should include a description of the health effects for each chemical of concern and the basis for the selected TRV. For chemicals that are not listed by Health Canada in Part II (HC, 2010b), health effects associated with the study used for derivation of the TRV should be summarized and fully referenced.			
2.5 Risk Characterization				
Are the results of the risk assessment clear?	The risk assessment report should provide a clear statement of the predicted risks and HQs for each chemical, exposure pathway, and critical receptor.			
Where there were pathway specific TRVs, were HQs calculated for individual exposure pathways?	See Sections 2.7.1 and 2.7.2, Part I (HC, 2010a).			
If alternate TRVs were used, were risks calculated for both Health Canada TRVs (if available) and the alternate TRV?	If Health Canada TRVs are available, then risks should be calculated for those TRVs and alternate TRVs, if applicable. See Section 2.7, Part I (HC, 2010a).			
Were on-site exposures calculated using a HQ of ≤ 0.2 for non-carcinogens?	Health Canada considers HQs of 0.2 or less as negligible. See Section 2.7.1, Part I (HC, 2010a) for a PQRA. For a DQRA, where background estimated daily intake (EDI) is included, a target HQ of 1 may be used. If any other agency has been identified as having jurisdiction (for example, provinces for off-site areas), then the acceptable HQ may be different and should be documented in the risk assessment.			
If a HQ of 1.0 was used, were background exposure levels adequately estimated?	The risk assessor may choose to sum the exposures and risks associated with the site and the EDI from background sources, 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 ≤ 0.2 for on-site exposure would still apply. See Section 2.7.1, Part I (HC, 2010a). For contaminants for which no data exist regarding background exposures, on-site exposures are evaluated on the basis of HQ ≤ 0.2.			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
Are all cancer risks less than 1×10^{-5} (or other levels) defined as essentially negligible?	Health Canada considers risks of one in one hundred thousand (1×10^{-5}) or less as essentially negligible. If another agency has been identified as having jurisdiction (for example, provinces for off-site areas), then the negligible risk level may be different and should be documented in the HHRA.			
For chemicals and pathways affecting the same target organ, are the HQs summed for non-cancer effects?	HQs should be summed for chemicals that affect the same target organ. Generally, oral and dermal exposures will be summed unless there is a dermal-specific TRV. See Section 2.7.3, Part I (HC, 2010a).			
For carcinogens, have risks been summed for chemicals and pathways causing the same form of cancer?	Risks for chemicals that produce the same form of cancer should be summed. Generally, oral and dermal exposures will be summed. See Section 2.7.3, Part I (HC, 2010a).			
If carcinogenic polycyclic aromatic hydrocarbons (PAHs), polychlorinated dibenzo-*p*-dioxins/polychlorinated dibenzofurans (PCDDs/PCDFs), or certain dioxin-like polychlorinated biphenyls (PCBs) were assessed, was Health Canada guidance used regarding toxic equivalence factors (TEF) or potency equivalence factors (PEF)?	See Section 2.7.3, Part I (HC, 2010a) for further guidance.			
Is the uncertainty of the results discussed?	The risk assessment should provide an evaluation of the uncertainty in the results. This evaluation may be a qualitative discussion for PQRAs, or may be quantitative in more DQRAs. In either case, the report should indicate the variables and assumptions for which the results are most sensitive. Uncertainty should also be discussed in terms of: • sufficiency of sampling • analytical detection limits • data gaps • QA/QC • seasonal or other environmental factors on sampling • quality of historical use information relative to identification of all COPCs, etc.			
Do the recommendations identify requirements for additional work at the site, based on significant uncertainty in certain parameters?				

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
2.6 Risk Management				
If any non-cancer HQs exceed 0.2 or any cancer risks exceed 1 x 10^{-5}, are remedial or risk management measures proposed?	If the calculated cancer risks or HQs exceed the levels considered acceptable by Health Canada (or other jurisdiction, if applicable), then the risk assessment report may provide recommendations for remediation (i.e. calculation of remedial criteria) and/or a detailed description of risk management measures to control exposures to acceptable levels.			
Are recommendations proposed, and is the responsible department or agency clearly identified if other than the client department that solicited the risk assessment?	Recommendations may include, but are not restricted to: • the need for DQRA or additional site investigation to better delineate the contamination or address any critical data gaps, based on significant uncertainty in risk assessment parameters; • any measures that need to be taken immediately to protect human receptors that may be accessing the site; • any recommended remedial and/or risk management measures should be consistent with the spatial scale of the site and the magnitude of the risks; and • the need for any ongoing monitoring of environmental media. The responsible department or agency should be clearly identified if other than the client department that solicited the risk assessment.			
2.7 Overall Comments				
Is the risk assessment report complete and generally acceptable (i.e. are there only minor issues or no issues) or do major gaps or outstanding issues exist that preclude a generally acceptable evaluation of potential human health risk?	**Minor gaps** A minor gap generally consists of issues that require clarification or justification. They do not prevent the evaluation of potential health risk, but may warrant consideration to improve the overall quality of the report. **Major gaps** Major gaps or outstanding issues may involve missing information that precludes the defensible evaluation of risks, or prevents peer reviewers from verifying the data and information in the HHRA. Resolution of major gaps may require the recalculation of the risk estimates. Minor or major gaps may be discussed under separate cover to the risk assessment report if revision of the report itself is not feasible. Both minor and major gaps may be associated with a "no" response to one or			

QUERY	SUPPLEMENTARY EXPLANATION	ANSWER TO QUERY		
		YES	NO	N/A
	more questions in the Checklist. However, this does not exclude other issues specific to the assessment under review being discussed. Any concerns, outstanding issues, required explanations, and/or data requirements should be discussed.			

Note: N/A, not applicable

3.0 HEALTH CANADA'S CHECKLIST FOR PEER REVIEW OF HUMAN HEALTH RISK ASSESSMENTS FOR FEDERAL CONTAMINATED SITES IN CANADA

The following checklist is intended to be completed with reference to Health Canada's guidance contained in this document as well as other Health Canada guidance documents.

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

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
3.1 Background and Objectives				
Is the purpose of the risk assessment clear? (i.e. Why is the risk assessment being conducted?)				
Is the scope of the risk assessment clear?				
Does the report indicate who currently owns the site, or whether there are plans for divestiture of the site and to whom? If the site is not federally owned, does the report indicate the scope of federal responsibility for management of the site?				
3.1.1 Site description				
Have previous site investigations been conducted, and have they been adequately summarized?				
Are all relevant site characteristics documented?				
Has the site been adequately described in terms of physical setting by maps and site plans?				
Does the report include a description of both current and historical land uses of the site and surrounding land?				
If there was potable groundwater on the site, or in the vicinity of the site (within 500 m), was it tested?				
3.2 Problem Formulation				
3.2.1 Site characterization				
Have all relevant media been tested?				

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
Have contaminant concentrations been adequately summarized for the site?				
Were sufficient samples collected from known/suspected locations at the site that the likely maximum concentration was measured?				
Have areas of contamination been delineated horizontally and vertically?				
Does the list of contaminants that were selected for analysis include all those typically associated with the historical uses of the site or their potential degradation products?				
Were samples of media discrete (i.e. not composite)?				
If the report refers to groundwater monitoring wells, are borehole logs and details of the monitoring well installations provided?				
Does the report include a description of the sampling quality assurance and quality control measures employed?				
Are sampling methodologies and chemical analysis protocols described and do they follow a standard method?				
Were the chemical analyses completed by a laboratory that was certified by CALA or other organization for the analyses?				
Does the report include laboratory Certificates of Analysis?				
Does the report include a description of laboratory QA/QC measures employed?				
3.2.2 Identification of chemicals of potential concern				
Were all COPCs screened using CCME guidelines, or if guidelines other than CCME were used, was their use appropriate?				
Were COPCs screened using the maximum measured on-site concentrations?				

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
Was the screening process transparent and were screening guidelines used correctly?				
If chemicals were screened out in previous site investigations, was there sufficient information provided in the HHRA to evaluate whether the screening was conducted appropriately and correctly?				
If chemicals were screened out for reasons other than comparison to screening guidelines, were the reasons for exclusion adequately justified and referenced?				
If chemicals were screened out because their concentrations fell within background levels, were background concentrations calculated appropriately and used correctly?				
3.2.3 Receptors and pathways				
Have all relevant receptor age groups been identified (e.g. infant, toddler, child, teen, adult)?				
If relevant, have all potentially sensitive receptor population groups been identified (e.g. the elderly, First Nations communities)?				
Have all relevant exposure pathways been considered? For those pathways that were excluded, was their exclusion adequately justified?				
Was a CSM provided, summarizing all land use, receptor groups, critical receptors, potential exposure pathways, and COPCs?				
3.3 Exposure Assessment				
3.3.1 Chemicals of potential concern: exposure estimation				
Was an appropriate exposure site concentration used (e.g. maximum for PQRA)? If a statistic other than the maximum concentration was used for exposure site concentrations in a DQRA, is a statistical analysis of the data presented, and is the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given sample size and other factors?				
3.3.2 Fate and transport modelling				
If models were used to predict the environmental fate and transport of a contaminant from one environmental medium to another, was their use appropriate?				

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
If a unique model was created from first principles, was comment and assistance provided by an appropriate expert to determine its validity and applicability?				
Are all model assumptions and equations explained? Are intermediate results included (e.g. predicted concentrations at relevant locations) and do they make sense?				
3.3.3 Receptor characterization				
Were all receptor exposure characteristics drawn from Health Canada guidance? If an alternate source of receptor characteristics was used, was this because no Canadian data or value has been published? Was the source/citation for alternate source(s) for exposure characteristics clearly documented? Were the assumptions used appropriate and adequately justified for the alternate source(s) of exposure characteristics?				
Were assumptions regarding exposure duration and exposure frequency appropriate and adequately justified?				
If exposures of less-than-chronic duration were considered for non-carcinogens, was their use appropriate and justified?				
3.3.4 Exposure estimation				
Were Health Canada equations used to estimate dose (i.e. exposure)? If no, were alternate equations provided, fully justified, referenced, and all assumptions explained?				

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
Does the report include sample calculations for estimating dose via each exposure pathway? Can those calculations be reproduced? (i.e. Check the math.) Are all equations dimensionally consistent and are all units correct?				
Has 100% oral bioavailability been assumed? (If a variable representing bioavailability is not included, then 100% is implicitly assumed.) If no, then were the values based on tests of on-site soil? If no, was the value based on scientific literature and properly referenced?				
If dermal absorption was a pathway evaluated, were dermal absorption factors drawn from Health Canada advice? If no, was the value based on scientific literature and properly referenced?				
If inhalation was a pathway evaluated, was absorption by this pathway assumed to be 100%? (If a variable representing inhalation bioavailability is not included, then 100% is implicitly assumed.) If no, was the value based on scientific literature and properly referenced?				
In calculating lifetime average daily dose for cancer risks, was the assumption of lifetime exposure included?				
If exposures of less-than-chronic duration are considered, was their use appropriate and justified with references?				
3.4 Toxicity Assessment				
Were all TRVs drawn from Health Canada? If no, was it because Health Canada had no TRV for the particular COPC?				
Are the selected TRVs clearly stated, with references, for each chemical and for each pathway?				

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
Are the health effects associated with each COPC and the basis for the TRV described?				
3.5 Risk Characterization				
Are the results of the risk assessment clear?				
Where there were pathway specific TRVs, were HQs calculated for individual exposure pathways?				
If alternate TRVs were used, were risks calculated for both Health Canada TRVs (if available) and the alternate TRV?				
Were on-site exposures calculated using a HQ of ≤ 0.2 for non-carcinogens?				
If a HQ of 1.0 was used, were background exposures levels adequately estimated?				
Are all cancer risks less than 1×10^{-5} (or other level) defined as essentially negligible?				
For chemicals and pathways affecting the same target organ, are the HQs summed for non-cancer effects?				
For carcinogens, have risks been summed for chemicals and pathways causing the same form of cancer?				
If carcinogenic PAHs, PCDDs/PCDFs, or certain dioxin-like PCBs were assessed, was Health Canada guidance used regarding TEFs or PEFs?				
Is the uncertainty of the results discussed?				

QUERY	ANSWER TO QUERY			
	YES	NO	N/A	PAGE REFERENCE IN HHRA
Do the recommendations identify requirements for additional work at the site, based on significant uncertainty in certain parameters?				
3.6 Risk Management				
If any non-cancer HQs exceed 0.2 or any cancer risks exceed 1×10^{-5}, are remedial or risk management measures proposed?				
Are recommendations proposed, and is the responsible department or agency clearly identified, if other than the client department that solicited the risk assessment?				
TO BE COMPLETED BY HEALTH CANADA ONLY				
3.7 Overall Comments				
Is the risk assessment report complete and generally acceptable (i.e. there only minor issues or no issues), or do major gaps or outstanding issues exist that preclude an evaluation of potential human health risk?				

Note: N/A, not applicable

4.0 REFERENCES

Health Canada (HC). 2010a. Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0. Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

Health Canada. 2010b. Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0. Contaminated Sites Division, Safe Environments Directorate, Health Canada, Ottawa.

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

United States Environmental Protection Agency (U.S. EPA). 1997. Exposure Factors Handbook. EPA/600/P-95/002Fa. National Center for Environmental Assessment. Office of Research and Development. U.S. EPA, Washington, DC. Accessed on March 17, 2010, at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12464

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