



FEDERAL CONTAMINATED SITE
RISK ASSESSMENT IN CANADA:

Overview of Health Canada
Guidance Documents Related
to Human Health Risk Assessment
of Federal Contaminated Sites



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L'évaluation des risques pour les sites contaminés fédéraux au Canada : Vue d'ensemble des documents d'orientation de Santé Canada concernant l'évaluation des risques pour la santé humaine des sites contaminés fédéraux

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PREFACE

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

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

This guidance document provides an overview of Health Canada’s (HC’s) published guidance documents for assessing potential human health risks at federal contaminated sites in Canada. This guidance is relevant throughout the 10 steps of the *FCSAP DMF*.

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

New and updated guidance on various aspects of HHRA will be published as the practice of HHRA advances and as FCSAP proceeds. As a result, it is anticipated that revisions and/or addendums to this document will be necessary from time to time to reflect the new information. Please consult the HC website above to confirm that the version of the document in your possession is the most recent.

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



ABBREVIATIONS AND ACRONYMS

CCME	Canadian Council of Ministers of the Environment
COPC	contaminant of potential concern
DQRA	detailed quantitative risk assessment
DWSV	drinking water screening value
HC	Health Canada
HHRA	human health risk assessment
FCSAP	Federal Contaminated Sites Action Plan
PQRA	preliminary quantitative risk assessment
P/T	provincial/territorial
RBA	relative bioavailability
SOW	statement of work
SSV	soil screening value
TRV	toxicity reference value



1.0 PURPOSE

The purpose of this document is to provide a summary of the content and potential application of the various technical guidance documents developed by Health Canada (HC) for assessing potential human health risks at federal contaminated sites in Canada. It is intended to assist risk assessors in making decisions on the environmental media to be assessed and on the technical guidance documents to be considered at a particular site.

General guidance is provided in **Section 1.0**. The sections that follow provide an overview of each guidance document and include the following:

- Reference to core documents that apply to the topic
- Additional resources/publications
- A summary of the scope and contents of the key guidance documents
- For some documents, a decision tree to help determine when to apply the guidance

HC's human health risk assessment (HHRA) guidance is designed specifically for the assessment of sites that are the property and/or the responsibility of federal departments, agencies and crown corporations (referred to as federal custodians in this publication). For properties being divested to a private party or to provincial/territorial (P/T) or municipal governments, or for assessments that address human health risks associated with off-site migration of contamination (e.g., to an adjacent P/T water body or neighbouring private property), HHRA's may have to be conducted in accordance with P/T regulatory requirements. These local regulatory requirements may differ from the standardized methods described in HC guidance documents. When the assumptions, methods and interpretations being employed in such cases vary from those presented in HC guidance, the differences should be noted in the risk assessment report, particularly if they may result in divergence in HHRA conclusions.

1.1 PUBLISHED GUIDANCE DOCUMENTS

HC has developed the following core guidance documents, applicable at most federal contaminated sites for which risk assessment is considered:

- *Federal Contaminated Site Risk Assessment in Canada:*
 - › *Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 (2021)*
 - › *Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0 (2010)*
 - › *Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA_{Chem}) (2010)*
 - › *Toxicological Reference Values (TRVs), Version 3.0 (2021)*

The following HC supplemental guidance was developed to address particular areas of HHRA that may be applicable only at certain sites:

- *Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment (DQRA_{RAD}) (2010)*
- *Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites (2010)*
- *Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment (HHRA) (2010)*



- *Supplemental Guidance on Developing a Contract Statement of Work (SOW) for Human Health Preliminary Quantitative Risk Assessment (PQRA) and Detailed Quantitative Risk Assessment (DQRA) (2010)*
- *Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRA_{Foods}) (2010)*
- *Supplemental Guidance on Human Health Risk Assessment of Air Quality, Version 2.0 (2017)*
- *Supplemental Guidance on Human Health Risk Assessment of Contaminated Sediments: Direct Contact Pathway (2017)*
- *Supplemental Guidance on Human Health Risk Assessment for Oral Bioavailability of Substances in Soil and Soil-Like Media (2017)*
- *Supplemental Guidance on Human Health Risk Assessment of Indoor Settled Dust (HHRA_{DUST}) (2018)*

In addition to the guidance documents listed above, HC has also developed fact sheets and other tools related to federal contaminated site risk assessment. A list of available publications is provided in **Appendix A**.

1.2 UNDERSTANDING THE SCOPE OF THE RISK ASSESSMENT

The scope of the risk assessment must be understood in order to determine which guidance documents are applicable at a federal contaminated site. HHRA may be conducted at different levels of detail and complexity depending on what is needed to inform risk management decisions. The scope and level of effort vary depending on a number of factors, including current vs. future land use, site divestiture, site complexity, data availability, off-site migration of contaminants, and site management goals. Examples of specific questions to consider would include:

- What are the objectives of the risk assessment?
- Is the risk assessment intended to consider only current land uses or also potential future land uses?
- What media are affected by the contamination?
- Is the spatial delineation of the contamination limited in nature (e.g., limited to hot spots), or is the contamination delineated in all affected media?
- Is additional data collection needed to support the risk assessment (e.g., supplemental site investigation)?
- Is there a potential for off-site transport of contaminants (e.g., via groundwater or fugitive dust)?
- What level of complexity is required (e.g., preliminary/screening level or a detailed risk assessment) to inform risk management decisions?
- Are people exposed to substances at the site on a chronic basis or infrequently?
- Are foods consumed from an area that may be impacted by site contaminants?
- Is air quality impacted?



1.3 DETERMINING WHICH GUIDANCE DOCUMENTS APPLY

The decision about which guidance documents should be considered in the risk assessment can be made through a two-step process:

- Complete a general screening to determine which media or specific HHRA topics covered by the HC supplemental guidance documents may need to be taken into consideration (see list in **Section 1.2**).
- Determine the applicable guidance to be considered using the flowcharts in this document or through professional judgement.

The following sections of this document present a brief summary of each guidance document and an overview of when the guidance may be applicable.



2.0 PRELIMINARY QUANTITATIVE RISK ASSESSMENT GUIDANCE

Federal Contaminated Site Risk Assessment in Canada: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 (HC, 2021) provides a standardized conservative approach to assessing potential human health risks associated with federal contaminated sites.

The purpose of a PQRA is to quantitatively and conservatively assess potential human health risks associated with exposure to contaminants at federal contaminated sites. PQRAs are generally conducted where data are limited and a decision is required on whether additional information is needed.

The guidance defines the applicability of a PQRA and provides direction for its completion in the specific context of FCSAP. It prescribes conservative and standardized risk assessment methods and assumptions. If a PQRA determines that potentially unacceptable human health risks exist, a DQRA may be undertaken to reduce uncertainties and refine the risk assessment. The PQRA may also identify specific data and/or considerations that require further characterization in order to refine the risk assessment (**Figure 1**).

In certain cases, a PQRA may provide sufficient information to enable a risk management decision to be made. However, a DQRA may be recommended to reduce uncertainties or to assess more complex sites, i.e., those with impacts on multiple media (soil, groundwater, food, sediment, air, etc.) or with considerable variability across the site in terms of human activities, contaminant types and concentrations (see **Section 3.0**).

The PQRA guidance document includes:

- Identification of “operable” exposure pathways (i.e., the manner by which people may be exposed to contaminants of potential concern [COPCs], such as through ingestion, skin contact or inhalation)
- Recommended human receptor groups and their characteristics
- Generic exposure duration and frequency assumptions
- Recommended general equations for dose and risk estimation
- A summary of common issues in the conduct and reporting of HHRA
- Worked examples

At a minimum, it is recommended that the following HC guidance be used in conjunction with the PQRA guidance:

- *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 (2010)*
- *Federal Contaminated Site Risk Assessment in Canada: Toxicological Reference Values (TRVs), Version 3.0 (2021)*



3.0 DETAILED QUANTITATIVE RISK ASSESSMENT GUIDANCE

Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (HC, 2010) provides guidance on assessing human health risks associated with sites for which a PQRA is considered overly conservative or not adequate to support a risk management plan (e.g., sites with several affected environmental media or sites with a large degree of variability in terms of human activities, contaminant types and concentrations).

The purpose of a DQRA is to produce a more refined, robust and representative estimate of risk than that generated by a PQRA, in which more conservative assumptions are made. Although the level of detail of an HHRA can vary considerably, a DQRA typically includes more comprehensive site characterization data, more representative or site-specific exposure information and, in some cases, a higher level of sophistication in the fate, transport and exposure modelling or assessment (**Figure 1**). A DQRA may therefore provide a more representative assessment of exposure.

The guidance document includes information related to:

- A human health risk assessment framework
- Specific characteristics of a PQRA and a DQRA
- Problem formulation (chemical screening, identification of receptors and exposure pathways, conceptual site model development, including examples in various formats)
- Common contaminant sources, release mechanisms and receiving media
- The pathway screening process for air, surface water, sediment, soil, food and groundwater
- Components of exposure assessment: characterization and estimation of chemical exposure concentrations, receptor characterization, equations for exposure assessment
- Components of toxicity assessment: determination of toxicity reference values, development of *de novo* toxicity reference values, consideration of other factors affecting toxicity
- Estimation of risk and interpretation of risk estimates
- Deterministic vs. probabilistic risk assessment
- Development of site-specific risk-based remedial objectives
- Worked examples for relative bioavailability adjustments, exposure estimation, evaluation of background exposure and estimation of risks

Many of the supplemental HC guidance documents may be applicable to support information in the DQRA. At a minimum, it is recommended that the following guidance be used in conjunction with the DQRA guidance:

- *Federal Contaminated Site Risk Assessment in Canada, Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment (2010)*
- *Federal Contaminated Site Risk Assessment in Canada: Toxicological Reference Values (TRVs), Version 3.0 (2021)*



4.0 WHEN TO USE THE PRELIMINARY OR DETAILED QUANTITATIVE RISK ASSESSMENT GUIDANCE

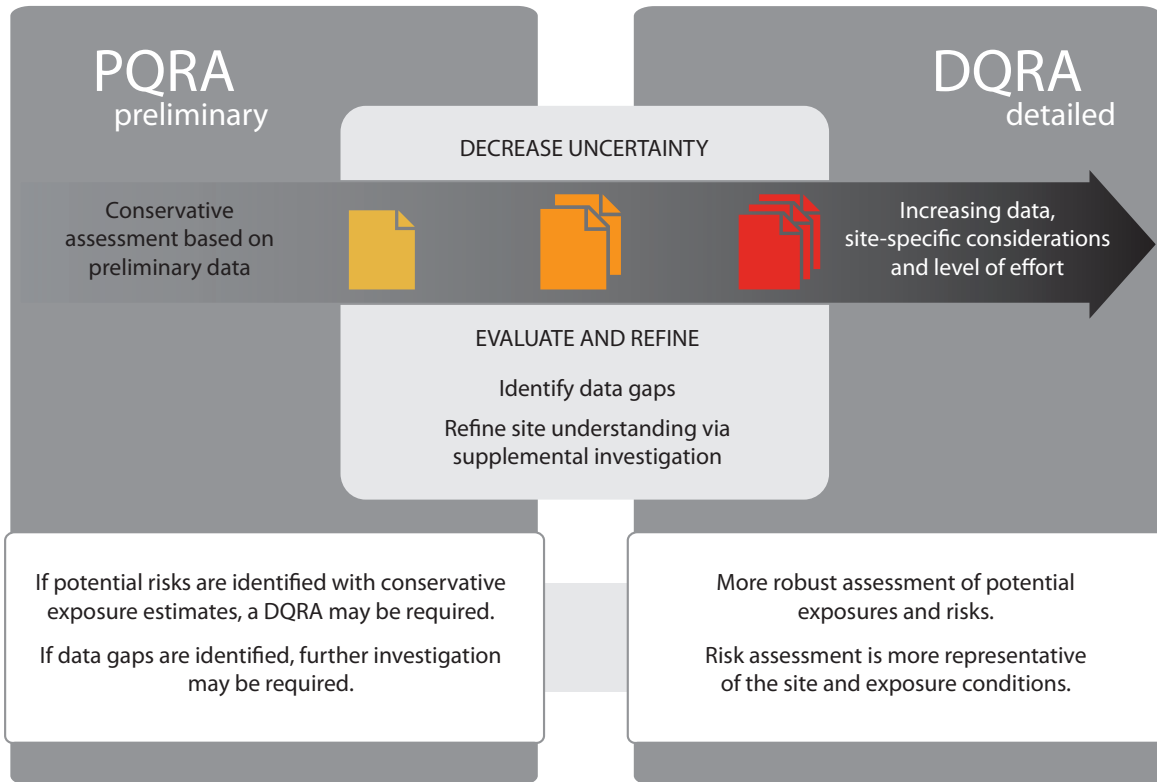
HC developed the PQRA and DQRA guidance documents to support the needs of federal custodians through the FCSAP decision-making framework, which is designed to provide a common approach to managing contaminated sites. PQRAs and more in-depth DQRAs are part of a graduated approach to human health risk assessment, from more simplified and conservative to more complex and refined (**Figure 1**). It is possible that both a PQRA and DQRA may be completed for a site at different stages of site assessment, depending on available site investigation data and goals of the assessment. The need for a greater level of detail is usually assessed in the context of the benefits of reduced uncertainty in the risk estimates as compared with the costs and resources to collect additional data and/or to conduct a more detailed assessment, or as compared with those required for the implementation of remediation or risk management.

A DQRA provides a more refined and robust estimate of health risks than a PQRA, as it is based on more representative estimates of exposure and site-specific assumptions. This includes consideration of the nature and temporal pattern of human activities at the site and the use of a statistical representation of contaminant concentrations in environmental media that is more representative of potential exposure.

If a PQRA identifies potential human health risks, a DQRA may be considered in order to refine the assessment and reduce uncertainties in the assumptions related to exposure at the site. In some cases, this may require further investigation to address data gaps and better characterize the contamination in various media at the site. A DQRA is most appropriate for informing the majority of risk management/mitigation decisions.



FIGURE 1: Preliminary vs. Detailed Quantitative HHRA for Federal Contaminated Sites



5.0 GUIDANCE ON TOXICOLOGICAL REFERENCE VALUES

Federal Contaminated Site Risk Assessment in Canada: Toxicological Reference Values (TRVs), Version 3.0 (HC, 2021) provides guidance on the selection and application of TRVs for use in characterizing human health risks associated with environmental contaminants found at federal contaminated sites in Canada. This is a companion document to the PQRA and DQRA guidance documents.

TRVs are prescribed by a variety of national and international government organizations/agencies for the purpose of characterizing risks associated with exposure to environmental contaminants. Estimated exposures to contaminants are compared with TRVs to quantify potential human health risks. For the assessment of human health risks at federal contaminated sites in Canada, the TRVs presented in the guidance are recommended for consistency. The TRVs presented in the guidance are intended for exposures of chronic duration. Short-term TRVs from other regulatory jurisdictions or advisory agencies may be used in HHRAs of federal contaminated sites, as required, with supporting technical rationale.

This guidance document applies to every quantitative risk assessment for federal contaminated sites, and therefore no decision tree is provided.

The guidance document includes:

- HC-recommended TRVs for several environmental contaminants, including those that are also considered essential trace elements
- A summary of the study and toxicological endpoint(s) upon which the recommended TRVs are based
- Guidance on selection of TRVs from other sources, for substances with no HC-recommended TRVs
- Dermal relative absorption factors for select substances



6.0 PEER REVIEW CHECKLISTS

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 (HC, 2010) and *Federal Contaminated Site Risk Assessment in Canada, Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment* (HC, 2010) were prepared to provide a structured and consistent framework for technical peer reviews of HHRAs.

These guidance documents present checklists that can be used by risk assessors conducting HHRAs or by federal custodians to confirm that the relevant information and details are captured in the risk assessment report. The checklists are not intended to serve as a regulatory instrument or approval tool.

Peer review is an important part of the scientific process and is especially helpful in instances in which highly technical information is being assessed. Third-party, independent peer review of HHRAs has become a routine part of the assessment of health risks at contaminated sites. Peer review by subject matter experts or qualified reviewers increases the probability that oversights and/or errors will be identified and corrected before they affect risk management decisions or human health.

Peer review incorporates the knowledge of subject matter experts and provides rigorous scrutiny. Peer review can also identify whether the HHRA methodologies applied are consistent with HC guidance and similar to those used at federal contaminated sites across the country, and whether the work conducted has met accepted scientific standards of rigour and accountability.



7.0 GUIDANCE ON DEVELOPING A STATEMENT OF WORK

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Developing a Contract Statement of Work (SOW) for Human Health Preliminary Quantitative Risk Assessment (PQRA) and Detailed Quantitative Risk Assessment (DQRA) (HC, 2010) provides guidance that can be applied by federal custodians to develop an SOW. The SOW can be used in soliciting proposals and administering contracts for HHRAs prepared by consultants, as well as for monitoring performance of the contractor(s) and the work and/or deliverables completed under contract.

Risk assessments may be conducted at many different levels of detail and complexity. The scope, level of effort and objectives of an HHRA will vary among sites, depending on such factors as data availability, site complexity, the purpose of the study and site management goals. The guidance explains how to tailor the scope of the HHRA so that the level of detail and expenditure of resources are appropriate to its intended application.

This guidance document applies to the preparation of an SOW for federal contaminated sites that require an HHRA, and therefore no decision tree is provided.

The guidance document includes:

- An outline of the information that should be delineated in the SOW to allow contractors/consultants to adequately gauge the level of effort of the HHRA
- Information on what should be considered in an HHRA
- A suggested outline of an HHRA report
- Sample SOWs to assist federal custodians in preparing requests for proposals for HHRAs at federal contaminated sites



8.0 RADIOLOGICAL RISK ASSESSMENT GUIDANCE

Federal Contaminated Site Risk Assessment in Canada, Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment (HC, 2010) provides guidance on the assessment of potential risks associated with radiological contamination at federal sites.

This document provides guidance for conducting typical radiological risk assessments. It provides a background to the principles applied to radiological risk assessments and a comparison with conventional chemical risk assessments. There is also a brief discussion of more sophisticated methodologies for conducting these assessments. The document provides considerable background information and outlines the various steps in the assessment process.

This guidance document applies to federal contaminated sites where radiological contamination has been identified, and therefore no decision tree is provided.

It is recommended that federal custodians consult with HC prior to undertaking a risk assessment of radiological substances to determine whether updated methodological guidance is available since the date of publication.

The guidance document includes information on how to:

- Apply the radiological risk assessment framework, including documenting the assumptions, rationale, decisions and processes to allow the reviewer to track, re-trace and reproduce the path followed in the application of this risk assessment guidance
- Determine whether the data collected for the site are appropriate and of sufficient quality and quantity to be used in the assessment
- Decide when to use a deterministic or a probabilistic approach in the risk assessment
- Select appropriate values for input parameters and necessary assumptions or, in the case of a probabilistic assessment, probability distribution functions that consider site-specific conditions and land use
- Identify appropriate references, databases, modelling methods and other resources that may be required in the process
- Select appropriate default radiological dose-conversion factors to be used in the assessment
- Select appropriate radiological exposure limits
- Provide the federal site custodian with a clear understanding of risks to assist in communication with site managers, regulators, and other stakeholders, and to identify appropriate risk management measures, including remediation



9.0 COUNTRY FOODS GUIDANCE

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods (HC, 2010) provides guidance to address the assessment of human exposure to chemicals through the consumption of non-commercial food, such as in backyard settings, or food obtained through hunting, gathering or fishing, that may be affected by contamination at federal sites.

In situations where commercial foods may be affected by a contaminated site (either on-site or from contamination migrating off the site), federal custodians are advised to contact HC prior to initiating a risk assessment.

This guidance document is applicable to any federal contaminated site where the potential for consumption of country foods has been identified. If the harvesting of food items does not occur, then this pathway is not considered operable and this pathway does not need to be addressed in the risk assessment. This may be the case, for example, where there is no occurrence of harvestable species at the contaminated site or that may be affected by the site, or where the remoteness of the site and absence of people render the consumption of country foods unlikely.

Key topics covered in the guidance include:

- Assessing if the country foods ingestion pathway is operable
- Developing a conceptual model
- Tissue sampling and analytical considerations
- An overview of considerations in the use of modelling for estimating tissue concentrations
- Determination of consumption rates of country foods or traditional foods
- Integrating the country foods ingestion pathway into a risk assessment

An HHRA should include consumption of country foods as a possible exposure pathway where there is potential for people to consume foods that may be affected by contamination at the site (e.g., contaminated soil, sediment, water, air) (**Figure 2**). In particular, substances that bioconcentrate, bioaccumulate or potentially biomagnify need to be considered. Additionally, if contaminated soil or dust particulates may adhere to foods, then this should also be considered.

The guidance identifies key questions to consider in a country foods risk assessment, which may include:

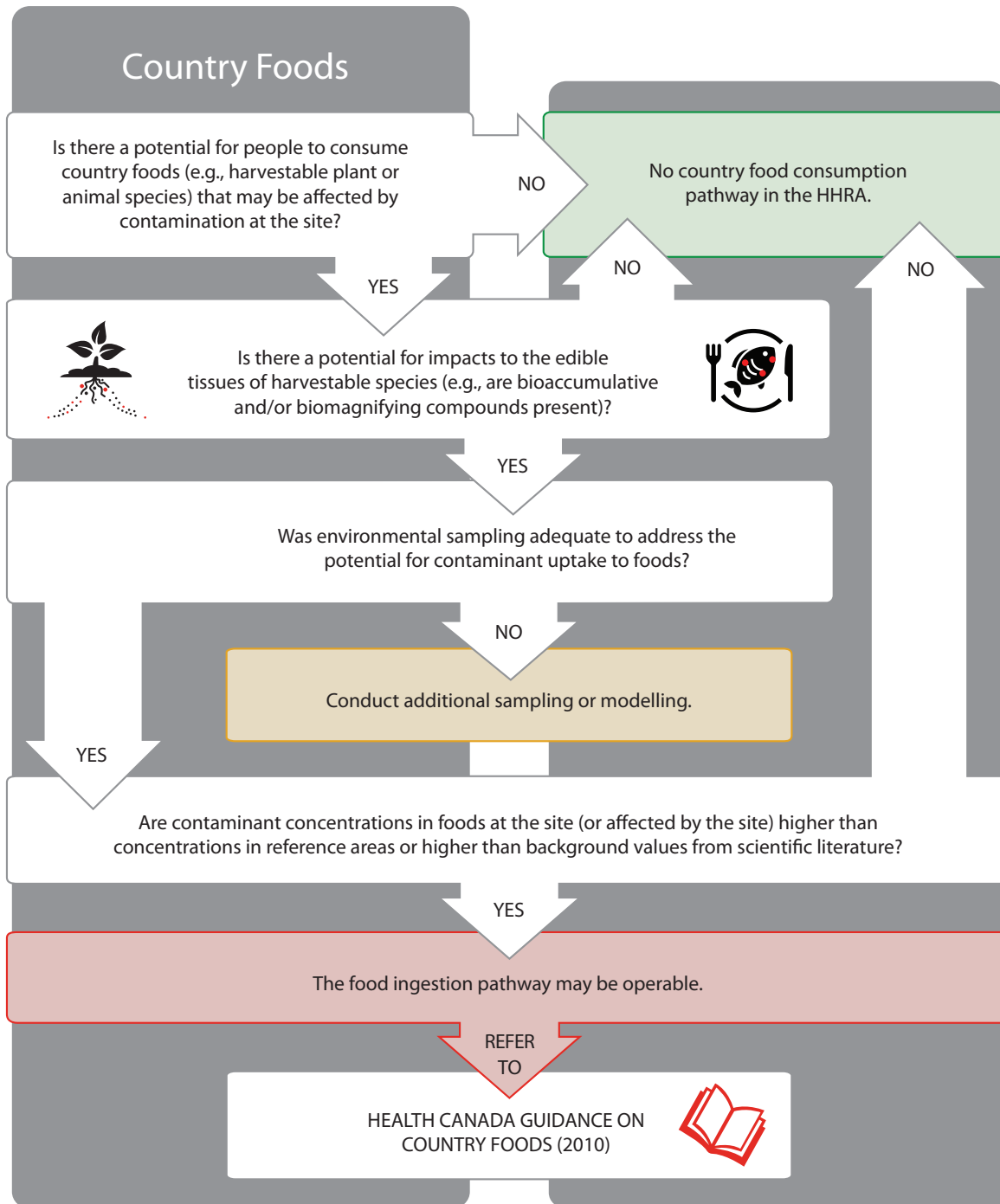
- Are there potential impacts to country foods resulting from site contamination?
- Are local species harvested, and if so, which tissues (or parts of the plant or animal) are consumed?
- How is the food prepared (e.g., are food items peeled, washed or preserved for later consumption)?
- How often are the country foods consumed and by whom? Are only the hunters and/or gatherers consuming the foods, or are they taken back to the community for others to also consume?



Site-specific information on consumption of local country foods is recommended in order to obtain representative estimates of exposure. An additional consideration in an HHRA involving country foods is that many populations, including remote communities, may consume greater-than-average amounts of country foods or have greater reliance upon country foods and may not be well-represented by country food consumption estimates for the general population. In addition to the variability in the proportion of the diet represented by country foods in a given subpopulation, consumption of specific foods may be community-specific and may be affected by seasonal variation.



FIGURE 2: When to Consider Country Foods in Federal Contaminated Sites HHRA



10.0 GUIDANCE ON DIRECT CONTACT WITH CONTAMINATED SEDIMENTS

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment of Contaminated Sediments: Direct Contact Pathway (HC, 2017) provides guidance to address potential human health risks associated with direct exposure to contaminated sediments at federal sites (i.e., via incidental ingestion, dermal contact and particulate inhalation). It does not address human health risks associated with consumption of seafood (i.e., freshwater and marine aquatic biota consumed by people) that may be affected by contaminants in sediment (refer to **Section 9.0**).

Key topics covered in the guidance include:

- Exposure scenarios involving direct contact with sediments
- Screening and identification of COPCs
- Identification of receptors and exposure pathways
- Exposure-related parameters such as sediment ingestion rates and dermal adherence factors

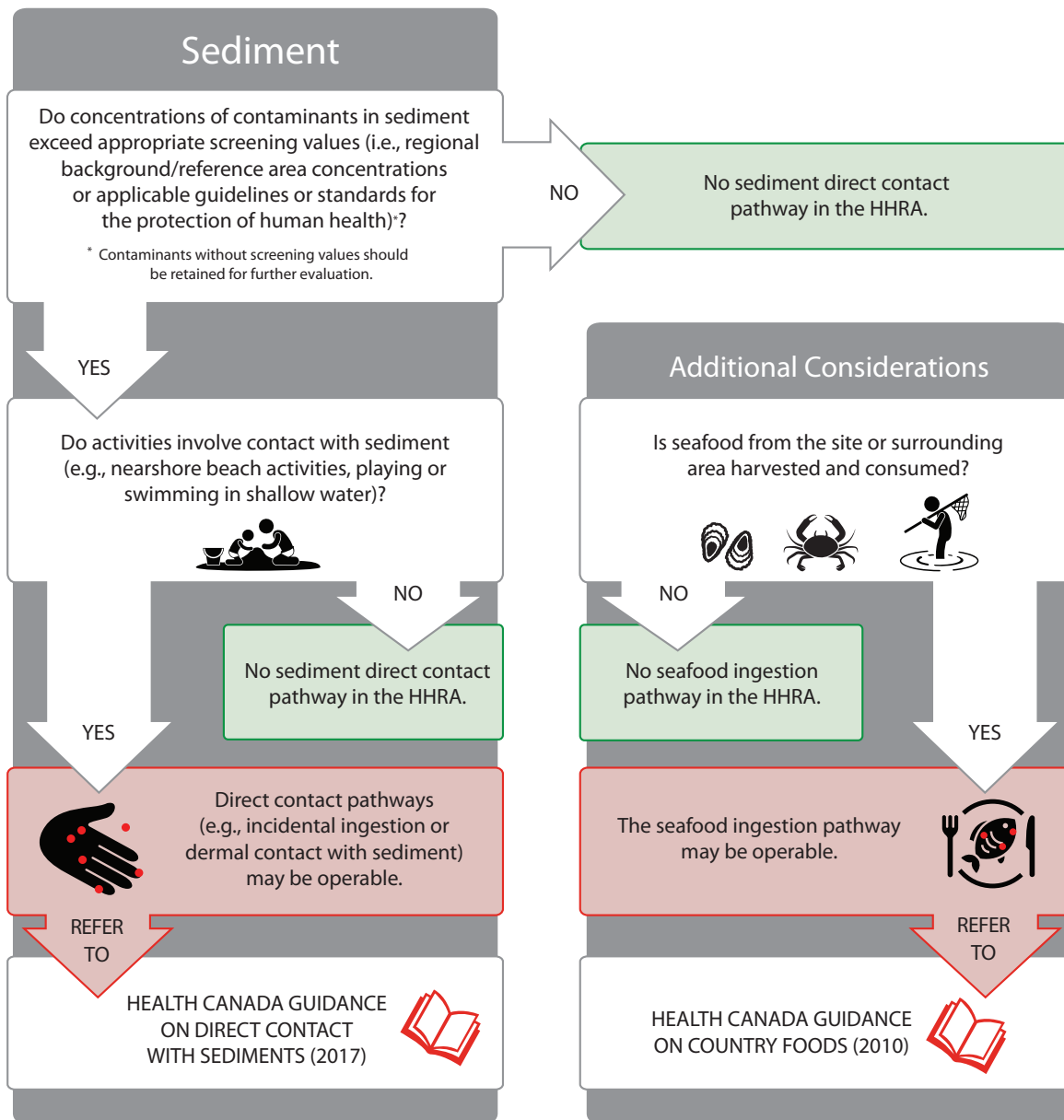
A risk assessment should consider direct contact with sediment as a potential exposure pathway if contaminant concentrations in sediments are above appropriate screening values (e.g., regional background/reference site concentrations or applicable guidelines or standards for the protection of human health), and there is potential for people to come into direct contact with the contaminated sediments (**Figure 3**). Exposure can occur via contact with submerged or partially exposed (e.g., intertidal) bedded sediments and with suspended sediments in the water column. This guidance document provides a methodology for deriving site-specific values with regard to protection of human health from direct contact exposure.

Key questions to consider include:

- Are concentrations of chemicals in sediment above regional background levels or reference site concentrations?
- Has the contamination been delineated adequately?
- How and where do people spend their time at the site?
- How often do people spend time in contact with sediments?



FIGURE 3: When to Consider Direct Contact with Sediments in Federal Contaminated Sites HHRA



NOTE: Seafood is defined as all freshwater and marine aquatic biota that may be consumed by people.



11.0 ORAL BIOAVAILABILITY GUIDANCE

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Oral Bioavailability of Substances in Soil and Soil-like Media (HC, 2017) provides guidance on when and how to incorporate oral bioavailability in detailed HHRAs for sites with contaminated soils or soil-like material/media (e.g., indoor settled dust, sediment and waste materials such as mining tailings or slag). The bioavailability of a substance is the amount of that substance that is absorbed and available to cause effects in the human body. The application of oral bioavailability adjustments in risk assessments may be used to refine the exposure and risk estimates associated with exposure via ingestion. This can provide support for site-specific remediation targets while achieving adequate protection of human health, depending on the contaminant(s) and the site.

Key topics covered in the guidance include:

- The overall framework, approach and requirements for inclusion of oral bioavailability adjustments in HHRAs, particularly for inorganic substances (e.g., arsenic, lead)
- Specific technical methods considered current at the time of publication

Oral relative bioavailability adjustments of a COPC allow comparison of the bioavailability of the COPC in soil or other environmental medium relative to its bioavailability in the reference (dosing) medium used in the toxicity assessment. This is “relative bioavailability” (RBA) and may be used to refine COPC exposure estimates, when appropriate.

Key questions to consider in order to assess whether it is worthwhile to incorporate oral bioavailability adjustments in an HHRA, include:

- What are the COPCs that may present a potential risk with ingestion exposure?
- Is there a validated bioaccessibility test (extraction fluid test used to mimic digestion) or a bioavailability (animal) test that can be used to determine the RBA for the contaminant?
- Are there site data to support the selection of a bioaccessibility or bioavailability test that is appropriate for the contaminant, contaminant range and media?
- Can the application of an RBA adjustment potentially change site management decisions (i.e., how a site is managed or remediated)?
- Can the test be performed in a time frame that is feasible for the project/site and at a reasonable cost?



12.0 GUIDANCE ON HUMAN HEALTH RISK ASSESSMENT OF AIR QUALITY

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment of Air Quality, Version 2.0 (HC, 2017) provides guidance for HHRA of air quality at federal contaminated sites in Canada and/or at contaminated sites undergoing risk management or remediation, where the work involved may affect air quality. Guidance on vapour intrusion of COPCs from subsurface sources (e.g., contaminated soil, groundwater) to indoor air is provided in a separate document (see **Section 13.0**).

Key topics covered in the guidance include:

- Work scope
- Problem formulation for air quality HHRA, including identification of COPCs, receptors and exposure pathways
- Estimating exposure to contaminants in air
- Evaluating background exposure
- Selecting appropriate TRVs
- Characterizing risks from exposure to contaminants in air
- Assessing uncertainties/data gaps
- Deriving air screening concentrations protective of human health

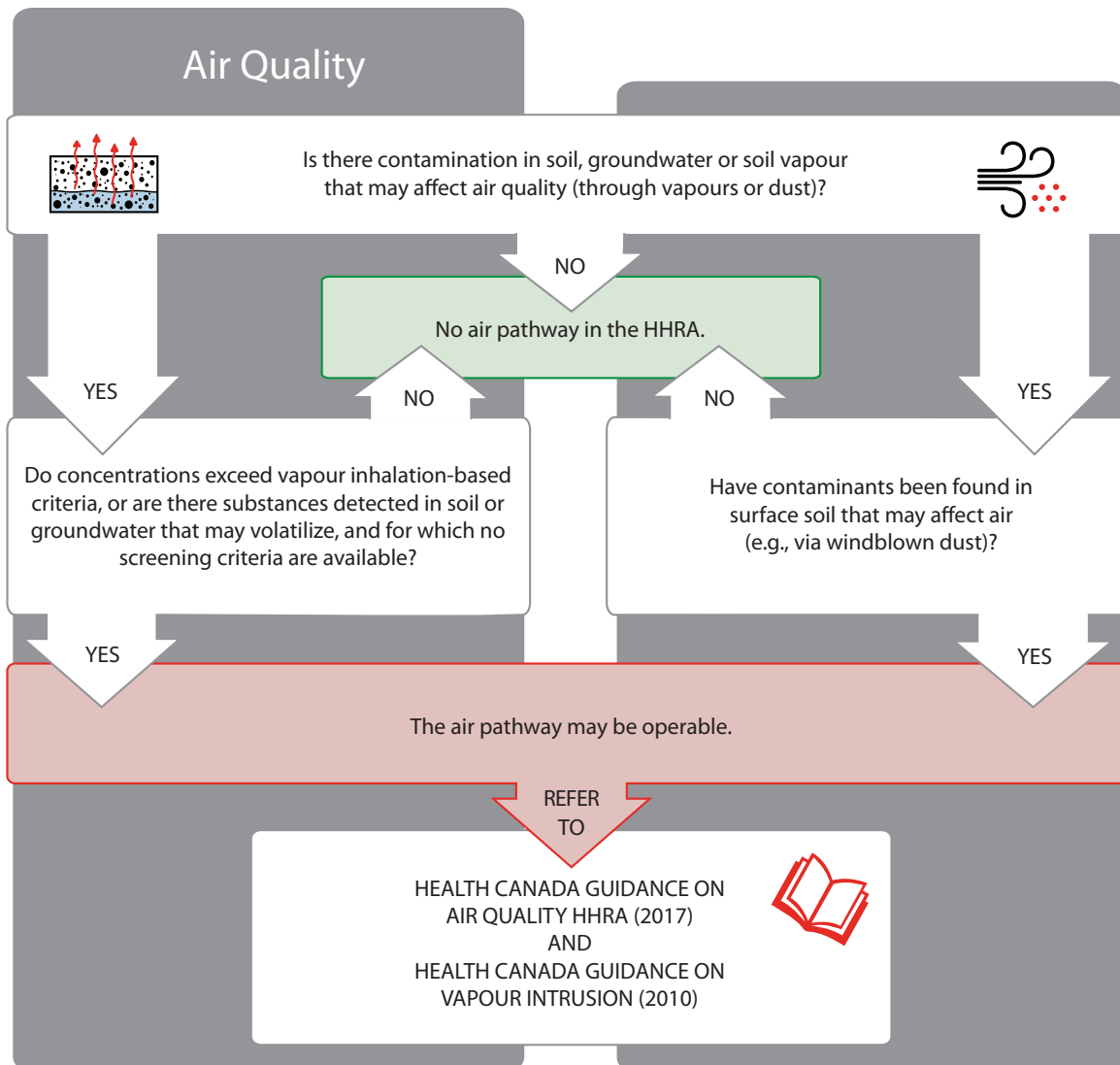
Air quality should be assessed in a contaminated site risk assessment when chemical concentrations in air may exceed applicable guidelines/standards or human health-based screening levels (**Figure 4**).

Key questions to consider include:

- Are concentrations of chemicals in soil or groundwater above screening levels based on vapour inhalation?
- Are there volatile chemicals present at the site for which there are no vapour inhalation screening criteria?
- Could windblown dust result in inhalation of contaminated soil particles?
- Has modelling predicted risks based on exposure to indoor or outdoor air?
- Are there other sources of airborne chemicals associated with the contaminated site?



FIGURE 4: When to Consider Air Quality in Federal Contaminated Sites HHRA



13.0 VAPOUR INTRUSION GUIDANCE

Federal Contaminated Site Risk Assessment in Canada, Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites (HC, 2010) provides an overall framework for the assessment of the vapour intrusion pathway (migration of volatile compounds from the subsurface to indoor air) at federal contaminated sites. Guidance on risk assessment of air quality is presented in a separate document (see **Section 12.0**).

The guidance addresses key factors in evaluating and making decisions associated with potential risks to human health from vapour intrusion into buildings. It provides a flexible, science-based approach based on multiple lines of evidence and site-specific conditions. The guidance can be applied to different types of residential and non-residential buildings that may be affected by vapour intrusion.

Key topics covered in the guidance include:

- Identifying conditions that warrant immediate action
- Identifying where there is a potential for the vapour intrusion pathway to be operable
- Developing a vapour intrusion conceptual site model and identifying COPCs
- Determining special considerations and precluding factors that may affect how soil vapour intrusion is assessed
- Using multiple lines of evidence to assess soil vapour intrusion
- Using the Johnson & Ettinger model to predict indoor air concentrations from groundwater or soil vapour data

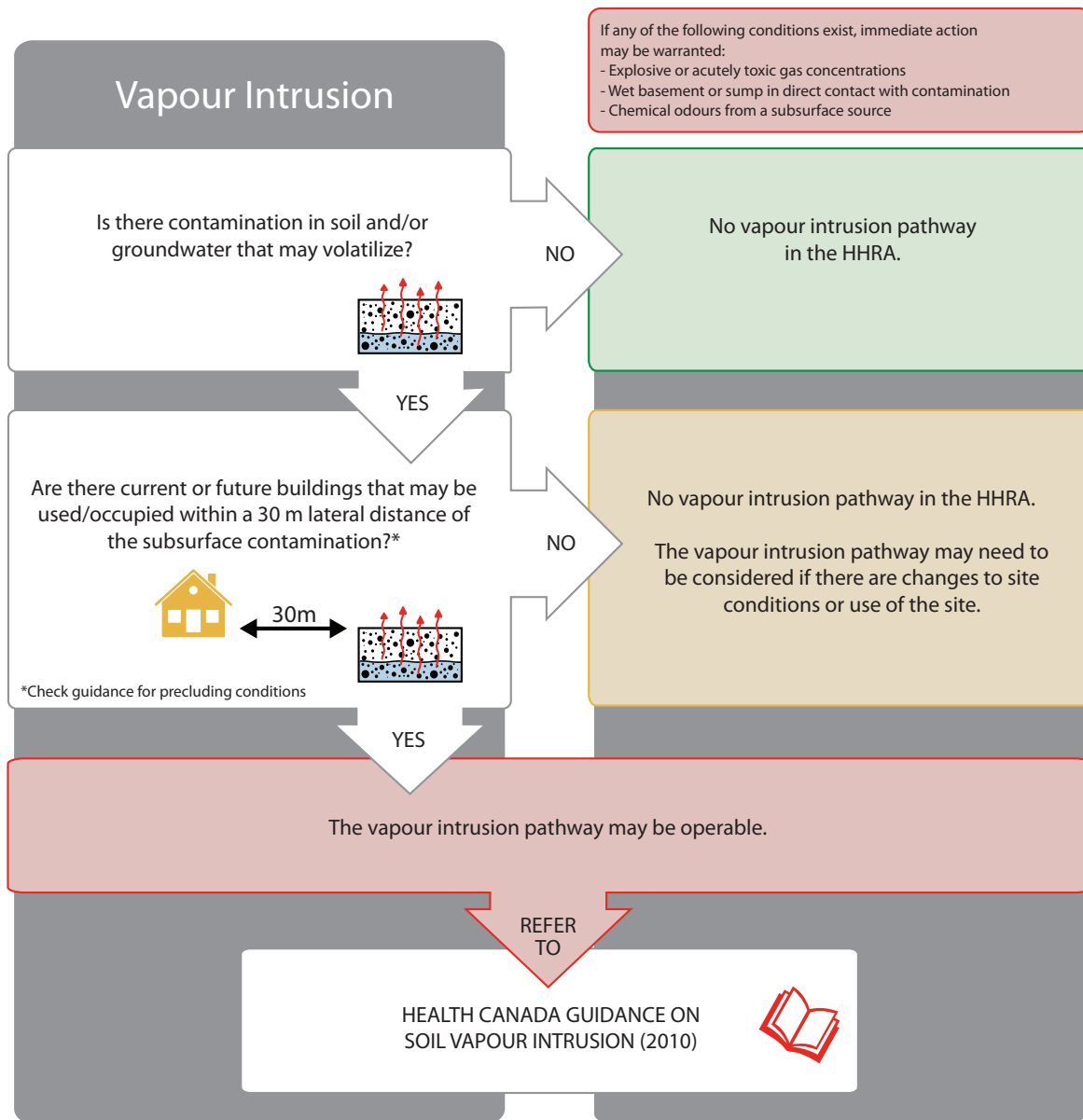
The vapour intrusion pathway should be assessed if there are volatile contaminants in soil or groundwater in proximity to buildings that may be occupied (**Figure 5**).

Key questions to consider in a risk assessment where volatile substances are of concern include:

- Have volatile contaminants been detected in the subsurface, and are they beneath or close to an occupied building?
- Do conditions requiring immediate action exist (e.g., explosive or acutely toxic gas concentrations, chemical odours, wet basement or sump in direct contact with contamination)?
- Has the volatile contamination been delineated, and have the hydrogeological and geological characteristics of the site been characterized?
- Have the building characteristics been documented (e.g., foundation type, presence of a crawlspace or basement, presence of a ventilation system)?
- Are there preferential pathways that may influence the soil vapour to indoor air pathway?
- Are there any conditions that may preclude the use of screening criteria or attenuation factors?



FIGURE 5: When to Consider Vapour Intrusion in Federal Contaminated Sites HHRA



14.0 INDOOR SETTLED DUST GUIDANCE

Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment of Indoor Settled Dust (HC, 2018) provides methods for assessing health risks from substances in contaminated soils that may affect settled dust inside buildings at federal contaminated sites. Indoor dust in buildings on and adjacent to contaminated sites may be affected through tracking of soil indoors, windblown dust, and emissions during remediation or construction activities.

Key topics covered in the guidance include:

- When to consider assessing indoor settled dust
- Development of a conceptual site model for the indoor dust pathway
- How to sample indoor dust
- Identifying COPCs in indoor settled dust
- Exposure assessment methodology
- Equations for calculating dust screening concentrations

The guidance is not intended for occupational exposures, as these are subject to occupational health and safety legislation.

The document is focused on indoor dust settled on surfaces as opposed to airborne particulate matter (refer to **Section 12.0**).

WHEN SHOULD INDOOR SETTLED DUST BE ASSESSED?

Many risk assessments do not require sampling and analysis of indoor dust if the soil ingestion rate used to characterize exposure to soils includes soil and dust. Assessment of indoor dust may need to be considered where comprehensive assessment of multiple environmental media is desired, or at sites where local stakeholders have expressed concern over chemical concentrations inside buildings and dust impacts can be reasonably anticipated to be from contaminated soils at or near the site.

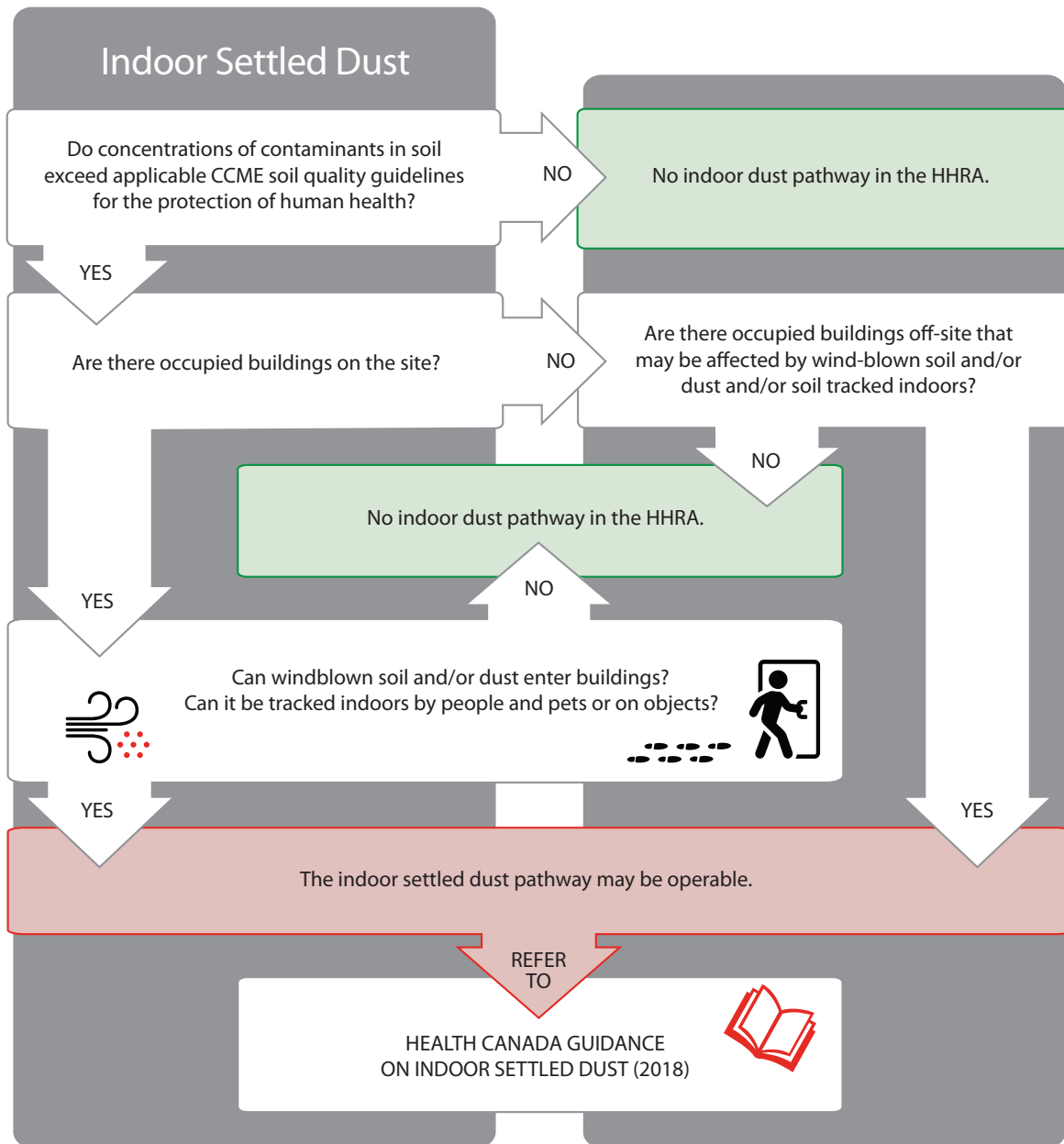
Incidental ingestion and dermal contact with indoor settled dust are considered operable exposure pathways if contaminated soil migrates indoors (e.g., if soil is tracked in on shoes or via windblown dust) and becomes incorporated in indoor settled dust that people may come in contact with (**Figure 6**). This guidance may be relevant if the risk assessment would benefit from assessment of soil and dust concentrations separately.

Key questions to consider in order to assess when it is appropriate to evaluate the indoor dust pathway include:

- Is there a transport mechanism through which COPCs in contaminated soil, outdoor dust and/or outdoor air at the site can affect indoor dust?
- Is the contaminated site likely to be a significant source of indoor dust contamination?
- What are the exposure patterns and characteristics of the receptors?
- Do chemical concentrations in indoor dust exceed calculated dust screening concentrations?



FIGURE 6: When to Consider Indoor Settled Dust in Federal Contaminated Sites HHRA



APPENDIX A: LIST OF HEALTH CANADA CONTAMINATED SITES GUIDANCE

GUIDANCE DOCUMENTS

Federal Contaminated Site Risk Assessment in Canada

- *Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 (2021)*
- *Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0 (2010)*
- *Part IV (RESCINDED): Spreadsheet Tool for Human Health Preliminary Quantitative Risk Assessment (PQRA) — discontinued and not recommended for use*
- *Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA_{Chem}) (2010)*
- *Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment (DQRA_{RAD}) (2010)*
- *Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites (2010)*
- *Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment (HHRA) (2010)*
- *Supplemental Guidance on Developing a Contract Statement of Work (SOW) for Human Health Preliminary Quantitative Risk Assessment (PQRA) and Detailed Quantitative Risk Assessment (DQRA) (2010)*
- *Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRA_{Foods}) (2010)*
- *Interim Guidance on Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites (2013)*
- *Supplemental Guidance on Human Health Risk Assessment of Air Quality, Version 2.0 (2017)*
- *Supplemental Guidance on Human Health Risk Assessment of Contaminated Sediments: Direct Contact Pathway (2017)*
- *Supplemental Guidance on Human Health Risk Assessment for Oral Bioavailability of Substances in Soil and Soil-Like Media (2017)*
- *Supplemental Guidance on Human Health Risk Assessment of Indoor Settled Dust (HHRA_{DUST}) (2018)*
- *Toxicological Reference Values, Version 3.0 (2021)*

FACT SHEETS

- *Risk Assessment and Public Involvement at Contaminated Sites (2006)*
- *Benefits of Public Involvement for Custodial Departments (2006)*
- *Health Impacts of Site Remediation: An Approach to Identify and Mitigate Potential Health Impacts (2006)*



PUBLIC INVOLVEMENT

- *A Guide to Involving Aboriginal Peoples in Contaminated Sites Management (2010)*
- *Improving Stakeholder Relationships: Public Involvement and the Federal Contaminated Sites Action Plan: A Guide for Site Managers (2006)*
- *Addressing Psychosocial Factors Through Capacity Building: A Guide for Managers of Contaminated Sites (2005)*
- *Public Involvement Plan Tool (2011)*

HEALTH CANADA SOIL SCREENING VALUES (SSVs) AND DRINKING WATER SCREENING VALUES (DWSVs)

Select SSVs and DWSVs are available on request for screening COPCs at federal contaminated sites when no Guidelines for Canadian Drinking Water Quality or Canadian CCME Soil Quality Guidelines for the Protection of Human Health exist for a specific substance (contact hc.cs-sc.sc@canada.ca for more information).

