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**Supplemental Guidance on Site-Specific
Risk Assessments in Alberta**

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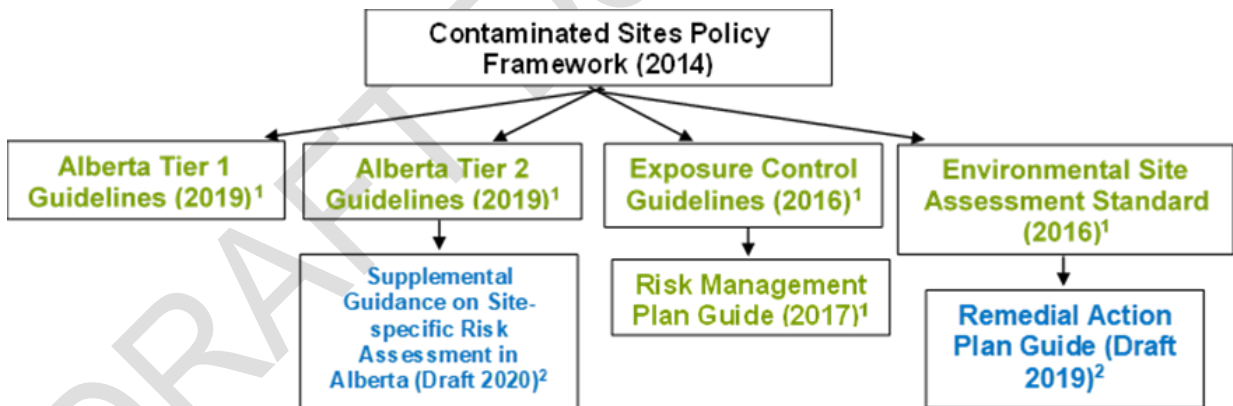
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Introduction

1.1 General

This supplemental guidance document provides additional clarification on the requirements and expectations set out by the Government of Alberta's *Contaminated Sites Policy Framework* (ESRD, 2014) and the *Alberta Tier 1 Soil and Groundwater Remediation Guidelines* (Tier 1 Guidelines) (Government of Alberta 2019a) and *Alberta Tier 2 Soil and Groundwater Remediation Guidelines* (Tier 2 Guidelines) (Government of Alberta, 2019b) with respect to the completion of site-specific risk assessments (SSRAs) for contaminated sites in Alberta. A SSRA has two components: a human health risk assessment (HHRA) and an ecological risk assessment (ERA). Both are normally required to assess risks associated with contaminated sites and are together referred to as a Human Health and Ecological Risk Assessment (HHERA). A SSRA is a particular type of HHERA that only applies to contaminated sites and it must be completed in accordance to jurisdiction-specific legislation and policy expectations, considerations and requirements (see Figure 1).

Figure 1: Risk Management for Contaminated Sites: Relationship between Legislation and Policy Documents



¹Documents are incorporated into the *Remediation Regulation* by direct reference.

²Documents are supplemental guidance to the primary reference that has been incorporated into the *Remediation Regulation*.

1.2 Legislative Context

Alberta's *Environmental Protection and Enhancement Act* prohibits the release of substances in an amount that causes, has caused or may cause adverse effect. "Release", "substance", and "adverse effect" are defined in the EPEA.

Whenever a release causes, has caused or may cause adverse effect, appropriate remedial measures must be taken. Alberta's *Remediation Regulation* further clarifies the Duty to Take Remedial Measures, as outlined in the *Environmental Protection and Enhancement Act*. Section 2 of the *Remediation Regulation* adopts the following documents under the *Alberta Contaminated Sites Policy Framework* (ESRD, 2014) for this purpose;

1. *Alberta Tier 1 Soil and Groundwater Remediation Guidelines* (Tier 1 Guidelines), (Government of Alberta, 2019a),
2. *Alberta Tier 2 Soil and Groundwater Remediation Guidelines* (Tier 2 Guidelines) (Government of Alberta, 2019b),
3. *Environmental Site Assessment Standard* (Government of Alberta, 2016b),
4. *Exposure Control Guide* (Government of Alberta 2016a),
5. *Risk Management Plan Guide* (Government of Alberta 2017b).

Section 2.3 of the *Remediation Regulation* requires that land *must* be remediated to meet the requirements of the Tier 1 Guidelines. However, section 2.4 of the Regulation specifies that a person *may* remediate an area of land or site in accordance with the Tier 2 Guidelines if they can meet two conditions:

1. the Tier 2 Guidelines meets the equivalent protection of environment and human health as outlined in the Tier 1 Guidelines to the satisfaction of the Director, and
2. the area of land or site is remediated to the satisfaction of the Director.

Options available under the Tier 2 Guidelines are further explained in that document and the *Alberta Contaminated Sites Policy Framework* (ESRD, 2014). A SSRA is a Tier 2 option outlined in the Policy Framework. This document directly supports the SSRA option under the Tier 2 Guidelines.

1.3 Scope and Objectives

This document provides general policy guidance rather than prescriptive technical guidance. The overall goal is to ensure consistent quality and completeness of contaminated site risk assessments when a SSRA option is chosen. SSRA is a multi-disciplinary process that must be conducted by qualified professionals familiar with generally accepted risk assessment

methodologies along with Alberta-specific policies. This guidance covers the basic principles and requirements of a SSRA. However, some requirements are conditional on the complexity of the SSRA (e.g., less complex SSRAs may have less requirements). Where justified, proponents are encouraged to discuss appropriateness of specific requirements with the appropriate Regulator (i.e., Alberta Environment and Parks or Alberta Energy Regulator) and/or key reviewers such as Alberta Health or Alberta Health Services.

It is expected that, where technical guidance is available in documents referenced herein, qualified professionals will follow the recommended guidance. This technical guidance is supplemental to the Tier 2 Guidelines and as such, the professional will need to ensure that the assessment is consistent with guideline recommendations to meet the requirements in the *Remediation Regulation*. Where technical guidance is not available in the documents referenced herein, this guidance is to be applied in conjunction with other applicable and relevant sources of information, along with appropriate experience and sound professional judgement.

SSRA is one option available under the Tier 2 Guidelines; other Tier 2 options include pathway exclusion and guideline modification. Although the principles of risk assessment underlie Tier 2 and are applied entirely to the various Tier 2 options, this document is solely focused on providing further information for the Tier 2 SSRA option. Readers are referred to the Tier 2 Guidelines for guidance with respect to the other options. SSRAs may also be conducted in support of the exposure control and risk management options for site management.

This guidance document can be consulted along with other relevant guidance as identified in Section 1.4.

The basic steps involved in a SSRA are summarized in the Tier 1 Guidelines and Tier 2 Guidelines. This document provides more specific guidance on methodologies and information sources acceptable to the Government of Alberta or the appropriate Regulator when conducting a SSRA under the Tier 2 Guidelines. Adherence to this document is required for any SSRA under the Tier 2 Guidelines. This document will facilitate regulatory review and acceptance of the SSRA. Where unique or complex situations justify the use of alternative approaches, it is suggested that these be discussed at the outset with the appropriate Regulator and/or with key reviewers.

1.4 Organization of Document

This document provides guidance on conducting a SSRA together with how it is implemented within the *Alberta Contaminated Sites Policy Framework* (ESRD, 2014). The document is organized into the following sections:

- Section 2 – Relation to the Contaminated Sites Policy Framework

- Section 3 – Scoping of Site-Specific Risk Assessment.
- Section 4 – General Human Health and Ecological Risk Assessment Methods.
- Section 5 – Reporting Requirements.
- Section 6 – Implementation of Site-Specific Risk Assessment Results.
- Section 7 – References.
- Section 8 – List of Acronyms.

1.5 Relationship to other Alberta Policy and Guideline Documents

This document directly supports requirements for SSRAs as outlined in the following key documents:

- Alberta Contaminated Sites Policy Framework (ESRD, 2014).
- Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2019a).
- Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2019b).
- Alberta Exposure Control Guide (Government of Alberta, 2016a).
- Alberta Risk Management Plan Guide (Government of Alberta, 2017b).

Any SSRA submitted to a Regulator or key reviewers must adhere to the principles provided in this document.

2 Relation to the Contaminated Sites Policy Framework

2.1 Alberta Contaminated Sites Policy Framework

Under the Alberta *Contaminated Sites Policy Framework* (ESRD, 2014), three management options are provided: Tier 1, Tier 2, and Exposure Control. Tier 1 Guidelines provide generic remedial standards. They were developed to protect sensitive receptors expected to be present within a given land use and can be used at most sites without modification. The approach in the Tier 2 Guidelines allows the consideration of site-specific conditions through the modification of Tier 1 guidelines, removing exposure pathways that may not be applicable to the site through the pathway exclusion option, adjusting the exposure assumptions through the guideline modification option, and/or the development of site-specific remedial objectives (SSROs) based on a SSRA. Exposure Control involves risk management through exposure barriers or administrative controls. Regardless of the site management option selected, the target level of human health and ecological protection afforded by Tier 1, Tier 2 or Exposure Control is the same.

Tier 1 Guidelines provide simple tabular remediation values that require the least site information for their use. Conservative assumptions about soil and groundwater characteristics have been used to develop the generic values in the Tier 1 Guidelines to protect sites likely to be sensitive to contamination. In this way, less sensitive sites under the applicable land use are also protected.

Applying the Tier 2 Guidelines requires more information from the site than Tier 1 Guidelines. This additional information allows the assessor to develop guidelines that are tailored to the particular characteristics of the site.

Regulatory closure is available for sites remediated to achieve Tier 1 or Tier 2 using the Tier 1 Guidelines or the Tier 2 Guidelines respectively. Regulatory closure is not available for sites under exposure control. (Government of Alberta, 2019a,b).

2.2 Role of SSRA in the Management of Contaminated Sites

The Tier 2 pathway exclusion and guideline adjustment approaches allows for limited site-specific modifications to the Tier 1 Guidelines, through guideline adjustment or exposure pathway removal, as described in the Tier 2 Guidelines. However, where major adjustments to parameters or models are needed, where conditions violate Tier 1 assumptions, or where

modifications are outside the scope of the prescriptive Tier 2 approaches, completion of a SSRA may be used to develop appropriate SSROs (Government of Alberta, 2019b).

SSRAs that do not require restrictions on the typical land use activities and do not require ongoing risk management may be acceptable for regulatory closure. SSRAs may therefore be conducted as an option under the Tier 2 Guidelines. The exposure control option for site management relies on ongoing risk management to control risks to both human health and the environment. This management option is used for sites that require administrative controls or require ongoing physical controls to manage risk. In this case, a SSRA is typically required to support the identification and selection of risk management options.

For more information, see the *Contaminated Sites Policy Framework* (ESRD, 2014) and other supporting documents listed in Section 1.4.

2.3 Role of the Professional in an SSRA

Any report submitted under the *Contaminated Sites Policy Framework* (ESRD, 2014) requires a professional declaration with a professional signature and stamp/seal or professional registration number. This includes SSRAs that are submitted to Alberta Environment and Parks (AEP) or the Alberta Energy Regulator (AER).

Members of one of the following seven professional organizations must be involved in and sign-off on all work:

- Alberta Institute of Agrologists (AIA)
- Alberta Society of Professional Biologists (ASPB)
- Association of the Chemical Profession of Alberta (ACPA)
- Association of Professional Engineers and Geoscientists of Alberta (APEGA)
- Association of Science and Engineering Technology Professionals in Alberta (ASET)
- College of Alberta Professional Foresters (CAPF)
- College of Alberta Professional Forest Technologists (CAPFT).

The Professional must maintain professional competency and have a minimum of five-years verifiable experience related to the *Competencies for Remediation and Reclamation Advisory Committee Recommendations Report* (AENV, 2006). Persons who conduct risk assessments shall possess knowledge based on an appropriate combination of formal education, skills, experience, and training in order to provide a technically sound and rational risk assessment. The Professional shall remain objective and free from influence throughout the process. When a SSRA is submitted to AEP or the AER, the Professional must follow appropriate procedures as specified in this document and recommended guidance. In addition, the Professional will:

- Follow relevant regulatory requirements outlined by provincial and municipal governments for Environmental Site Assessment (ESA), risk assessment, remediation, risk management, and reclamation;
- Not undertake any activity that she or he is not qualified (and licensed/permitted, where applicable) to perform;
- Promptly communicate to the responsible party any limitations imposed on the assessment resulting from the time frame and the scope of work, the environmental condition of the site as determined by the risk assessment, and any significant deviations from the original scope of work, prior to carrying out these new activities;
- Disclose possible and perceived conflicts of interest to the client and other relevant parties before entering into agreement for work;
- Provide sign-off for the work that was performed or coordinated;
- Ensure that any limitations imposed on the risk assessment or deviations from the initial scope are clearly communicated in the report;
- Carry adequate insurance throughout the duration of the process, including but not limited to general liability and errors and omission insurance; and
- Ensure that any practitioners or contributing Professionals working under the Professional's supervision are qualified and adhere to all of the above requirements.

3 Scoping of Site Site-Specific Risk Assessment

3.1 Risk Assessment Goals

In the specific context of the Alberta *Contaminated Sites Policy Framework* (ESRD, 2014), as discussed above, SSRAs are primarily conducted with the goal of developing SSROs (Government of Alberta, 2019a,b). SSRAs may also be conducted based on pre-remediation contaminant concentrations or residual (post-remediation) conditions to determine whether current risks are acceptable and to identify the need, if any, for further remediation or risk management.

Where risk management is proposed under the exposure control option, or where remediation involves the use of long-term techniques such as monitored natural attenuation, a SSRA can be of value in identifying pathways and/or receptors requiring protection as well as determining relevant concentrations for ongoing monitoring purposes. However, if risk management is proposed, Alberta's *Exposure Control Guide* (Government of Alberta, 2016a) requires that risk assessments be conducted in the absence of any risk management assumptions, even when a Risk Management Plan (RMP) has been approved. The risk assessment will need to provide information on the pathways and receptors that require risk management and what the consequences are for not managing those pathways and receptors. Please consult the Alberta *Risk Management Plan Guide* (Government of Alberta, 2017b) for RMP details. In summary, if a RMP is approved and is in place, SSRAs with and without the RMP in place are required.

The goals of any SSRA must be clearly established and articulated, and the resulting scope and data collection requirements should reflect those goals.

3.2 Complexity and Level of Effort

SSRAs can fall within a spectrum of complexity ranging from a screening level risk assessments to a detailed quantitative risk assessment. Screening level or preliminary risk assessments typically utilize maximum contaminant concentrations and other conservative assumptions, often in combination with simple exposure models, in order to obtain a conservative estimate of risk. If the estimated risks exceed levels considered acceptable from a regulatory standpoint, the assessment may then progress to a more detailed stage. A detailed quantitative risk assessment typically involves refinement of assumptions, parameters and modelling methods, and usually requires additional data collection to support the more detailed analysis. In all cases, adequate conservatism must be incorporated to provide sufficient protection to receptors. If the Regulator

or appropriate key reviewers determine that the level of conservatism in a SSRA is insufficient, the SSRA will need to be revised incorporating greater conservatism.

The scope of a risk assessment may be refined during or following completion of the problem formulation stage (see Section 4.1.1). While all contaminants of potential concern (COPCs), exposure pathways and receptors must be considered during the problem formulation, it is possible that not all COPCs, pathways and/or receptors need to be carried forward for detailed assessment.

The complexity and level of effort of any risk assessment must allow defensible conclusions to be drawn with respect to the level of risk or the derivation of SSROs. A conclusion of acceptable risk must not be based on limited or sparse data, or on non-conservative assumptions or modelling methods. The *Contaminated Sites Policy Framework* (ESRD, 2014) requires complete delineation both vertically and horizontally, for all COPCs, in soil, groundwater, and other relevant media before any assessment can be made. All assumptions must be fully substantiated. This document describes SSRA requirements that must be met when conducting a SSRA. However, not all requirements are relevant when undertaking SSRAs of a less complex nature. Where justified, proponents are encouraged to discuss specific requirements with the appropriate Regulator and/or key reviewers.

3.3 Data Collection Considerations

The information required to conduct a SSRA must include:

- Complete site and COPC characterization (horizontal and vertical delineation);
- Data pertinent to fate and transport modelling including local information such as but not limited to elevated background concentrations, fractured bedrock, high permeable materials etc.;
- Receptor characteristics;
- Toxicity information; and
- Completed and detailed Conceptual Site Model (CSM).

This information is required to determine a defensible quantification of SSRA and the establishment of SSROs.

Site information may vary both spatially and/or temporally. Information provided must be comprehensive enough to fully identify any spatial and temporal variations that may be involved. This variability can lead to uncertainty in risk predictions, which may require additional monitoring and possibly further modelling. The goal is to demonstrate that remedial objectives are being met and that model predictions correlate with actual concentrations.

The data collection required for a SSRA depends on critical exposure pathways, receptors and the availability and applicability of relevant data from other sources for aspects such as toxicity. A detailed data collection procedure is beyond the scope of this document but a SSRA should determine with a reasonable level of confidence, the following:

- Nature, degree and spatial distribution of COPCs including potential byproducts, impurities, and degradation products.
- Physical, chemical and hydrogeological characteristics of impacted soil and/or groundwater and assess for possibility of vapor intrusion.
- Building characteristics, if applicable.
- Human and ecological receptors and their associated exposure factors. In both instances the choice of receptors must consider the need for preservation of the entire range of human or ecological function within the given land use category. It may therefore be necessary to develop a complete inventory of potential human and ecological receptors that may be important to a site prior to determination of the sensitive receptors, especially in the context of valued ecosystem components (VECs), endangered species or traditional land use considerations.
- Receptor-specific toxicity information which, in the case of ecological receptors, may require toxicity testing and, at more detailed levels of ecological risk assessment, tissue sampling and analysis.

SSRA requires some form of monitoring to verify predictions. Usually, this includes monitoring after completion of the risk assessment to verify predictions. Therefore, data collection must also provide sufficient information to serve as a baseline for long term monitoring of relevant parameters.

The following sources provide guidance on site characterization for human health and ecological risk assessment:

- Alberta Environmental Site Assessment Standard (Government of Alberta, 2016b).
- Canadian Council of Ministers of the Environment (CCME) Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment (CCME, 2016a,b,c,d).

4 General Human Health and Ecological Risk Assessment Methods

4.1 Overview of HHERA Framework

HHERAs are carried out according to a common framework that was originally established by the US EPA in the 1980s for human and ecological risk assessment of Superfund sites (NAS, 1983; US EPA, 1989). This framework has subsequently been adopted by Alberta (Government of Alberta, 2019a,b) and many other jurisdictions, including Health Canada (2012; 2010a), Environment Canada (Government of Canada 2012a), and the Canadian Council of Ministers of the Environment (CCME, 2006). The risk assessment framework follows a four-stage process consisting of problem formulation, exposure assessment, toxicity or effects assessment and risk characterization (Figure 4.1).

Any user of this document must be familiar with the process. A brief overview of the four stages is provided below. Sources of detailed guidance for completion these stages with respect to human health and ecological risk assessment are provided in Sections 4.2 and 4.3, respectively. Where applicable, specific or additional requirements for a SSRA will be noted in the appropriate sections.

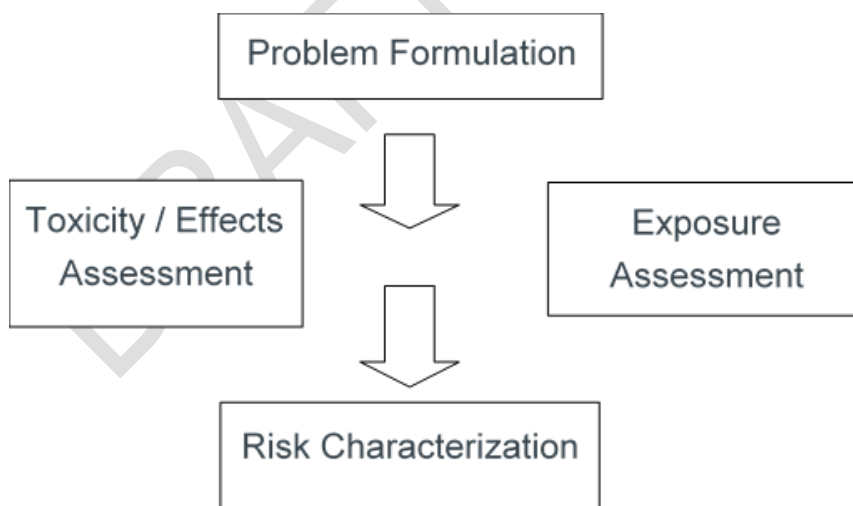


Figure 4.1 HHERA Framework

4.1.1 Problem Formulation

Problem formulation is the first stage of any risk assessment and involves identification and screening of the three main components of risk: COPCs, primary and sensitive/vulnerable receptors (both human and/or ecological) and relevant exposure pathways of the site and its setting. The goal of this stage is to focus the SSRA on those COPCs, pathways and receptors that contribute to human health and ecological risk. An exposure pathway requires a COPC source, a mechanism of chemical release to the transport medium, a transport pathway from the COPC source to the receptor, and a route of intake at the receptor location. Ecological receptors are often identified in terms of valued ecosystem components (CCME, 2020, Government of Canada, 2012a), which may not be limited to individual species but may include communities and populations as well as ecological processes or functions. Ecological receptors must be selected to be representative of all relevant trophic levels, and may require the identification of surrogates to proceed through the risk assessment process. VECs can be defined for any relative “social, economic or cultural importance— any particular species or group that is of special importance would typically be included as a receptor of concern. These include domestic pets, livestock, species of significance to Indigenous peoples, and species of commercial or recreational importance. Such receptors may be subject to a different level of protection than other receptors of concern” (CCME, 2020, Government of Canada, 2012a).

A CSM is a “visual representation and narrative description of the physical, chemical, and biological processes occurring, or that have occurred, at a site as related to” the COPCs and COPCs migration (Government of Alberta, 2016b). COPCs, receptors, and operative exposure pathways are screened at this stage and are incorporated into a CSM, which serves as the basis for the subsequent steps of the assessment. The CSM also assists in determining what additional data may be required to complete the risk assessment, and which of the COPCs, pathways and receptors are relevant to the site or project and surrounding area. The CSM must be provided in tabular, flowchart, and/or pictorial format.

At the end of the problem formulation stage if there is no potential human health or ecological risk, the SSRA may be concluded. No potential human health or ecological risk can be demonstrated in the following ways:

- No COPCs present.
- No potential receptors present.
- No operative exposure pathways identified.

Regardless, a CSM is a required output of the problem formulation.

4.1.2 Exposure Assessment

Exposure assessment defines the relationship between a COPC concentration at the source and the exposure or intake at the receptor location, considering both the fate and transport of the contaminant and the behavioral characteristics of the receptor. For direct pathways, exposure assessment involves determining the intake as a direct function of the source concentration to which the receptor is exposed. For indirect pathways, the exposure assessment normally involves modelling of the fate and transport mechanisms, including cross-media partitioning of the substance into soil, air, water, food or other relevant exposure or transport media.

Exposure assessment may include intake modelling through consideration of receptor characteristics and exposure factors (e.g., ingestion rates) as well as other chemical- and media-specific factors such as bioavailability and absorption. A HHERA must always consider chronic exposure, except where the HHERA is limited to assessment of short-term exposure scenarios such as remedial operations. Exposure averaging may be appropriate in certain cases for short term and/or intermittent exposures, depending on the chemical classification, frequency and duration of exposure, and receptor type. In such cases, however, the risk assessment must also account for potential sub chronic and acute exposure risks that may be associated with the actual exposure scenario. When conducting an exposure assessment for a SSRA, any exposure averaging, amortization, or extrapolation must be reviewed and accepted by the appropriate Regulator or key reviewers.

4.1.3 Toxicity / Effects Assessment

The toxicity/effects assessment is conducted to determine toxicological reference values (TRVs) for each COPC and exposure scenario. This stage involves identification of the potential toxic effects of each COPC, the mode(s) of action and toxicological endpoints, and the TRVs associated with those effects. TRVs are commonly selected from values published by appropriate regulatory agencies. Where regulatory values are not available the development of TRVs based on published toxicity studies may be required. The Government of Alberta (2017a) has published guidance on the selection of TRVs for the Alberta Tier 1 and Tier 2 soil and groundwater remediation guidelines. Further discussion on TRV selection and development is provided in Sections 4.2 and 4.3 below.

4.1.4 Risk Characterization

Risk characterization consists of combining the estimated exposure or intake of each COPC with the established TRV to obtain a risk estimate. In ERA, risk is expressed in terms of a hazard index or hazard quotient, defined as the ratio of the estimated exposure to the appropriate threshold TRV. Risk is also expressed in this way for most substances exhibiting non-carcinogenic effects in HHRA. Carcinogenic risk is typically presented as an incremental lifetime

cancer risk (ILCR), determined by applying a non-threshold TRV (e.g., unit risk or cancer slope factor) to the estimated dose. Risks thus determined are compared to target levels considered acceptable from a regulatory standpoint (Sections 4.2.2 and 4.3.2).

For characterization of human health risk, hazard indices and ILCRs for a given substance must be added across all exposure routes and receptor types unless the toxicity of the substance is route-specific. Similarly, for mixtures or groups of chemicals, hazard indices and ILCRs must be added for substances having the same mechanism of toxicity and target organ.

Where the purpose of the risk assessment is to derive SSROs, as part of the risk characterization process the established relationships between source concentration and adverse effect are used to back-calculate source concentrations corresponding to target risk levels. In this way SSROs are established for each pathway and receptor. The critical exposure pathway is identified on the basis of the lowest applicable SSRO, which then becomes the governing SSRO for the site.

An essential, and required, component of risk characterization is an uncertainty analysis. Throughout the SSRA, assumptions are made with respect to characterizing contaminant sources, assigning exposure parameters and TRVs, and in modelling physical, chemical and biological processes. These assumptions involve uncertainty (e.g., natural variability, lack of data or knowledge). Within an SSRA, an appropriate level of conservatism is required and incorporated to account for the uncertainties.

A discussion of uncertainty is necessary to assess the level of confidence in the results of the risk assessment, to guide the collection of additional data and to assist in the communication of risks.

4.2 Human Health Risk Assessment

4.2.1 General Guidance

For HHRA, Alberta Health (AH) and AEP recommend the use of the following guidance. Except where noted in subsequent sections, priority must be given to Canadian sources of guidance, in particular sources from Health Canada and CCME.

General HHRA guidance includes the following:

- Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2019a).
- Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2019b).
- Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2017a).

- Guidance on Human Health Risk Assessment for Environmental Impact Assessment in Alberta (Government of Alberta, 2011; 2019 - in preparation).
- Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (Health Canada, 2012).
- Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0 (Health Canada, 2010b)
- Federal Contaminated Site Risk Assessment in Canada, Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0 (Health Canada 2010c).
- Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA_{Chem}) (Health Canada (2010a).
- Federal Contaminated Site Risk Assessment in Canada, Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessment (HHRA) (Health Canada 2010d)
- Federal Contaminated Site Risk Assessment in Canada, Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRA_{Foods}) (Health Canada 2010e).
- Federal Contaminated Site Risk Assessment in Canada, Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites (Health Canada (2010f).
- A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME 2006).
- Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale (CCME 2008).

If available, Alberta specific policy must be used in interpretation or application of other guidance. If Alberta policy is silent on a particular issue or guideline, then the appropriate Canadian document is to be consulted as a primary reference source. In case that there is no Alberta specific policy and there is conflict or inconsistency between the referenced sources of guidance it is recommended that the appropriate Regulator or key reviewers be consulted for further direction.

The use of alternative approaches or methodologies to those presented in the referenced guidance may be considered in certain circumstances; however, full supporting rationale must be provided and it is the responsibility of the user to verify that methods used will be acceptable to the appropriate Regulator or key reviewers.

SSRA for a contaminated site in Alberta must consider all potential contaminant sources, exposure pathways and receptors applicable to the site, at least at the problem formulation stage. This requirement applies whether or not the corresponding source-pathway-receptor combination has been explicitly assessed in the development of the generic Tier 1 Guidelines for the specific

land use. An example would be where unique human receptors and exposure pathways are present, such as at natural area sites where traditional land uses may be practiced.

4.2.2 Human Health Protection Endpoints

The overall human health protection endpoint for contaminated sites in Alberta is the same at all tiers of site management, including the use of SSRA. The endpoint is expressed as an allowable exposure level at which the likelihood of an individual experiencing adverse health effects is essentially negligible.

For a COPC exhibiting non-carcinogenic effects (i.e., where there is a threshold level below which it is not expected to cause adverse effects), the total exposure of an individual, including background exposure, must not exceed the allowable exposure limit or TRV. In other words, the total hazard index for exposure to a substance must not exceed a value of one (1.0).

For a COPC exhibiting carcinogenic effects (i.e., where there is no threshold level), the incremental lifetime cancer risk (ILCR), in excess of that due to background exposure, must not exceed 1 in 100,000 (1.0×10^{-5}), the value considered by Health Canada (2010a, 2012) and the Government of Alberta (2011, 2019a,b; ESRD 2014) to be essentially negligible.

Both carcinogenic and non-carcinogenic effects must be assessed for COPC. See Section 4.2.3.2 for further discussion of the assessment of carcinogenic and non-carcinogenic endpoints.

4.2.3 Chemical Classification and Toxicological Reference Values

4.2.3.1 Toxicological Reference Values Selection

Human health risk-based TRVs for management of contaminated sites in Alberta are selected in accordance with *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (Government of Alberta, 2017a). The guidance presented herein is intended to provide risk assessors with a consistent approach to the selection and application of TRVs in the risk assessment of contaminated sites (i.e., SSRA).

The TRVs used in the derivation of the numerical Tier 1 guidelines are presented in the Tier 1 Guidelines. The *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (Government of Alberta, 2017a) provides guidance for updating existing TRVs in the Tier 1 and Tier 2 Guidelines. Where TRVs are available in the Tier 1 Guidelines (Government of Alberta, 2019a), the risk assessor must use the values provided. Where values are not available, the risk assessor must use the *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (Government of Alberta, 2017a) in selecting appropriate TRVs.

The *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (Government of Alberta, 2017a) identifies three categories of information sources for human health TRVs: primary, secondary and tertiary. Primary sources have been adopted by the Government of Alberta and used as the basis for developing and updating the existing Tier 1 Guidelines. These sources must be used, in order of preference as outlined in the guide, as the primary sources of TRVs for site-specific HHRA (as part of SSRA) where TRVs are not available in the Tier 1 Guidelines. Secondary sources are intended to be used where primary sources are not available. Tertiary sources are not specifically identified but would only be used in exceptional cases where no information is available from primary or secondary reference sources. For more information, see the *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines*. (Government of Alberta, 2017a).

4.2.3.2 Assessment of Carcinogenic versus Non-carcinogenic Endpoints

COPCs may display a threshold (e.g., non-carcinogenic) or non-threshold (e.g., carcinogenic) dose-response relationship. The TRV may therefore be expressed as an exposure limit or reference dose at which toxic effects are not expected to occur (threshold), or a factor describing the relationship between dose and incidence or severity of effect (non-threshold).

Some COPCs exhibit both threshold and non-threshold effects or may be considered carcinogenic via certain exposure routes and non-carcinogenic via other routes. Both carcinogenic and non-carcinogenic endpoints must be evaluated where appropriate in a HHRA as part of the SSRA. In particular, carcinogenic effects need to be evaluated where a non-threshold TRV is in one or more of the primary sources listed in the *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (Government of Alberta, 2017a) even if it is not provided in the Tier 1 Guidelines.

In determining ILCR, in which exposures are averaged over a lifetime, consideration must be given to the potential for higher risks associated with exposure to certain substances (notably mutagenic carcinogens) at specific life stages. For non-threshold carcinogens exhibiting a mutagenic mode of action, age dependent adjustment factors (ADAF) should be used in the estimation of the lifetime average daily dose (LADD), as recommended by Health Canada (2013).

4.2.3.2.1 Endpoint Exceptions

For a COPC that has a threshold-based mode of carcinogenic action (e.g., where there is a level that must be reached before cancers can be developed), a threshold-approach (e.g., hazard index) can be applied as long as it is clearly documented or demonstrated by a primary source and provided that the COPC's carcinogenic effect is secondary to its non-carcinogenic effects. In

other words, the non-carcinogenic TRV of a COPC is lower or more protective than its equivalent carcinogenic TRV. An example of such a COPC is chloroform (US EPA, undated [a]).

For a COPC that does not appear to have a threshold for its non-carcinogenic effect, a non-threshold approach such as ILCR may be adopted. Such an example would be lead, where a safe level of exposure in children has not been identified (Health Canada, 2019). In the case of lead, its neurodevelopmental effects are found at lower concentrations in drinking water than its carcinogenic effects.

4.2.3.3 Bioavailability and Relative Absorption Factors

Bioavailability describes the absorption and uptake of a substance into an organism through a particular exposure route. The bioavailability considered in an exposure assessment should be consistent with that associated with the exposure route used to derive the TRV. Bioavailability is normally evaluated through the use of relative absorption factors (RAFs). RAFs used in the development of the Tier 1 guidelines are presented in the Tier 1 Guidelines for the oral, dermal and inhalation exposure routes and must also be used for the HHRA as part of the SSRA. Health Canada (2010b) has also published RAF values. In the absence of a published value, a default RAF of 1.0 must be assumed.

Relative bioavailability has been defined as the absolute bioavailability from the site-specific soil samples divided by the absolute bioavailability of the same substance under the conditions used to derive the TRV (Health Canada 2010a). While a HHRA may include an evaluation of the relative bioavailability in support of an endpoint, it is important to note that methodologies are still under development. The risk assessor must consult with the appropriate Regulator or key reviewers before considering re-evaluation. Some guidance on the evaluation of bioavailability has been published by Health Canada (2017; 2010a) and the US EPA (US EPA, undated [b]). Adequate justification and site-specific assessment must be provided in the use of any relative bioavailability analysis.

4.2.3.4 Toxicity of Substances in the Absence of Published TRVs

In some cases, substances may be encountered for which published TRVs are not available from the primary or secondary sources (Government of Alberta, 2017a). In the absence of a credible TRV, a TRV may be derived in accordance with guidance published by Health Canada (2010a). Where required, a rationale will be required that is consistent with the *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (Government of Alberta, 2017a). It is strongly recommended that the appropriate Regulator or key reviewer be consulted with respect to the development and use of derived TRVs. Any proposed TRV must be accepted by the appropriate Regulator or key reviewers prior to being used in the SSRA.

4.2.4 Human Exposure Parameters

Human exposure parameters (e.g., receptor characteristics, intake rates, time-activity patterns), also referred to as exposure factors, are used to estimate contaminant intake or exposure dose, and are available in various published sources. Values used in the development of the Tier 1 guidelines are tabulated in the Tier 1 Guidelines and Tier 2 Guidelines. These values are from CCME (2006) and based on values published prior to that date by Health Canada. Health Canada has subsequently updated a number of these exposure factors (Health Canada, 2012). It is recommended that the most recent of the values published by Government of Alberta (2019a) or if not available then Health Canada (2012) be used in a HHRA as part of SSRA.

A number of additional sources of exposure parameters are available, and may be used in the absence of Alberta (Government of Alberta 2019a) or Health Canada (2012) values. They may also be used if considered more appropriate to specific populations and/or exposure scenarios that are not described in Tier 1 (2019a), with supporting rationale. These include:

- Inventory and Analysis of Exposure Factors for Alberta (Government of Alberta, 2018a)
- Canadian Exposure Factors Handbook (Richardson and Stantec, 2013)
- Exposure Factors Handbook (US EPA, 2011 and updates)

Intake rates for Indigenous people practicing traditional lifestyles may differ from standard assumptions and should be obtained where appropriate (e.g., Chan et al., 2016; Government of Alberta, 2018a). If a contaminated site is on traditional land it may be useful to obtain site specific receptor characterization factors.

In all cases, Canadian sources must be given first priority, although the use of data from other countries may be appropriate if Canadian data are lacking with appropriate justification. If using data from other countries the appropriate Regulator or key reviewers must be consulted for further direction.

In addition to chronic exposure an SSRA must also consider acute or sub-chronic effects that may not be included within the chronic exposure. For example, pica exposure to direct soil contact is an example of an acute exposure that is not covered within the chronic exposure assumptions.

4.2.5 Fate and Transport Modelling and Exposure Estimation

The exposure assessment stage of a risk assessment usually involves some form of contaminant fate and transport modelling to estimate exposure media concentrations based on contaminant source concentrations. In addition, intake modelling may be required for certain exposure routes (e.g., soil, water and food ingestion) in order to estimate intake or dose.

Numerous fate and transport models are available for evaluating contaminants in various media; model selection must take into account applicability and relevance to the transport media and processes, defensibility and regulatory acceptance of the model(s), and availability of appropriate data. Models used in the development of the Alberta Tier 1 guidelines are required for use in performing Tier 2 guideline modifications, and are described in the Tier 1 Guidelines and Tier 2 Guidelines. While these models are also recommended for use, where appropriate, in SSRA, it is noted that these models represent simplifications of the actual transport mechanisms and are only valid if used within appropriate ranges and maintaining appropriate assumptions. It is up to the risk assessor to ensure that the models are used appropriately and validated with sufficient monitoring data.

Intake modelling for SSRA generally involves the application of receptor characteristics such as inhalation or ingestion rates (Section 4.2.4) to relevant exposure media concentrations using simple equations that characterize intake, absorption and/or bioavailability. The intake models used in the development of the Tier 1 Guidelines must be used in SSRA. However, as SSRA are site specific the intake scenarios used for the Tier 1 Guidelines may be insufficient or intake modelling may require additional modelling to ensure all receptors are protected. All deviations from the Tier 1 intake models must be documented within the SSRA analysis.

For example, Alberta Tier 1 residential guidelines typically only consider toddler and adult life stages because these intake scenarios were critical to development of the Tier 1 Guidelines. However, when conducting an SSRA these assumptions may not be appropriate and intake from 5 life stages, as noted by Health Canada (2010a, 2012) must be considered in the assessment. Any deviation from these intake characteristics requires prior approval from the appropriate Regulator or key reviewers.

Other sources of information on intake models that have gained regulatory acceptance include, but are not limited to:

- A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME 2006).
- Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale (CCME 2008).
- Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (Health Canada, 2012).
- Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA_{Chem}) (Health Canada (2010a).

Other fate and transport or intake models may be used where appropriate and with adequate justification. Proprietary models are not recommended because of the lack of ability to review underlying processes, mechanisms, assumptions and algorithms used in the modelling exercise. When proprietary models are used, sufficient information must be provided with respect to the underlying processes, mechanisms and associated algorithms to enable independent review of the modelling and reproduction of the modelling results. The appropriate Regulator or key reviewers must be provided complete access to the proprietary model including all user manuals for the model, model assumptions and limitations and any other information that is required for evaluation.

Physical and chemical parameters for many COPCs are also listed in the above references. Selection of physical and chemical parameters must follow a similar process as prescribed in other sections of this guidance, with referenced Alberta Government and Canadian sources taking priority over other sources. Where parameters are not available from referenced sources, other parameter choices must be accepted by the appropriate Regulator or key reviewers.

4.3 Ecological Risk Assessment

4.3.1 General Guidance

For ERA, use of the following guidance is recommended. Except where noted in subsequent sections, priority must be given to Canadian sources of guidance, in particular CCME and Environment Canada. The applicable Alberta guidance must be consulted for Alberta-specific policy decisions and interpretation of guidance provided by other jurisdictions.

Sources of general ERA guidance include the following:

- Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2019a).
- Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2019b).
- Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta, 2017a).
- Protocol to Develop Alberta Water Quality Guidelines for Protection of Freshwater Aquatic Life (AEP 1996).
- Environmental Quality Guidelines for Alberta Surface Waters (Government of Alberta 2018b).
- Canadian Council of Ministers of the Environment (CCME) Ecological Risk Assessment Guidance (2020).
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance (Government of Canada, 2012a).

- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 1: Toxicity Test Selection and Interpretation (Government of Canada 2010a).
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 2: Selection or Development of Site-specific Toxicity Reference Values (Government of Canada 2010b).
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 3: Standardization of Wildlife Receptor Characteristics (Government of Canada 2012b).
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 4: Causality Assessment Module (Government of Canada 2013).
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 5: Defining Background Conditions and Using Background Concentrations (Government of Canada 2015-draft).
- Protocols for Deriving Water Quality Guidelines for the Protection of Agricultural Water Uses (Irrigation and Livestock Water) (CCME (1999b).
- A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME 2006).
- A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life (CCME 2007).
- Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale (CCME 2008).

In case of conflict or inconsistency between the above referenced sources, it is recommended that the appropriate Regulator or key reviewers be consulted for further direction. The use of alternative approaches or methodologies to those presented in the referenced guidance may be considered in certain circumstances; however, full supporting rationale must be provided and it is the responsibility of the user to verify that methods used will be acceptable to the appropriate Regulator or key reviewers.

4.3.2 Ecological Protection Endpoints

Risk-based guidelines fulfil two main goals from the ecological standpoint: protection of ecological receptors expected to be present at a site based on land use, and preservation of an appropriate level of ecological function of the site and its ecosystem components (Government of Alberta 2019a). Since all tiers of site management under the Alberta regulatory framework are required to provide the same level of environmental protection, these two protection goals also apply to ERA.

Protection goals are often expressed in ERA in terms of assessment endpoints, which are typically narrative in form, such as maintaining species abundance and diversity or ensuring a low level of adverse ecological effect. For the purposes of ERA, assessment endpoints require the identification of corresponding measurement endpoints, which measure the change in the attribute(s) of the respective assessment endpoint. Measurement endpoints, and the lines of

evidence selected to evaluate them, are generally quantifiable expressions of effect size, (e.g., survival rate, biomass change or COPC concentration in a relevant medium).

Assessment and measurement endpoints must be identified for each receptor of concern or VEC. As noted previously, a VEC must include individual members of a species as well as communities and populations. For SSRA, the assessment of effects at the community or population level is generally appropriate but in some circumstances assessment at the individual organism level is also required. For instance, when rare or endangered species are present, assessment at the individual organism level will be required. In addition, when assessing traditional lands of Indigenous communities, culturally appropriate VECs need to be considered which often will include individual species.

Assessment and measurement endpoints should be aligned across a common level of ecological organization. The ecological effects endpoints that are normally required to be addressed include acute (e.g., development, germination, lethality) and chronic processes (e.g., reproductive, growth, maintenance and critical development). Refer to Government of Canada (2012a) for further guidance with respect to the identification of assessment and measurement endpoints. Measurement endpoints are compared to acceptable effects levels in order to evaluate whether site-specific risks are considered acceptable. Acceptable effects levels may vary by receptor, by endpoint or by site, and depend on a number of considerations such as: whether protection is aimed at individuals, communities or populations; whether species at risk are present; and what effect size is ecologically relevant for the receptor of concern (Government of Canada 2012a). An example of an acceptable effect level is a 25% Effective Concentration (EC₂₅), or the concentration resulting in a 25% response level within a plant or invertebrate species sample referenced for the ecological soil contact pathway (as described in CCME, 2006).

Acceptable effects levels are often implicitly incorporated into the derivation of ecological toxicological reference values (EcoTRVs) where the latter are expressed as threshold effects concentrations or doses (see Section 4.3.3). In terms of guideline development, the CCME has determined that soil guidelines should achieve a level of ecological function that sustains the primary activities associated with a given land use. In this regard, the level of protection for commercial and industrial land use does not need to be as stringent as for agricultural or residential/parkland land uses (CCME 2006). This can be achieved either through the use of different response levels for different land uses, or through the selection of concentrations corresponding to different rank percentiles (e.g. 25% or 50%) on the estimated species sensitivity distribution (CCME 2006). For SSRA, acceptable effects levels must be equivalent to those used in the derivation of the Tier 1 Guidelines for the protection of ecological receptors (Government of Alberta 2019a, CCME 2006).

Under most circumstances, risks to ecological receptors are assessed for two main categories of exposure pathways: direct contact with soil or groundwater, and ingestion of soil, water and food. Inhalation risks are typically not assessed unless it is indicated that this is a primary route of exposure for a particular species.

4.3.3 Ecological Toxicological Reference Values (EcoTRVs)

As with TRVs for HHRA, the starting point for EcoTRVs for ERA as part of a SSRA in Alberta will be the values used in the derivation of the Tier 1 Guidelines. These are based on protocols described in A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME 2006) or on *Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale – Supporting Technical Document* (CCME 2008) for petroleum hydrocarbons. *Protocols for Deriving Water Quality Guidelines for the Protection of Agricultural Water Uses (Irrigation and Livestock Water)* (CCME 1999b) and *A Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life* (CCME 2007) were used for determining water quality guidelines.

As per the referenced CCME protocols, soil and water quality guidelines for ecological protection are developed on the basis of EcoTRVs derived from the scientific literature and expressed in a number of ways (e.g. threshold effects concentration, effects concentration low, maximum acceptable toxicant concentration, daily threshold effects dose, etc.). EcoTRVs are commonly expressed as exposure medium concentrations for receptors at lower trophic levels and as allowable doses or daily intakes for receptors at higher trophic levels, and are typically published for specific species that are then used as surrogates for site-specific receptors. They may also be expressed as allowable tissue concentrations. Many of these parameters incorporate uncertainty factors as well as the concept of acceptable effects level. The derivation process is documented on a chemical-specific basis in the respective CCME supporting documents (CCME, various dates) and in the Canadian Environmental Quality Guideline fact sheets (CCME 1999a and updates).

For SSRA of substances in Alberta for which Tier 1 Guidelines and/or surface water quality guidelines (Government of Alberta, 2018b) have been published, the applicable guideline values must be adopted as the pathway-specific EcoTRVs. In the absence of published Alberta guideline values, CCME soil or surface water quality guidelines (CCME, 1999a and updates) should be used for the respective pathways. For pathways involving ingestion modelling, daily threshold effects doses (or equivalent) should be obtained from CCME (1999a and updates, 2008) where applicable values are not specified in the referenced Alberta guidelines. The primary sources of EcoTRVs recommended for SSRA in Alberta are summarized in Table 4.1.

Table 4.1: Recommended EcoTRVs where Tier 1 and/or Surface Water Quality Guidelines Exist		
Exposure Pathway/Receptor	Recommended EcoTRV	Reference(s)
Direct contact with soil (terrestrial plants and soil organisms)	Tier 1 ecological direct soil contact guideline Canadian soil quality guideline (ecological soil contact)	Government of Alberta (2019a) CCME (1999a and updates)
Direct contact with water (freshwater aquatic life)	Alberta surface water quality guideline for protection of aquatic life	Government of Alberta (2018b)
Direct contact with water (terrestrial plants and soil organisms)	Tier 1 groundwater guideline for ecological soil contact Alberta surface water quality guideline for irrigation	Government of Alberta (2019a) Government of Alberta (2018b)
Soil and food ingestion (terrestrial and avian receptors)	Daily threshold effects dose (or equivalent)	CCME (1999a and updates) CCME (2008) – petroleum hydrocarbons
Water ingestion (terrestrial and avian receptors)	Tier 1 groundwater guideline for livestock and/or wildlife watering Daily threshold effects dose (or equivalent)	Government of Alberta (2019a) CCME (1999a and updates) CCME (2008) – petroleum hydrocarbons

In case of conflict or inconsistency between the referenced sources of guidance, it is recommended that the appropriate Regulator or key reviewers be consulted for further direction.

For SSRA of substances for which guidelines are not available in the Alberta Tier 1

Guidelines and/or Alberta or CCME surface water quality guidelines from the above primary sources are not available, or cannot be readily adopted as TRVs, the following guidance is recommended for the development of site-specific EcoTRVs:

- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 2: Selection or Development of Site-specific Toxicity Reference Values (Government of Canada, 2010b).

The above guidance recommends four approaches for the selection or development of site-specific EcoTRVs:

- Use of published TRVs. Examples include US EPA Ecological Soil Screening Levels (Eco-SSLs) (US EPA, various dates), US EPA's ECOTOX database (US EPA, undated [c]) and values published in Oak Ridge National Laboratory's Ecological Benchmark Tool (ORNL, undated [online]).
- Derivation of literature-based TRVs using published toxicological data. Note that this option may only be used for SSRA in Alberta if the derived TRVs have first been published in the peer-reviewed literature and at the discretion of the appropriate Regulator or key reviewers.
- Modifying existing guidelines to develop site-specific TRVs. This approach would be similar to the approach recommended above for use when Tier 1 Guidelines are available, but with the application of site-specific assumptions.
- Use of site-specific toxicity testing. Site-specific toxicity testing may be conducted using the same methods and suite(s) of test organisms used in the development of Alberta Tier 1 or surface water quality guidelines (CCME 1999a, 1999b, 2006, 2007, 2008) or in accordance with Government of Canada (2010a).

In all instances, the selection of the most appropriate toxicity reference value must be consistent with *Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines* (2017a). The selection or development of site-specific EcoTRVs must be supported by adequate documentation and rationale. It is also required that the appropriate Regulator or key reviewers be consulted regarding the development and/or use of EcoTRVs other than direct adoption of those values used in the Tier 1 Guidelines and Alberta surface water quality guidelines.

4.3.4 Ecological Exposure Parameters

Ecological exposure parameters (e.g., receptor characteristics, intake rates, time-activity patterns), also referred to as exposure factors, are used to estimate contaminant intake or exposure dose, and are available in various published sources. Exposure doses are estimated for soil, food and water ingestion pathways, for which EcoTRVs are expressed in terms of dose rather than exposure concentration.

Ecological exposure parameters can be obtained from the following sources, as applicable, in order of preference:

- Values used in the development of Tier 1 Guidelines (CCME 1999b, 2006, 2007, 2008; Government of Alberta 2019a).
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 3: Standardization of Wildlife Receptor Characteristics (Government of Canada 2012b).
- Wildlife Exposure Factors Handbook (US EPA, 1993)

Appropriate justification must be provided for the selection of values other than those used in the derivation of applicable numerical risk-based guidelines.

4.3.5 Fate and Transport Modelling and Exposure Estimation

Similar to HHRA, the exposure assessment stage of an ERA may involve fate and transport modelling in order to estimate contaminant concentrations in applicable exposure media. It may also involve intake and/or uptake modelling to estimate doses associated with soil and water ingestion and food chain pathways. In addition to modelling, an ERA often includes sampling of biota in order to measure concentrations in plant or animal tissue. When modelling is required for a SSRA, it is required that the models used in the development of the Alberta Tier 1 Guidelines be used where applicable (Government of Alberta, 2019a). As noted in the previous sections, these models have limitations and must be limited to use within appropriate ranges and verified through monitoring data.

Other sources of information on models that have gained regulatory acceptance include, but are not limited to:

- A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines (CCME 2006).
- Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale (CCME 2008).
- Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (Health Canada, 2012).

Ecological risk assessment may involve food chain modelling, especially where actual tissue concentration measurements are not available. Equations for estimating exposure through food ingestion for various types of ecological receptor, as used in the derivation of soil quality guidelines, are provided by CCME (2006, 2008). Bioaccumulation factors (BAF) and bioconcentration factors (BCF) for various contaminants of concern may be found in the respective soil quality guidelines scientific criteria documents (CCME, various dates). Food chain modelling must be carried out for substances that bioaccumulate and/or biomagnify; in such cases receptors of concern must include secondary and tertiary consumers, and linkages to human health risk assessment must also be considered.

Physical and chemical parameters for many COPCs are also listed in the above references. Selection of physical and chemical parameters must follow a similar process as prescribed in other sections of this guidance, with referenced Alberta Government and Canadian sources preferred over other sources. Where parameters are not available from referenced sources, other parameter choices must be supported with reference to appropriate literature sources and discussed with the appropriate Regulator or key reviewers. In addition, the basis for any site-specific parameters used in modelling must be documented (see also Section 3.3).

4.3.6 Lines of Evidence and Weight of Evidence Approaches

As noted previously, ERAs frequently involve multiple lines of evidence established to evaluate different assessment endpoints. Evaluation and aggregation of different lines of evidence to characterize overall ecological risk is a potentially complicated process, particularly where lines of evidence differ in terms of ecological relevance, spatial representation, and how different contaminants and receptors are evaluated. A weight of evidence (WoE) approach is commonly applied in order to integrate multiple lines of evidence into a conclusion about risk. WoE approaches may be qualitative or quantitative, but it is important that they be consistent and transparent. A recommended default weight of evidence procedure, which considers magnitude of effects and spatial extent, causal relationships between contaminants and effects, ecological relevance, confidence and uncertainty, is provided by Government of Canada (2012a).

5 Reporting Requirements

A SSRA must be a stand-alone report, organized in such a way that the four fundamental stages of the general HHERA process (Section 4.1) are clearly documented for both human health and ecological risks. The report must summarize applicable site data, with reference to original reports, and must provide a list of assumptions along with adequate justification for all assumptions, parameters, TRVs and modelling methods used, particularly where approaches deviate from applicable guidance. Clear and comprehensive rationale must be provided for decisions made with respect to identification of COPCs, exposure pathways and receptors and their screening or selection for detailed assessment. A discussion of assessment limitations is also required. The report must contain a CSM in tabular, flowchart and/or pictorial format.

Incomplete reports may result in rejection of the SSRA or delay of the regulatory review process. Examples of deficiencies that would lead to a SSRA being automatically declined without further review, pending a complete submission are presented in Table 5.1. It is important to note that this is not an exhaustive list and other deficiencies may also lead to rejection or deferral of a submission.

Table 5.1: Examples of Deficiencies in SSRA Reports

Conditions under which a submitted SSRA will be declined without further review, until the necessary data, components, sections, or any requirements specified by an appropriate Regulator or key reviewer are deemed complete, include, but are not limited to:
Incomplete delineation
Missing or incomplete CSM
Failure to demonstrate source control and/or stable or decreasing plume size
Failure to include all COPC, with resulting potential underestimation of risks
Use of inappropriate receptor characteristics
No prior acceptance or a secondary or tertiary toxicological reference value (TRV) or guideline

Incorporation of risk management assumptions without an accepted risk management plan
RMP that is outdated or has not received prior regulatory acceptance ¹
Failure to identify and consider vulnerable populations or unique receptors
Incompatible land use assumptions (in particular failure to consider future land use)
No prior acceptance for non-default bioavailability factor
No prior acceptance for site-specific background level of a COPC
Missing or incomplete statements of assumptions and uncertainties

¹ Even with an accepted RMP, a Regulator requires that a SSRA be conducted without incorporating the provisions of the RMP.

6 Implementation of Site-Specific Risk Assessment Results

6.1 Determining Requirement for Remediation

Section 2.2 of Alberta's *Remediation Regulation* sets out requirements for remedial measures. Section 2.3 and 2.4 of the Regulation prescribes how these requirements are tied to the Tier 1 Guidelines and Tier 2 Guidelines. A SSRA is an option under the Tier 2 Guidelines (2019b) and therefore is an option under section 2.4 of the Regulation provided it meets requirements of the Regulation and this document.

A SSRA permits the assessor to identify requirements for remediation. In a SSRA conducted to determine risks associated with existing levels of contamination, an estimated risk greater than a target level indicates that remediation and/or risk management is required. An estimated risk below the target level generally signifies that the site meets applicable remediation guidelines (subject to all COPC having been addressed) and that no further action is required. Under the *Alberta Contaminated Sites Policy Framework* (ESRD, 2014), the latter only applies if the SSRA does not involve any assumptions that would necessitate ongoing management or site restrictions (see Section 6.3 below).

Where risks exceed target levels, the SSRA may be used to determine allowable contaminant concentrations in applicable media that do not result in unacceptable human health or ecological risks. Remediation would then typically be required to meet these SSROs. Provided the human health and ecological protection endpoints used in the calculation of the SSROs are the same as those used in the derivation of the Tier 1 Guidelines, remediation to the SSROs would achieve the same level of protection as Tier 1, as required by the regulatory framework.

6.2 Identification of Risk Management/Exposure Control Requirements

A potential outcome of a SSRA is that certain exposure pathways may require ongoing risk management under the Exposure Control option, in order to achieve acceptable risk. The results of the SSRA would enable identification of the individual pathway(s) requiring management, thereby directing the selection and design of exposure control measures, and estimating risks that may arise should the exposure control measures fail (Government of Alberta, 2017b). For more information on risk management options please see the *Alberta Risk Management Plan*

Guide (Government of Alberta, 2017b) and the *Alberta Exposure Control Guide* (Government of Alberta, 2016a).

6.3 Site, Land and Water Use Restrictions

As stated previously, the Tier 1 Guidelines, Tier 2 Guidelines and the *Contaminated Sites Policy Framework* are intended to provide the same level of protection of human health and the environment at all levels or tiers of site management. At Tier 1, this is accomplished by the use of relatively conservative risk -based numerical guidelines that can be applied to the large majority of sites without condition or restriction. Tier 2 provides the same level of protection by incorporating site-specific data into the development appropriate guidelines through guideline modification, pathway elimination or SSRA. Contaminated sites remediated to the Tier 1 Guidelines or Tier 2 Guidelines are eligible for regulatory closure.

Certain types of site-specific data or assumptions dictate the need for ongoing site management to ensure that the assumptions used to assess human and ecological risks or to develop SSROs remain valid. Ongoing management of a site, or of the contaminants present, will generally invoke a land or water use restriction or other condition that will preclude Tier 1 or Tier 2 regulatory closure. Therefore, site-specific adjustments or assumptions that would imply or necessitate ongoing management requirements can only be implemented under the Exposure Control option. For more information on risk management options please see the *Alberta Risk Management Plan Guide* (Government of Alberta, 2017b) and the *Alberta Exposure Control Guide* (Government of Alberta, 2016a).

A SSRA must clearly identify assumptions that lead to conditions or restrictions, in order to determine eligibility for regulatory closure and the requirement for exposure control.

6.4 Regulatory Consultation and Review

The *Remediation Regulation* sets out regulatory tools that are available to the proponent when assessing, managing risks at contaminated sites and seeking regulatory closure. The Alberta Tier 2 Guidelines set out a requirement for the proponent to seek acceptance of any SSRA by the Regulator. Proponents conducting or planning to conduct assessment SSRAs for a contaminated site are encouraged to consult with the appropriate Regulator or key reviewers at appropriate stages of the project, and may be required to consult where prescribed by the Tier 2 Guidelines and this document. The appropriate Regulator for contaminated sites is either AEP or the AER. The reviewer may be AEP, AER, Alberta Health (AH) or Alberta Health Services (AHS).

For contaminated sites a number of regulatory triggers exist for AEP or AER review of a SSRA. For example, guidance for submitting applications for Site-based Remediation Certificates,

Limited Remediation Certificates and Tier 2 Compliance Letters prescribe AEP review of risk assessments where prepared in support of the applications (Government of Alberta, undated [online]). The *Limited Remediation Certificate Guide* (Government of Alberta 2019c) and the *Site-Based Remediation Certificate Guide* (Government of Alberta 2019d) specifically indicate that any Tier 2 risk assessments must have been submitted and reviewed prior to application for a certificate. Additionally, guidance for the preparation and submission of risk management plans under the Exposure Control option (Government of Alberta, 2016, 2017b) discuss the role of risk assessment in risk management plans and the review thereof.

In addition to the above specific triggers, regulatory review by AEP or AER and/or AH or AHS may also be required for risk assessments conducted for other purposes such as spills and other public health or environmental concerns. In all cases, it is the responsibility of the submitting risk assessor to ensure that any risk assessment meets the requirements of the appropriate Regulator or key reviewers and that they are meeting all of the legal requirements in the legislative regime.

7 References

- AEP (Alberta Environmental Protection) (1996). *Protocol to Develop Alberta Water Quality Guidelines for Protection of Freshwater Aquatic Life*. Available at: <https://open.alberta.ca/publications/1799374> [Accessed March 2019].
- CCME (Canadian Council of Ministers of the Environment) 2020. *Ecological Risk Assessment Guidance Document*. Winnipeg, MB. PN 1585 ISBN 978-1-77202-044-1 PDF. Available at: https://www.ccme.ca/en/resources/contaminated_site_management/remediation-objectives.html [Accessed January, 2020].
- CCME (Canadian Council of Ministers of the Environment) (2016a). *Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment. Volume 1 Guidance Manual*. Winnipeg, MB. PN 1551. ISBN 978-1-77202-026-7 PDF. Available at: http://www.ccme.ca/en/files/Resources/csm/Volume%201-Guidance%20Manual-Environmental%20Site%20Characterization_e%20PN%201551.pdf [Accessed March 2019].
- CCME (Canadian Council of Ministers of the Environment) (2016b). *Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment. Volume 2 Checklists*. Winnipeg, MB. PN 1553. ISBN 978-1-77202-028-1 PDF. Available at: http://www.ccme.ca/en/files/Resources/csm/Volume%202-Checklists-Environmental%20Site%20Characterization_e%20PN%201553.pdf [Accessed March 2019].
- CCME (Canadian Council of Ministers of the Environment) (2016c). *Guidance Manual for Environmental Site Characterization in Support of Environmental and Human Health Risk Assessment. Volume 3 Suggested Operating Procedures*. Winnipeg, MB. PN 1555. ISBN 978-1-77202-030-4 PDF. Available at: http://www.ccme.ca/files/Volume%203-Suggested%20Operating%20Procedures-Environmental%20Site%20Characterization_e%20PN%201555.pdf [Accessed March 2019].

- 1042 CCME (Canadian Council of Ministers of the Environment) (2016d). *Guidance Manual for*
1043 *Environmental Site Characterization in Support of Environmental and Human Health Risk*
1044 *Assessment. Volume 4 Analytical Methods*. Winnipeg, MB. PN 1557. ISBN 978-1-77202-
1045 032-8 PDF. Available at: [http://www.ccme.ca/en/files/Resources/csm/Volume%204-
1046 Analytical%20Methods-
1047 Environmental%20Site%20Characterization_e%20PN%201557.pdf](http://www.ccme.ca/en/files/Resources/csm/Volume%204-Analytical%20Methods-Environmental%20Site%20Characterization_e%20PN%201557.pdf) [Accessed March
1048 2019].
- 1049 CCME (Canadian Council of Ministers of the Environment) (2008). *Canada-Wide Standard for*
1050 *Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale – Supporting Technical*
1051 *Document*. Winnipeg, MB. ISBN 978-1-896997-77-3 PDF. PN 1399. Available at:
1052 http://www.ccme.ca/files/Resources/csm/phc_cws/pn_1399_phc_sr_std_1.2_e.pdf
1053 [Accessed March 2019]
- 1054 CCME (Canadian Council of Ministers of the Environment) (2007). *A Protocol for the Derivation of*
1055 *Water Quality Guidelines for the Protection of Aquatic Life*. Winnipeg MB. Available at:
1056 <http://cegg-rcqe.ccme.ca/download/en/220> [Accessed March 2019].
- 1057 CCME (Canadian Council of Ministers of the Environment) (2006). *A Protocol for the Derivation of*
1058 *Environmental and Human Health Soil Quality Guidelines*. Winnipeg, MB. ISBN-10 1-
1059 896997-45-7 PDF. ISBN-13 978-1-896997-45-2 PDF. PN 1332. Available at: [http://cegg-
1060 rcqe.ccme.ca/download/en/351](http://cegg-rcqe.ccme.ca/download/en/351) [Accessed March 2019]
- 1061 CCME (Canadian Council of Ministers of the Environment) (1999a and updates). *Canadian*
1062 *Environmental Quality Guidelines*. Winnipeg, MB. Available at:
1063 https://www.ccme.ca/en/resources/canadian_environmental_quality_guidelines/index.htm
1064 | [Accessed March 2019].
- 1065 CCME (Canadian Council of Ministers of the Environment) (1999b). *Protocols for Deriving Water*
1066 *Quality Guidelines for the Protection of Agricultural Water Uses (Irrigation and Livestock*
1067 *Water)*. Winnipeg, MB. Available at: <http://cegg-rcqe.ccme.ca/download/en/131>
1068 [Accessed March 2019].
- 1069 CCME (Canadian Council of Ministers of the Environment) (various dates). *Scientific Criteria*
1070 *Documents for the Development of the Canadian Environmental Quality Guidelines*
1071 *(Multiple Documents)*. Winnipeg, MB. Available at:

1072 https://www.ccme.ca/en/resources/canadian_environmental_quality_guidelines/scientific
 1073 [supporting_documents.html](https://www.ccme.ca/en/resources/canadian_environmental_quality_guidelines/scientific) [Accessed March 2019].

1074 Chan, L., Receveur, O., Batal, M., David, W., Schwartz, H., Ing, A., Fediuk, K. and C. Tikhonov
 1075 (2016). *First Nations Food, Nutrition and Environment Study (FNFNES): Results from*
 1076 *Alberta 2013*. [online]. Ottawa: University of Ottawa, 2016. Print. Available at:
 1077 http://www.fnfnes.ca/docs/Alberta_Reports/FNFNES_Alberta_Regional_Report_.pdf
 1078 [Accessed March 2019].

1079 ESRD (Environment and Sustainable Resources Development) (2014). Contaminated Sites
 1080 Policy Framework. Land and Forestry Policy Branch, Policy Division. Available at:
 1081 <https://open.alberta.ca/publications/978146010579> [Accessed March 2019].

1082 Government of Alberta (2019a). *Alberta Tier 1 Soil and Groundwater Remediation Guidelines*.
 1083 [online]. Alberta Environment and Parks (AEP). January 10, 2019. AEP, Land Policy,
 1084 2019, No. 1. Available at: <https://open.alberta.ca/publications/1926-6243> [Accessed
 1085 February 2019].

1086 Government of Alberta (2019b). *Alberta Tier 2 Soil and Groundwater Remediation Guidelines*.
 1087 [online]. Alberta Environment and Parks (AEP). January 10, 2019. AEP, Land Policy,
 1088 2019, No. 1. ISBN: (Printed Edition) 978-1-4601-2692-9 ISBN: (On-line Edition) 978-1-
 1089 4601-2693-6. Available at: <https://open.alberta.ca/publications/1926-6251> [Accessed
 1090 February 2019].

1091 Government of Alberta (2019c). *Alberta Limited Remediation Certificate Guide*. AEP January 1,
 1092 2019. Land Policy. Available at: [https://open.alberta.ca/publications/alberta-limited-](https://open.alberta.ca/publications/alberta-limited-remediation-certificate-guide)
 1093 [remediation-certificate-guide](https://open.alberta.ca/publications/alberta-limited-remediation-certificate-guide) [Accessed January, 2020]

1094 Government of Alberta (2019d). *Alberta Site-based Remediation Certificate Guide*. AEP January
 1095 1, 2019. Land Policy. Available at: [https://open.alberta.ca/publications/alberta-site-based-](https://open.alberta.ca/publications/alberta-site-based-remediation-certificate-guide)
 1096 [remediation-certificate-guide](https://open.alberta.ca/publications/alberta-site-based-remediation-certificate-guide) [Accessed January, 2020].

1097 Government of Alberta (2019e). *Guidance on Human Health Risk Assessment for Environmental*
 1098 *Impact Assessment in Alberta Version 2*. Alberta Health, Available at:
 1099 <https://open.alberta.ca/publications/9781460143599> [Accessed January, 2020].

- 1100 Government of Alberta (2018a). *Inventory and Analysis of Exposure Factors for Alberta*. [PDF,
1101 ISBN: 978-1-4601-3591-4]. Edmonton, Alberta. Environmental Public Health Science
1102 Unit, Health Protection Branch, Public Health and Compliance Division, Alberta Health.
1103 Available at: <https://open.alberta.ca/publications/9781460135914> [Accessed February
1104 2019].
- 1105 Government of Alberta (2018b). *Environmental Quality Guidelines for Alberta Surface Waters*.
1106 Available at: <https://open.alberta.ca/publications/9781460138731> [Accessed March
1107 2019].
- 1108 Government of Alberta (2017a). *Guidance for Selecting Toxicity Reference Values for Alberta*
1109 *Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines*. Available at:
1110 <https://open.alberta.ca/publications/aep-land-policy-2017-no-1> [Accessed March 2019].
- 1111 Government of Alberta (2017b). *Alberta Risk Management Plan Guide*. Available at:
1112 <https://open.alberta.ca/publications/9781460136102> [Accessed March 2019].
- 1113 Government of Alberta (2016a). *Alberta Exposure Control Guide*. Available at:
1114 <https://open.alberta.ca/publications/9781460114902> [Accessed March 2019].
- 1115 Government of Alberta (2016b). *Alberta Environmental Site Assessment Standard*. Available at:
1116 <https://open.alberta.ca/publications/alberta-environmental-site-assessment-standard>
1117 [Accessed March 2019]
- 1118 Government of Canada (2015-draft) *Federal Contaminated Sites Action Plan (FCSAP). Ecological Risk*
1119 *Assessment Guidance. Module 5: Defining Background Conditions and*
1120 *Using Background Concentrations*. Unpublished draft.
- 1121 Government of Canada (2013) *Federal Contaminated Sites Action Plan (FCSAP). Ecological Risk*
1122 *Assessment Guidance. Module 4: Causality Assessment Module*. Available at:
1123 [https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-ERA_Module-204-ENG.pdf)
1124 [07650F3A68EA/13-049-ERA_Module-204-ENG.pdf](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-ERA_Module-204-ENG.pdf) [Accessed March 2019].
- 1125 Government of Canada (2012a) *Federal Contaminated Sites Action Plan (FCSAP). Ecological*
1126 *Risk Assessment Guidance*. Available at:
1127 [https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-ERA_Module-204-ENG.pdf)

- 1128 [07650F3A68EA/ERA-20Guidance-2030-20March-202012_FINAL_En.pdf](#) [Accessed
1129 March 2019].
- 1130 Government of Canada (2012b) *Federal Contaminated Sites Action Plan (FCSAP). Ecological*
1131 *Risk Assessment Guidance. Module 3: Standardization of Wildlife Receptor*
1132 *Characteristics*. Available at: [https://www.canada.ca/content/dam/eccc/migration/fcs-](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-EC-ID541-Module-3-ENG.pdf)
1133 [scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-EC-ID541-Module-3-ENG.pdf](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-EC-ID541-Module-3-ENG.pdf)
1134 [Accessed March 2019].
- 1135 Government of Canada (2010a) *Federal Contaminated Sites Action Plan (FCSAP). Ecological*
1136 *Risk Assessment Guidance. Module 1: Toxicity Test Selection and Interpretation*.
1137 Available at: [https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/ERA-20Module-201_en-20Final-R.pdf)
1138 [C0A8-4780-9124-07650F3A68EA/ERA-20Module-201_en-20Final-R.pdf](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/ERA-20Module-201_en-20Final-R.pdf) [Accessed
1139 March 2019].
- 1140 Government of Canada (2010b) *Federal Contaminated Sites Action Plan (FCSAP). Ecological*
1141 *Risk Assessment Guidance. Module 2: Selection of Development of Site-Specific Toxicity*
1142 *Reference Values*. Available at: [https://www.canada.ca/content/dam/eccc/migration/fcs-](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-20EC-20ERA-20Module-202_ENG.PDF)
1143 [scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-20EC-20ERA-20Module-](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-20EC-20ERA-20Module-202_ENG.PDF)
1144 [202_ENG.PDF](https://www.canada.ca/content/dam/eccc/migration/fcs-scf/B15E990A-C0A8-4780-9124-07650F3A68EA/13-049-20EC-20ERA-20Module-202_ENG.PDF) [Accessed March 2019].
- 1145 Health Canada (2013). *Interim Guidance on Human Health Risk Assessment for Short-Term*
1146 *Exposure to Carcinogens at Contaminated Sites*. ISBN: 978-1-100-21839-7, Cat.: H144-
1147 11/2013E-PDF. Available at: [http://publications.gc.ca/collections/collection_2013/sc-](http://publications.gc.ca/collections/collection_2013/sc-hc/H144-11-2013-eng.pdf)
1148 [hc/H144-11-2013-eng.pdf](http://publications.gc.ca/collections/collection_2013/sc-hc/H144-11-2013-eng.pdf) [Accessed March 2019].
- 1149 Health Canada (2012). *Part I: Guidance on Human Health Preliminary Quantitative Risk*
1150 *Assessment (PQRA), Version 2.0 (revised 2012)*. Federal Contaminated Site Risk
1151 Assessment in Canada, Contaminated Sites Division, Safe Environments Directorate,
1152 Ottawa. ISBN: 978-1-100-17671-0, Cat.: H128-1/11-632E-PDF. Available at:
1153 [https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html)
1154 [sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) [Accessed March 2019].
- 1155 Health Canada (2010a) *Part V: Guidance on Detailed Quantitative Human Health Risk*
1156 *Assessment of Chemicals (DQRACHEM)*. Federal Contaminated Site Risk Assessment

1157 in Canada. Available at: <https://www.canada.ca/en/environment-climate->
 1158 [change/services/federal-contaminated-sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) [Accessed March 2019].

1159 Health Canada (2010b). *Part II: Health Canada Toxicological Reference Values (TRVs) and*
 1160 *Chemical-Specific Factors, Version 2.0.* Federal Contaminated Site Risk Assessment in
 1161 Canada. Available at: <https://www.canada.ca/en/environment-climate->
 1162 [change/services/federal-contaminated-sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) [Accessed March 2019].

1163 Health Canada (2010c). *Part III: Guidance on Peer Review of Human Health Risk Assessments*
 1164 *for Federal Contaminated Sites in Canada, Version 2.0.* Federal Contaminated Site Risk
 1165 Assessment in Canada. Available at: Available at:
 1166 <https://www.canada.ca/en/environment-climate-change/services/federal-contaminated->
 1167 [sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) [Accessed March 2019].

1168 Health Canada (2010d) *Supplemental Guidance: Checklist for Peer Review of Detailed Human*
 1169 *Health Risk Assessment (HHRA).* Federal Contaminated Site Risk Assessment in
 1170 Canada. Available on request at: <https://www.canada.ca/en/environment-climate->
 1171 [change/services/federal-contaminated-sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) .

1172 Health Canada (2010e). *Supplemental Guidance on Human Health Risk Assessment for Country*
 1173 *Foods (HHRA Foods).* Federal Contaminated Site Risk Assessment in Canada. Available
 1174 at: <https://www.canada.ca/en/environment-climate-change/services/federal->
 1175 [contaminated-sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) [Accessed March 2019].

1176 Health Canada (2010f). *Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated*
 1177 *Sites.* Federal Contaminated Site Risk Assessment in Canada. Available at:
 1178 <https://www.canada.ca/en/environment-climate-change/services/federal-contaminated->
 1179 [sites/publications.html](https://www.canada.ca/en/environment-climate-change/services/federal-contaminated-sites/publications.html) [Accessed March 2019].

1180 NAS (National Academy of Sciences) (1983). *Risk Assessment in the Federal Government:*
 1181 *Managing the Process.* National Research Council (US) Committee on the Institutional
 1182 Means for Assessment of Risks to Public Health. National Academy Press, Washington,
 1183 DC. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25032414> [Accessed January
 1184 2019].

1185 ORNL (Oak Ridge National Laboratory (undated). *Ecological Benchmark Tool*. Risk Assessment
 1186 Information System. Available at: https://rais.ornl.gov/tools/eco_search.php [Accessed
 1187 March 2019].

1188 Richardson, G.M. and Stantec Consulting Ltd. (2013). *2013 Canadian Exposure Factors*
 1189 *Handbook Life Expectancy, Body Dimensions, Inhalation, Time-Activity, and Soil*
 1190 *Ingestion*. Available at: <https://www.usask.ca/toxicology/docs/cef> [Accessed February
 1191 2019].

1192 US EPA (United States Environmental Protection Agency) (2011 and updates). *Exposure Factors*
 1193 *Handbook: 2011 Edition [and available chapter updates]*. U.S. Environmental Protection
 1194 Agency, Washington, DC, EPA/600/R-09/052F. Available at:
 1195 <https://www.epa.gov/expobox/about-exposure-factors-handbook> [Accessed March 2019].

1196 US EPA (United States Environmental Protection Agency) (1989). *Risk Assessment Guidance for*
 1197 *Superfund: Volume I – Human Health Evaluation Manual (Part A)*. Interim Final.1993).
 1198 *Wildlife Exposure Factors Handbook*. Office of Emergency and Remedial Response.
 1199 Washington, DC. EPA/600/R-93/187. 540/1-89/002. Available at:
 1200 https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdf;
 1201 <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799> [Accessed March 2019].

1202 US EPA (United States Environmental Protection Agency) (1993). *Wildlife Exposure Factors*
 1203 *Handbook*. Office of Emergency and Remedial Response. Washington, DC. EPA/540/1-
 1204 89/002.600/R-93/187. Available at:
 1205 [https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799https://www.epa.gov/sites/pro](https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdfhttps://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799)
 1206 [duction/files/2015-](https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdfhttps://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799)
 1207 [09/documents/rags_a.pdfhttps://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799](https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdfhttps://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=2799)
 1208 [Accessed March 2019].

1209 US EPA (United States Environmental Protection Agency) (various dates). *Ecological Soil*
 1210 *Screening Level Guidance (Eco-SSL) Guidance and Documents*. Available at:
 1211 <https://www.epa.gov/risk/ecological-soil-screening-level-eco-ssl-guidance-and-documents>
 1212 [Accessed March 2019].

1213 US EPA (United States Environmental Protection Agency) (undated). [a]). *Integrated Risk*
1214 *Information System (IRIS)*. Available online at:
1215 https://cfpub.epa.gov/ncea/iris_drafts/AtoZ.cfm [Accessed March 2019].

1216 US EPA (United States Environmental Protection Agency) (undated [b]). *Soil Bioavailability at*
1217 *Super Fund Sites: Guidance*. Available at: [https://www.epa.gov/superfund/soil-](https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance)
1218 [bioavailability-superfund-sites-guidance](https://www.epa.gov/superfund/soil-bioavailability-superfund-sites-guidance) [Accessed June 2019].

1219 US EPA (United States Environmental Protection Agency) (undated [c]). *ECOTOX*
1220 *Knowledgebase, Version 5*. National Health and Environmental Effects Research
1221 Laboratory. Available at: <https://cfpub.epa.gov/ecotox/> [Accessed March 2019].

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8 List of Acronyms

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1224

1225	AEP	Alberta Environment and Parks
1226	AER	Alberta Energy Regulator
1227	AH	Alberta Health
1228	AHS	Alberta Health Services
1229	ATSDR	Agency for Toxic Substances and Disease Registry
1230	CCME	Canadian Council of Ministers of the Environment
1231	COPC	Contaminants of Potential Concern
1232	CSM	Conceptual Site Model
1233	DQRA	Detailed Quantitative Health Risk Assessment
1234	EIA	Environmental Impact Assessment
1235	EPA	Environmental Protection Agency
1236	ERA	Ecological Risk Assessment
1237	ESRD	Environment and Sustainable Resources Development
1238	FCSAP	Federal Contaminated Sites Action Plan
1239	HHERA	Human Health and Ecological Risk Assessment
1240	HHRA	Human Health Risk Assessment
1241	ILCR	Incremental Lifetime Cancer Risk
1242	IRIS	Integrated Risk Information System
1243	PQRA	Preliminary Quantitative Risk Assessment
1244	RfC	Reference Concentration
1245	RfD	Reference Dose
1246	RIVM	Netherlands National Institute of Public Health and the Environment
1247	RMP	Risk Management Plan
1248	RsC	Risk Specific Concentration

1249	RsD	Risk Specific Dose
1250	SSL	Soil screening level
1251	SSRA	Site-specific Risk Assessment
1252	SSRO	Site-specific Remedial Objective
1253	TRV	Toxicity Reference Value
1254	UR	Unit Risk
1255	VEC	Valued Ecosystem Component
1256	WHO	World Health Organization