ALBERTA ENVIRONMENT AND PARKS

Supplemental guidance on site-specific risk assessments in Alberta

Supplemental Guidance on Site-Specific Risk Assessments in Alberta | Alberta Environment and Parks

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- Alberta Health (AH),
- Alberta Environment and Parks (AEP),
- Alberta Energy Regulator (AER),
- Alberta Health Services (AHS)

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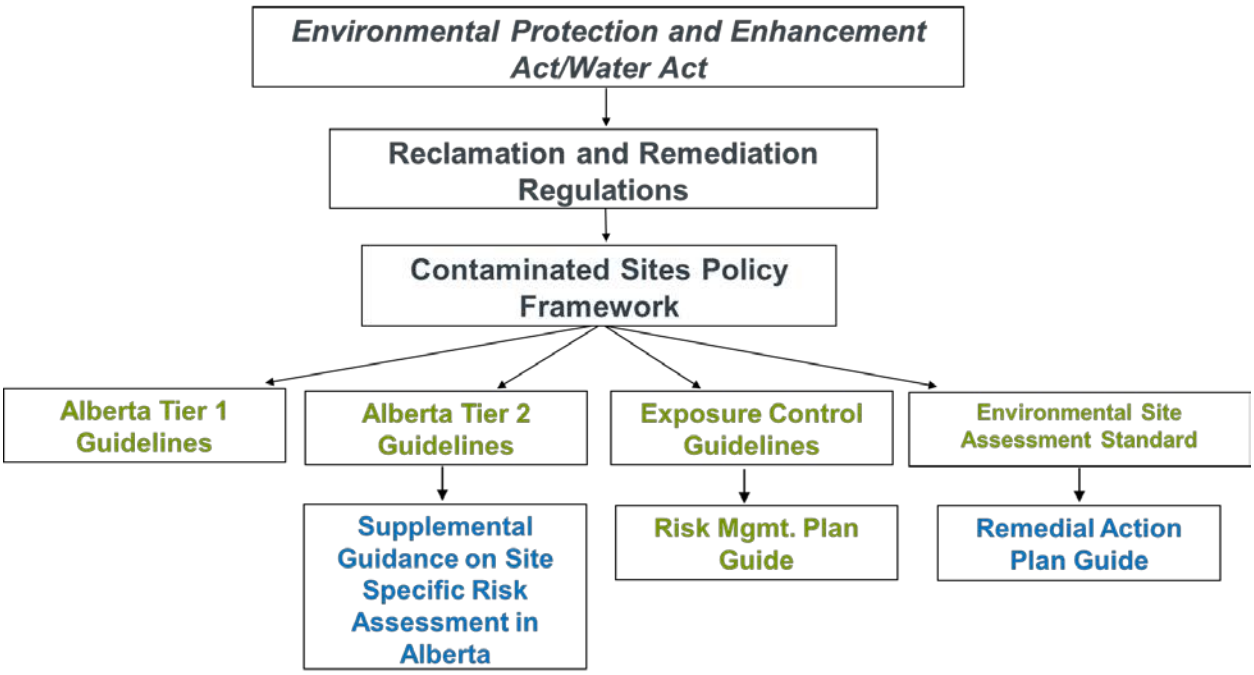
1 Introduction

1.1 Policy Context

This supplemental guidance document provides additional clarification on the requirements and expectations for completing site-specific risk assessments (SSRAs) for contaminated sites in Alberta, as set out by the Government of Alberta (see Figure 1).

Figure 1: Relationship between Legislation and Policy Documents*



*Documents in green are incorporated into the Remediation Regulation by direct reference. Documents in blue are supplemental guidance to the primary reference.

An SSRA has two components: a human health risk assessment (HHRA) and an ecological risk assessment (ERA). Both components are required to assess risks associated with contaminated sites. In some documents, an SSRA is also referred to as a Human Health and Ecological Risk Assessment (HHERA). This document will use the term SSRA, consistent with the Contaminated Sites Policy Framework (AEP, 2014, as amended). However, the two components, HHRA and ERA, will be discussed separately in this document.

1.2 Legislative Context

Alberta's *Environmental Protection and Enhancement Act* (EPEA) 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 EPEA.

EPEA Section 112, duty to take remedial measures, states: Where a substance that may cause, is causing or has caused an adverse effect is released into the environment, the person responsible for the substance shall, as soon as that person becomes aware of or ought to have become aware of the release:

- repair, remedy and confine the effects of the substance,
- remediate, manage, remove or otherwise dispose of the substance, and
- restore the environment to a condition satisfactory to the Director.

Alberta's *Remediation Regulation* further clarifies the duty to take remedial measures. Section 2 of the *Remediation Regulation* adopts the following documents under Alberta's Contaminated Sites Policy Framework for this purpose:

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

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* instead 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 meet 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.

SSRA is one approach available under the Tier 2 Guidelines for consideration of site specific conditions. An equivalent level of protection, as defined in the Tier 1 Guidelines, for the SSRA approach is further described in this document in section 4.2 (Human Health) and 4.3 (Ecological). Approaches available under the Tier 2 Guidelines are further explained within the *Remediation Regulation* and Alberta's Contaminated Sites Policy Framework. This document directly supports the SSRA approach presented within the Tier 2 Guidelines.

1.3 Scope and Objectives

The goal of this document is to describe the components of a complete and technically sound SSRA, For any assessment to be complete, the requirements in the *Remediation Regulation* and Tier 2 Guidelines must be met. This guidance document can be consulted along with other relevant guidance as identified in Section 1.5. If technical guidance is available from these sources, it is expected to be followed. Where specific technical guidance is not available in these documents, other applicable and relevant sources of information, experience and professional judgement can be applied.

Preparing an SSRA is a multi-disciplinary process that must be conducted by qualified professionals who have knowledge and experience with generally accepted risk assessment methodologies along with Alberta-specific policies. SSRAs submitted to the appropriate regulator must adhere to the principles provided in this document.

Some requirements are conditional on the complexity of the SSRA. Less complex SSRAs may have fewer requirements, and not all site-specific situations or contaminants of concerns will be addressed in detail in this Guide. Where justified, proponents are encouraged to discuss appropriateness of specific requirements with the appropriate regulator (i.e., Alberta Environment and Parks (AEP) or Alberta Energy Regulator (AER). It is expected that this document will be applied in conjunction with guidance identified in Section 1.5, along with other applicable and relevant sources of information and sound professional judgement.

The principles of risk assessment underlie the Tier 2 Guidelines and are applied to the various approaches under the Guidelines. This document is focused on providing further information for the SSRA approach under the Tier 2 Guidelines. The Tier 2 Guidelines can be referred to for policy guidance with respect to the other approaches. SSRAs may also be conducted in support of the Exposure Control option within in the Contaminated Sites Policy Framework (AEP, 2014, as amended) for site management.

The basic steps involved in an SSRA are summarized in the Tier 1 and Tier 2 Guidelines. This document provides more specific policy and technical guidance on methodologies and information sources acceptable to the Government of Alberta or the appropriate regulator when conducting an SSRA. Use of the guidance provided by 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.

1.4 Organization of Document

The document is organized into the following sections:

- Section 2 – Relationship 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 – Primary Reference Sources for Use in Alberta,
- Section 6– Reporting Requirements,
- Section 7 – Implementation of Site-Specific Risk Assessment Results,
- Section 8 – References,
- Section 9 – List of Acronyms,
- Section 10 – Glossary, and
- Appendix: Allocation Factor.

1.5 Relationship to other Alberta Policy and Guideline Documents

This document provides guidance related to requirements for SSRAs as outlined in the following key documents:

- Contaminated Sites Policy Framework (ESRD 2014, as amended),
- Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta 2019a, as amended),
- Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta 2019b, as amended),
- Alberta Environmental Site Assessment Standard (Government of Alberta 2016b, as amended),
- Alberta Exposure Control Guide (Government of Alberta 2016a, as amended),
- Alberta Risk Management Plan Guide (Government of Alberta 2017b, as amended), and
- Alberta Remedial Action Plan Guide (Government of Alberta 2020, as amended).

2 Relationship to the Contaminated Sites Policy Framework

2.1 Alberta's Contaminated Sites Policy Framework

Under Alberta's Contaminated Sites Policy Framework, three management options are provided: Tier 1 Guidelines, Tier 2 Guidelines, 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 Tier 2 Guidelines allow the consideration of site-specific conditions through the modification of the Tier 1 Guidelines. This includes the following approaches:

- 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
- Using an SSRA to develop site-specific remedial objectives (SSROs).

Exposure control involves risk management through exposure barriers or administrative controls, and may include conducting an SSRA.

Regardless of the site management option selected, Tier 1 Guidelines, Tier 2 Guidelines, or Exposure Control, the target level of human health and ecological protection is the same.

Tier 1 Guidelines provide a means of assessing risks at a site using simple tabular values. The values were developed using conservative assumptions regarding soil and groundwater characteristics. Provided the conditions of the subject site have similar or lower sensitivity to contamination to that assumed in the Tier 1 Guidelines, they may be applied to a generic risk assessment. Application of Tier 1 Guidelines generally requires less information than other assessments. The professional is responsible for collecting sufficient information to determine if its application is appropriate.

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

Regulatory closure is available for sites that are remediated to achieve Tier 1 or Tier 2 Guidelines, including those that are remediated to SSROs. Sites that do not meet Tier 1 or Tier 2 Guidelines, including those under Exposure Control, are not eligible for regulatory closure, as they require remediation and/or ongoing site management.

2.2 Role of SSRA in Contaminated Sites Management

The Tier 2 Guideline exposure pathway exclusion and guideline adjustment approaches allow for limited site-specific modifications to the Tier 1 Guidelines.

Completion of a SSRA may be used to develop appropriate SSROs if major adjustments to parameters or models are needed. This could include where conditions violate Tier 1 Guideline assumptions or where modifications are outside the scope of the prescriptive Tier 2 Guideline approaches.

The Exposure Control option for site management relies on ongoing administrative and/or physical controls to manage risk to both human health and the environment. In some instances, an SSRA may be conducted to support the development of a risk management plan (RMP) and identify critical exposure pathways that require management under the Exposure Control option. Where the SSRA is in support of a RMP, an initial SSRA must be conducted without any risk management assumptions in place. This will support determining which pathways and receptors must be managed in using Exposure Control.

SSRAs may 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. 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.

For more information, see the Contaminated Sites Policy Framework and other supporting documents listed in Section 1.5.

2.3 Role of the Professional in an SSRA

Any report submitted under the Contaminated Sites Policy Framework requires a professional declaration with a professional signature and stamp or seal or professional registration number. This includes SSRAs that are submitted to AEP or the 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), or
- 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* (Alberta Environment 2006).

SSRAs should be prepared by professionals with knowledge based on an appropriate combination of formal education, skills, experience, and training. Depending on the complexity of the impacted site and the specialized nature of developing SSRAs, it may be necessary for the professional to involve other specialists, such as individuals who specialize in toxicology, environmental health or various specializations of risk assessment.

When an SSRA is submitted to the appropriate regulator, the professional is required to:

- 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, the scope of work, or the environmental condition of the site as determined by the risk assessment,
- Promptly communicate to the responsible party 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,
- 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,
- Provide professional sign-off and stamp or registration number for the work that was performed or coordinated, 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 a Site-Specific Risk Assessment

3.1 Risk Assessment Goals

The goals of any SSRA must be clearly established and articulated. The scope and data collection requirements must be sufficient to meet the stated goals. Assumptions made during the problem formulation step must be clearly articulated to show the limitations for the risk assessment.

In the context of Alberta's Contaminated Sites Policy Framework, SSRAs are primarily conducted with the goal of developing SSROs. Specific goals will depend on the SSRA, the nature of the contaminants of potential concern (COPCs), pathways, and receptors present at the site.

3.2 Relationship Between Risk Assessment and Exposure Control

If Exposure Control is the proposed site management option to manage risk, or where remediation involves the use of long-term techniques such as monitored natural attenuation, an SSRA can be used to assess that risk. The SSRA identifies pathways and/or receptors requiring protection as well as determining relevant concentrations for ongoing monitoring purposes. For more information see the Contaminated Sites Policy Framework.

The Alberta Exposure Control Guide requires that the exposure control measures used to control the risk are not included in the baseline risk assessment. This is required whether the risk assessment is based on directly comparing to Tier 1 Guidelines or any of the pathway exclusion, guideline adjustment or SSRA options within the Tier 2 Guidelines. A risk assessment more accurately reflects which pathways must be controlled using Exposure Control. It also provides the consequence to human health, or the environment should the RMP fail to control exposure.

The Alberta Risk Management Plan Guide can be consulted for RMP details. When submitting a RMP, an SSRA with and without the RMP assumptions in place is required.

3.3 Complexity and Level of Effort

SSRAs can fall within a spectrum of complexity ranging from a screening level risk assessment to a detailed quantitative risk assessment (DQRA).

Screening level or preliminary risk assessments typically utilize maximum contaminant concentrations, default parameters, and other conservative assumptions related to contaminant exposure and transport. Screening level risk assessments also often use simple exposure models to obtain a conservative estimate of risk. If the estimated risks exceed levels considered acceptable from a regulatory standpoint (i.e., site concentrations exceed SSROs), the assessment may then progress to a more detailed stage.

A DQRA typically involves additional data collection and refinement of conservative assumptions, input parameters and modelling methods to support the more detailed analysis. If the regulator determines that the level of conservatism in an SSRA is insufficiently protective of receptors, the SSRA will need to be revised. References provided in this document provide some general guidance on the use of input parameters and statistical methods to ensure adequate conservatism is present in the risk assessment.

This document describes SSRA requirements in general. While general principles in the document are relevant to all SSRAs in Alberta, not all requirements are relevant when undertaking SSRAs of a less complex nature (see Figure 2). However, regardless of the complexity, the level of effort of any risk assessment must allow defensible conclusions to be drawn with respect to the level of risk and the derivation of SSROs. A conclusion of acceptable risk must be based on adequate data and robust modelling methods. For example, where data are limited, it may still be

possible to proceed to the screening level risk assessment stage based on use of maximum concentrations, but it is not likely that a DQRA can be developed based on the limited data.

In addition, there are several additional factors that are required for all risk assessments to be considered complete:

- The Contaminated Sites Policy Framework requires complete vertical and horizontal delineation in soil, groundwater, and other relevant media for all COPCs prior to undertaking risk assessment. All assumptions must be fully substantiated.
- The professional must develop an accurate conceptual site model (CSM) and ensure that the level of detail is scaled appropriately to the complexity of the risk assessment. Where uncertain, proponents are encouraged to discuss specific requirements with the appropriate regulator.
- While the scope of a risk assessment may be refined during or following completion of the problem formulation stage (see Section 4.1.1), all COPCs, exposure pathways and receptors must be considered during the problem formulation phase (see Table 1). It is possible that not all COPCs, pathways and/or receptors need to be carried forward for detailed assessment. However, while specific considerations can be refined based on the assessment, sufficient justification needs to be provided on why specific pathways or receptors were not considered in the detailed assessment.

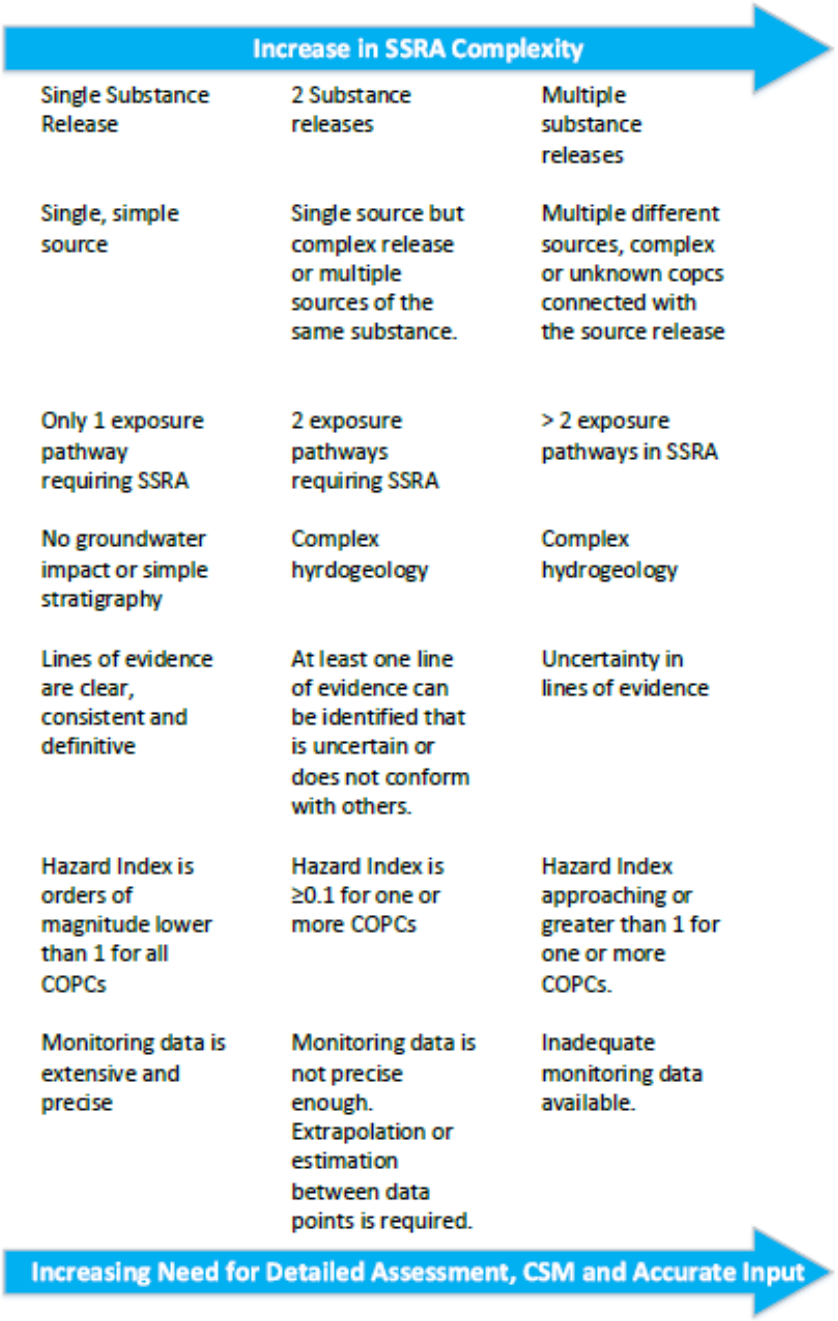


Figure 2. Illustration of relationship between the complexity of the SSRA and the level of detail required.

Table 1. Exposure Pathways and Receptors for Each Land Use [a]

Pathway	Natural area	Agricultural	Residential/ Parkland	Commercial	Industrial
Direct Contact with Soil[h]	Humans (all ages)[b] Soil Nutrient and Energy Cycling Processes, Soil Invertebrates, Plants, Wildlife,	Humans (all ages)[d], Soil Nutrient and Energy Cycling Processes, Soil Invertebrates, Crops/Plants, Livestock, Wildlife	Humans (all ages)[d], Soil Nutrient and Energy Cycling Processes, Soil Invertebrates, Plants, Wildlife	Humans (all ages)[d], Soil Nutrient and Energy Cycling Processes, Soil Invertebrates, Plants, Wildlife	Humans (all ages)[d], Soil Nutrient and Energy Cycling Processes, Soil Invertebrates, Plants, Wildlife
Direct Contact with Water	Aquatic Life, Plants, Soil Invertebrates, Humans (all ages)[f]	Aquatic Life, Plants, Soil Invertebrates, Humans (all ages)[f]	Aquatic Life, Plants, Soil Invertebrates, Humans (all ages)[f]	Aquatic Life, Plants, Soil Invertebrates, Humans (all applicable ages)[f]	Aquatic Life, Plants, Soil Invertebrates, Humans (all applicable ages)[f]
Vapour Inhalation[e,h]	Humans (all ages)[e], Wildlife[e]	Humans (all ages), Wildlife[e]	Humans (all ages), Wildlife[e]	Humans (all ages), Wildlife[e]	Humans (all ages) Wildlife[e]
Ingestion of Water[g]	Humans (all ages), Wildlife	Humans (all ages), Livestock, Wildlife	Humans (all ages), Wildlife	Humans (all ages), Wildlife	Humans (all ages), Wildlife
Soil and Food Ingestion[h]	Wildlife[a] Humans[b]	Wildlife[a], Humans (all ages), Livestock	Wildlife[a] Humans (all ages)	Wildlife[a, c] Humans (all ages)[b]	Wildlife[a, c] Humans (all ages)[b]

[a] Special attention will need to be paid to secondary and tertiary consumers if the COPC is a persistent pollutant and/or can biomagnify or bioaccumulate.
[b] While this pathway is not normally documented in the Tier 1 Guidelines for the land use, it will need to be evaluated for relevance in an SSRA. The following factors will increase relevance of this pathway:

- Can the COPC biomagnify or bioaccumulate?
- Is the COPC a persistent pollutant?
- Does the COPC have a long residence time in the body if consumed?
- Is there a reliance on wildlife or native plant species by populations in the area?

[c] Although this pathway is not included in the Tier 1 Guideline tables it will need to be reviewed at the SSRA level. It will be particularly relevant for COPC that are persistent pollutants and/or biomagnify or bioaccumulate.
[d] For persistent pollutants, the potential for soil ingestion through indoor dust will need to be considered for age groups and/or exposure times due to inadvertent exposure from a less sensitive land use to a more sensitive indoor exposure. Of particular relevance will be the potential for indoor residential exposure from a commercial, industrial or RMP scenario when an enforceable occupational/workplace safety plan to reduce transmission of these contaminants offsite is not in place.
[e] Indoor vapour inhalation is normally considered the most sensitive vapour pathway in a generic risk assessment. However, for RMPs and natural area where buildings are restricted, outdoor inhalation, worker exposure, and potential for ecological exposure are relevant pathways of concern. For natural areas, special attention needs to be paid to ecological exposure through the vapour pathway and human exposure from short-term contacts.
[f] Recreational use will need to be considered.
[g] Water ingestion applies to both groundwater and surface water bodies. Where the COPC has potential to interact with the surface water body, potential for human use of the surface water body as a source of drinking water will need to be considered at the SSRA level.
[h] For COPCs that are persistent in the human body, special consideration will need to be paid to exposure to pregnant women and breastfeeding women to account for potential exposure to the fetus and infant.

3.4 Data Collection Considerations

This section contains general principles that apply to all SSRAs related to data collection, and is not a detailed data collection guide, as that is beyond the scope of this document. The following sources provide more guidance on site characterization for HHRA and ERA and can be used in conjunction with this document:

- Alberta Environmental Site Assessment Standard, and

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

The information required to conduct an SSRA must include:

- Complete on-site and off-site and COPC characterization (horizontal and vertical delineation),
- Site data including local information that may be pertinent to fate and transport predictions. (For example, elevated background concentrations, fractured bedrock, highly permeable materials, present and future land use etc. may be pertinent to modelling analysis),
- Receptor characteristics,
- Identification of exposure pathways, and
- Toxicity information.

Information provided must be comprehensive enough to identify any spatial and temporal site information variations. Variability can lead to uncertainty in evaluating risk, which may require additional monitoring and possibly further modelling. The goal is to demonstrate that remediation or exposure control objectives are being met and that model predictions correlate with actual observations.

Data collection required for an SSRA depends on critical exposure pathways, receptors, and the availability and applicability of relevant data from other sources for aspects such as toxicity. An 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, groundwater, and/or other relevant media (e.g., soil vapour),
- Relevant exposure pathways and parameters,
- Human and ecological receptors and their associated exposure factors, and
- Receptor-specific toxicity information which, in the case of ecological receptors, may require toxicity testing and, at more detailed levels of ERA, tissue sampling and analysis.

An SSRA may require some form of monitoring to verify predictions. This can include monitoring after completion of the risk assessment. Data collection must provide sufficient information to serve as a baseline for long term monitoring of relevant parameters. The choice of receptors must consider the need for preservation of the entire range of human or ecological function that is required based on the definition of the given land use category. It may 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 (TLU) considerations.

4 General Site-Specific Risk Assessment Methods

4.1 Overview of SSRA Framework

As stated earlier, an SSRA is a specific type of HHRA and ERA. Both human health and ecological risk assessments are normally required to assess risks associated with contaminated sites. SSRAs are carried out according to a common framework that was originally established by the US Environmental Protection Agency (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 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) (CCME 2006; 2020). The risk assessment framework follows a four-stage process consisting of problem formulation, exposure assessment, toxicity or effects assessment and risk characterization (Figure 3).

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 of each stage with respect to HHRA and ERA are provided in Sections 4.2 and 4.3, respectively. Where applicable, specific, or additional requirements for an SSRA will be noted in the appropriate sections.

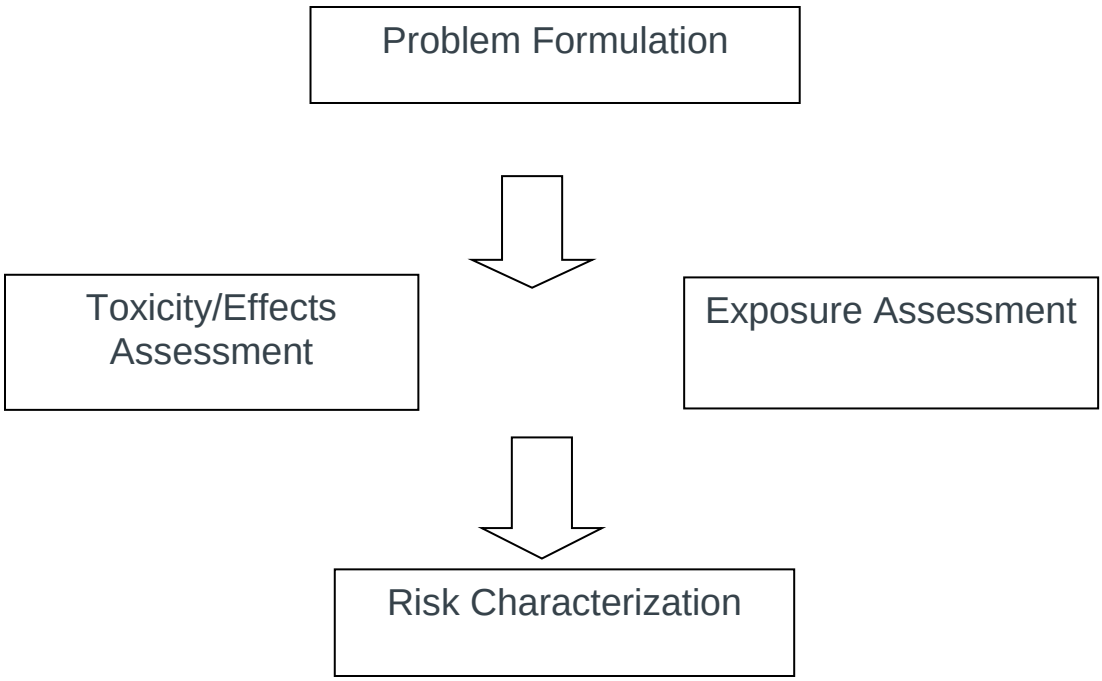


Figure 3: Site Specific Risk Assessment Framework

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, relevant exposure pathways, and primary and sensitive/vulnerable receptors (both human and/or ecological). The goal of this stage is to focus the SSRA on those COPCs, pathways, and receptors that contribute

to human health and ecological risk. To be active, an exposure pathway requires a COPC source, a transport pathway and/or mechanism from the COPC source to the receptor, and a route of intake at the receptor location. Ecological receptors are often identified in terms of VECs (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).

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

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

COPCs, receptors, and operative exposure pathways are screened at this stage and incorporated into a CSM, which serves as the basis for the subsequent steps of the assessment. A CSM is a visual representation and/or 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. 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 should be provided in tabular, flowchart, and/or pictorial format.

A CSM is a required output of the problem formulation. The effort required to draw these conclusions adequately and reasonably is dependent on the magnitude and complexity of the situation.

An 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. In a complete SSRA, assumptions associated with the development of Tier 1 Guidelines must be retested, and all potential pathways must be considered even if they are not explicitly recorded in the Tier 1 Guidelines (see Table 1). Additionally, exposure pathways that have low probability of being operative can still be important if risks become high when the exposure pathway becomes operative.

While this implies that if an SSRA is stopped at the CSM (problem formulation) stage, then the exposure assessment, toxicity assessment, and risk characterization will not be undertaken. It is important to appropriately assess these conclusions and confirm with the appropriate regulator before drawing this conclusion. Proper assessment of the presence of receptors and operative exposure pathways is also important. Where there is a low probability that an exposure pathway will become operative or a receptor would be present in a given scenario, it is important to properly assess that scenario. Specifically, where there may be a higher risk to the receptor if the exposure pathway becomes operative. Particular attention must be paid to risks associated with acute or sub-chronic exposure in these scenarios.

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 fate and transport mechanisms. This includes 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 rates. An SSRA must always consider chronic exposure, except where the HHRA and ERA is limited to assessment of short-term exposure scenarios such as during remedial operations. Exposure averaging may be appropriate in certain cases for short term and/or intermittent exposures. This depends 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 an SSRA, any exposure averaging, amortization, or extrapolation must be reviewed and accepted by the appropriate regulator.

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 has published guidance on the selection of TRVs for the Tier 1 and Tier 2 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 the calculation of an exposure ratio using the estimated exposure or intake of each COPC with the established TRV. In HHRA and ERA, risk is expressed in terms of a hazard quotient (HQ) for a single chemical via a single pathway or hazard index (HI) for a mixture of chemicals with similar toxic effects via all pathways. HQ is defined as the ratio of the estimated exposure to the appropriate threshold TRV (e.g., reference dose (RfD)), and HI is defined as the sum of the HQs of the chemicals in a mixture for all pathways. Both HQ and HI are used to characterize risk after various exposure scenarios. Risk is also expressed in this way for most substances exhibiting non-carcinogenic effects. 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. Calculated HI/HQ or ILCR values are subsequently compared to an acceptable risk-based target level to quantify risk (Sections 4.2.2 and 4.3.2).

For characterization of human health risk, hazard indices (HIs), 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, HIs and ILCRs must be added for substances having the same mechanism of toxicity and/or target organ. Substances with known or suspected non-additive relationships must be assessed accordingly.

Where the purpose of the risk assessment is to derive SSROs as part of the risk characterization process, the established relationships between media concentration and adverse effect are used to back-calculate source concentrations corresponding to target risk levels (CCME 2006). In this way SSROs are established for each pathway

and receptor. The critical exposure pathway is identified based on 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. This can be accomplished through an uncertainty analysis that tests a plausible range of values for sensitive input parameters to determine a range of possible outcomes. The SSRO will need to be protective of plausible scenarios within this range of outcomes.

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 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 Alberta, Health Canada, and CCME.

General HHRA guidance primarily includes, but not limited to the following:

- Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta 2019a, as amended), Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta 2019b, as amended),
- Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta 2017a, as amended),
- Guidance on Human Health Risk Assessment for Environmental Impact Assessment in Alberta (Government of Alberta 2019e, as amended),
- Federal Contaminated Site Risk Assessment in Canada, Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 (Health Canada 2021a),
- Federal Contaminated Site Risk Assessment in Canada, Part II: Health Canada Toxicological Reference Values, Version 3.0 (Health Canada 2021b),
- 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, Part VII: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites (Health Canada 2010f),
- 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: Supplemental Guidance on Human Health Risk Assessment of Oral Bioavailability of Substances in Soil and Soil-Like Media (Health Canada 2017a),
- Federal Contaminated Site Risk Assessment in Canada, Supplemental Guidance on Human Health Risk Assessment of Contaminated Sediments: Direct Contact Pathway (Health Canada 2017b),
- Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment of Indoor Settled Dust. (Health Canada 2018),
- Interim Guidance on Human Health Risk Assessment for Short-Term Exposure to Carcinogens at Contaminated Sites (Health Canada 2013),

- 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), and
- A Protocol for the Development of Soil Vapour Quality Guidelines for the Protection of Human Exposures via Inhalation of Vapours (CCME 2014).

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 cases where 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 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 risk assessor professional to verify that methods used will be acceptable to the appropriate regulator.

An 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 the corresponding source-pathway-receptor combination has been explicitly assessed in the development of generic Tier 1 Guidelines for the specific land use or not. For example, CCME (2006) recommends use of the ingestion of produce, meat, and milk pathway as a check only in circumstances where the substance is known to biomagnify or bioaccumulate. This is not reflected in the Alberta Tier 1 Guideline tables. The SSRA must include this evaluation as outlined in CCME (2006) for substances that are known to biomagnify. Similarly, in some circumstances, such as natural areas sites where TLU is practiced, there are unique human receptors and exposure pathways that must be considered for the risk assessment.

4.2.1 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 an 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 HI for exposure to a substance must not exceed a value of one (1.0). For substances where there are multiple routes of exposure for the same release, HIs must be added across all exposure routes unless the toxicity of the substance is route specific. Similarly, for mixtures or groups of chemicals, HIs must be added for substances having the same mechanism of toxicity and/or target organ. HIs for substances with known or suspected non-additive relationships must be assessed accordingly. For some COPCs, it may be possible to use a list of surrogate COPCs and the relative potency of a particular substance in calculating the overall HI. For example, see the process for deriving Tier 1 Guidelines for dioxins and furans.

For a COPC exhibiting carcinogenic effects (i.e., where there is no threshold level), the 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, 2021a) and the Government of Alberta (2019a, b, e; ESRD 2014) to be essentially negligible. For substances where there are multiple routes of exposure for the same release, ILCRs for a given substance must be added across all exposure routes and receptor types unless the carcinogenic toxicity of the substance is route specific. Similarly, for mixtures or groups of chemicals, ILCRs must be added for substances having the same mechanism of toxicity and/or target organ. In some instances, it may be possible to use a list of surrogate COPCs and the relative potency factor to calculate an overall HI for the mixture. For an example see the process for deriving Tier 1 Guidelines for polyaromatic hydrocarbons.

Both carcinogenic and non-carcinogenic effects must be assessed for COPCs. See Section 4.2.2.2 for further discussion of the assessment of carcinogenic and non-carcinogenic endpoints.

4.2.2 Chemical Classification and Toxicological Reference Values

4.2.2.1 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 (TRV Guide). 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.

The TRVs used in the derivation of the numerical Tier 1 Guidelines are presented in the Tier 1 Guidelines. AEP follows the process outlined in the TRV Guide when updating existing TRVs in the Tier 1 and Tier 2 Guidelines, as new information becomes available. Where TRVs are available in the Tier 1 Guidelines, the risk assessor must use the values provided. Where values are not available, the risk assessor must use the TRV Guide in selecting appropriate TRVs.

The TRV Guide 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 an 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 TRV Guide.

4.2.2.2 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, reference concentration or RfD 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.

There are instances where non-threshold TRVs are available in one or more of the primary sources listed in the TRV Guide but not provided in the Tier 1 Guidelines. In these cases, carcinogenic effects may need to be evaluated. This should be considered when assessing mixtures or investigating emerging chemical classes.

In determining an 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 such non-threshold carcinogens, age dependent adjustment factors should be used in the estimation of the lifetime average daily dose, as recommended by Health Canada (2013).

4.2.2.3 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., HI) can be applied if 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.

4.2.2.4 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 using relative absorption factors (RAFs) - see US EPA 2007. 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 (2021b) 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 before considering re-evaluation. Some guidance on the evaluation of bioavailability has been published by Health Canada (2017a; 2010a) and the US EPA (US EPA undated [b]). Adequate justification and empirical site-specific assessment must be provided in the use of any relative bioavailability analysis.

4.2.3 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. In the absence of a credible TRV, a TRV may be derived in accordance with guidance published by Health Canada (2010a) and the TRV Guide. It is strongly recommended that the appropriate regulator be consulted with respect to the development and use of derived TRVs. Any proposed TRV must be accepted by the appropriate regulator prior to being used in an 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 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 2021a). Where available, parameter selection should utilize Primary documents or sources as outlined in Section 5 of this document.

Additional exposure parameter sources are available and may be used in the absence of Alberta (Government of Alberta 2019a, as amended) or Health Canada (2021a) values. They may also be used if considered more appropriate to specific populations and/or exposure scenarios that are not described in the Tier 1 Guidelines, 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), and
- *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 traditional land use (TLU) is a consideration, it may be useful to obtain site-specific receptor characterization factors.

Canadian sources must be given first priority, although the use of data from other countries may be appropriate if Canadian data is lacking with appropriate justification. If using data from other countries the appropriate regulator must be consulted for further direction.

In addition to chronic exposure an SSRA must also consider acute or sub-chronic effects, if applicable, that may not be included within the chronic exposure. For example, risks to workers during ground disturbance activities are not included within the chronic assumption. 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 consider:

- 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 Tier 1 Guidelines are required for use in performing Tier 2 Guideline modification as described in the Tier 2 Guidelines. This is further described in the Tier 1 and Tier 2 Guidelines.

While these models are recommended for use, where appropriate, in an SSRA, these models represent simplifications of the actual transport mechanisms and are only valid if used within appropriate ranges and maintaining appropriate assumptions. It is the responsibility of the risk assessor to ensure that the models are used appropriately and validated with sufficient site-specific data.

Intake modelling for an SSRA involves the application of receptor characteristics (e.g., inhalation or ingestion rates (Section 4.2.4)) to relevant exposure media concentrations using simple equations characterizing intake, absorption, and/or bioavailability. The intake models used in the development of the Tier 1 Guidelines must be used in an SSRA. However, as an SSRA is 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 Guideline intake models must be documented within the SSRA analysis.

For example, Tier 1 residential guidelines only consider toddler and adult life stages for threshold contaminants. In the development of generic criteria, there were no instances where use of other life stages represented a lower criterion for a given land use. However, when conducting an SSRA changes to generic assumptions may result in other life stages producing a lower criterion. Therefore, it is necessary when conducting an SSRA to examine all life stages. This can become particularly critical when evaluating bioaccumulating or persistent substances or where specific life stages (e.g., infant, pregnant mother) may be critical to evaluating the health risk. For more information, see Table 1. Health Canada (2010a, 2021a) describes five life stages (infant, toddler, child, teen, and adult) which must be considered in an assessment. Any deviation from these intake characteristics requires prior approval from the appropriate regulator.

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, Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 (Health Canada 2021a), and
- 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. This is to enable independent review of the modelling and reproduction of the modelling results. The appropriate regulator 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 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. While it is specific to selection of TRVs, the TRV Guide lists primary reference sources for use in Alberta and is used to rank references for physical and chemical parameters. Where parameters are not available from referenced sources, other parameter choices must be accepted by the appropriate regulator.

4.3 Ecological Risk Assessment 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, as amended),
- Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta 2019b, as amended),
- Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta 2017a, as amended),
- Protocol to Develop Alberta Water Quality Guidelines for Protection of Freshwater Aquatic Life (AEP 1996, as amended),
- Environmental Quality Guidelines for Alberta Surface Waters (Government of Alberta 2018b, as amended),

- Canadian Council of Ministers of the Environment (CCME) Ecological Risk Assessment Guidance Document (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 2019a),
- Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance – Module 6: Ecological Risk Assessment for Amphibians for Federal Contaminated Sites (Government of Canada 2019b),
- 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), and
- Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale – Supporting Technical Document (CCME 2008).

In case of conflict or inconsistency between the above referenced sources, it is recommended that the appropriate regulator 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. If using an alternate approach or methodology, full supporting rationale must be provided. It is the responsibility of the risk assessor to verify that any alternate approach or method used will be acceptable to the appropriate regulator.

4.3.1 Ecological Protection Endpoints

Risk-based guidelines fulfil two main goals from the ecological standpoint:

1. protection of ecological receptors expected to be present at a site based on land use, and
2. preservation of an appropriate level of ecological function of the site and its ecosystem components (Government of Alberta 2019a, as amended).

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. For more information on selection of measurement endpoints and VECs, see the listed references above (e.g., CCME 2020, Government of Canada 2012a). As noted previously, a VEC must include individual members of a species as well as communities and populations. The SSRA should consider all ecological receptors in the problem formulation. It should then carry forward receptors for further assessment when exposure pathways are considered operable at either the population, community or individual level. For instance, when rare or endangered species are present, assessment at the individual organism level will be required. In addition, when working with Indigenous communities on traditional lands, culturally appropriate VECs (as defined by the community) need to be considered, which may 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) and CCME (2020) for further guidance with respect to the identification of assessment and measurement endpoints. Measurement endpoints are compared to acceptable effects levels to evaluate whether site-specific risks are considered acceptable.

Acceptable effects levels may vary by receptor, by endpoint or by site. They 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 (EC_{25}), 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. This may, however, be different for different receptors (e.g., protection of animals that may access a site vs. protection of plant species) so these differences will need to be considered. The level of ecological protection for a given land use is further described by CCME (CCME 2006). For an 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, as amended, CCME 2006).

It is important to consider the current land use and any reasonably foreseeable future land use when evaluating impacted areas. See Alberta's *Remediation Regulation* for requirements that are considered in determining land use.

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.

4.3.2 Ecological Toxicological Reference Values

As with TRVs for HHRA, the starting point for EcoTRVs for ERA as part of an SSRA in Alberta will be the values used in the derivation of the Tier 1 Guidelines. These follow protocols described in *A Protocol for the Derivation of*

Environmental and Human Health Soil Quality Guidelines (CCME 2006) or in *Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale – Supporting Technical Document* (CCME 2008). The following protocols were used for determining water guidelines: *Protocols for Deriving Water Quality Guidelines for the Protection of Agricultural Water Uses (Irrigation and Livestock Water) (CCME1999b)* and *Protocol for the Derivation of Water Quality Guidelines for the Protection of Aquatic Life (CCME 2007)*.

As per the referenced CCME protocols, soil and water quality guidelines for ecological protection are developed based on 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. They 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 an SSRA of substances in Alberta for which Tier 1 Guidelines and/or surface water quality guidelines have been published, the applicable guideline values must be adopted as 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 effect doses (or equivalent) should be obtained from the referenced Alberta Guidelines. If not, available values can be obtained from CCME (1999a and updates, 2008) reference documents. Primary sources of EcoTRVs recommended for an SSRA in Alberta are summarized in Table 2.

Table 2: Recommended EcoTRVs where Tier 1 Guidelines 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, as amended) 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, as amended)
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, as amended) Government of Alberta (2018b, as amended)
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, as amended) 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 be consulted for further direction.

If conducting an SSRA of a substance for which guidelines are not available from the above primary sources (Table 2), or cannot be readily adopted as TRVs, the following guidance is recommended for the development of site-specific EcoTRVs:

- Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta 2017a, as amended) (See Section 5 of the Document), and
- 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:

1. 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]).
2. Derivation of literature-based TRVs using published toxicological data. Note that this option may only be used for an SSRA in Alberta if the derived TRVs have first been published in the peer-reviewed literature and also at the discretion of the appropriate regulator.
3. 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.
4. Use of site-specific toxicity testing (CCME 1999a and updates, 1999b, 2006, 2007, 2008). Site-specific toxicity testing may be conducted using the same methods and suite(s) of test organisms used in the development of Tier 1 Guidelines or surface water quality guidelines or in accordance with Government of Canada (2010a).

In all instances, the selection of the most appropriate TRV must be consistent with the TRV Guide. The selection or development of site-specific EcoTRVs must be supported by adequate documentation and rationale. The appropriate regulator must be consulted regarding the development and/or use of EcoTRVs other than those values used in the Tier 1 Guidelines and Alberta surface water quality guidelines.

4.3.3 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:

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

4.3.4 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 to measure concentrations in plant or animal tissue. Numerous fate and transport models are available for evaluating contaminants in various media. Model selection must consider 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 Tier 1 Guidelines are required for use in performing Tier 2 Guideline modification, as described in the Tier 2 Guidelines. While these models are also recommended for use, where appropriate, in an 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 the responsibility of the risk assessor to ensure that the models are used appropriately and validated with sufficient site-specific 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 – Supporting Technical Document (CCME 2008), and
- Federal Contaminated Site Risk Assessment in Canada, Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 3.0 (Health Canada 2021a).

ERA 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 COPCs may be found in the respective soil quality guideline scientific criteria documents. Information sources need to be consistent with Alberta's policy in the TRV Guide for selection of primary, secondary, and tertiary reference sources (Government of Alberta, 2017a, as amended). Food chain modelling must be carried out for substances that bioaccumulate and/or biomagnify. In those cases, receptors of concern must include secondary and tertiary consumers, and linkages to HHRA must also be considered.

Physical and chemical parameters for many COPCs are also provided 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. In addition, the basis for any site-specific parameters used in modelling must be documented (see also Section 3.3).

4.3.5 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 of different lines of evidence characterizing overall ecological risk can be a 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 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.

Environment Canada (Government of Canada 2012a) recommends a default weight of evidence procedure that considers:

- magnitude of effects and spatial extent,
- causal relationships between contaminants and effects,
- ecological relevance,
- confidence in data parameters and assumptions, and
- uncertainty analysis.

5 Primary Reference Sources for Use in Alberta

The Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines (TRV Guide; Government of Alberta 2017a, as amended) describes how primary, secondary, and tertiary reference sources that are used for determination of toxicity reference values in Alberta are chosen. The appropriate regulator will use the same process to ensure other models, assumptions and parameters used in risk modelling are consistently applied and acceptable for use in Alberta. The risk assessor needs to ensure that their selection of parameters is consistent with the requirements described in the TRV Guide.

Sufficient information on parameter selection for the most common COPCs, receptors and pathways should be available from primary reference sources. Where secondary or tertiary reference sources are needed, the protocols described in the TRV Guide will apply equally to other parameters.

The following sources of information can be used as primary references for use in developing guidelines for use in Alberta. The list is in order of preference. If there are disagreements between primary reference sources, documents that are ranked higher in this list will be used as preferential sources of information:

Primary Documents for use in Alberta:

1. Alberta Tier 1 and Tier 2 Soil and Groundwater Remediation Guidelines[1],
2. Environmental Quality Guidelines for Alberta Surface Waters (for surface water and sediment guidelines related to aquatic life, recreation and aesthetics, and agriculture)[2] , and
3. Other documents adopted by the Province of Alberta that are in keeping with criteria for primary reference sources as outlined in the TRV Guide.

Primary Sources:

1. Health Canada (for human health-based endpoints),
2. Canadian Council of Ministers of the Environment (CCME) Canadian Environmental Quality Guidelines (CEQGs),
3. Environment Canada (for ecological based endpoints), and
4. United States Environmental Protection Agency (US EPA).

[1]The Tier 1 Guidelines do not meet the principles outlined in this document for primary reference sources, but references used in developing tables in Appendix C of the Guidelines do. The Tier 1 Guidelines will be updated based on information from other primary reference source documents listed here. It is included as a primary document in this list to ensure that its importance is recognized for management of sites in Alberta.

[2] The Environmental Quality Guidelines for Alberta Surface Waters have been developed based on primary reference materials that are consistent with the principles outlined in this document. The Guidelines themselves do not represent original sources of information. They are also considered a primary document.

6 Reporting Requirements

An SSRA must be a stand-alone report, organized in such a way that the four fundamental stages of the general HHRA and ERA 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 when required. A list of assumptions must be provided 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,
- screening or selection for detailed assessment, and
- discussion of assessment limitations.

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. Table 3 provides examples of common deficiencies that will result in an SSRA being declined without a further review. Further information on common deficiencies in SSRAs that may result in longer review times or rejection of the SSRA are provided by Health Canada (HC 2021, Appendix A). This guide should be consulted prior to submission of the SSRA.

Table 3: 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 are deemed complete, include, but are not limited to:
Insufficient delineation.
Missing or incomplete CSM, including site history.
Missing and/or incomplete evaluation of bioaccumulative and/or persistent pollutants, and the potential for these substances to be transferred and impact offsite receptors.
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.
Development of TRVs or guidelines from secondary or tertiary sources that do not follow the protocols outlined in the TRV Guide (Government of Alberta 2017a, as amended).
Incorporation of risk management assumptions without an accepted RMP.
When an RMP is necessary, failure to provide an SSRA that looks at scenarios without the RMP in place.

Failure to identify and consider vulnerable populations or unique receptors.
Incompatible land use assumptions (failure to consider future land use).
Non-default bioavailability factors that are developed based on generic rather than site-specific information.
Inappropriate development of site-specific background level of a COPC or site-specific background values based on insufficient information.
Missing or incomplete statements of assumptions and uncertainties.
Modelling without adequate sensitivity analysis.
Modelling without adequate monitoring data to support the analysis.

7 Implementation of Site-Specific Risk Assessment Results

7.1 Determining Remediation Requirements

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

An SSRA permits the assessor to identify remediation requirements by deriving SSROs.. Remediation to meet the SSROs achieves the same level of protection as the Tier 1 Guidelines, as required by the regulatory framework. This can be achieved when 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.

Under Alberta's Contaminated Sites Policy Framework, remediation to SSROs will only achieve regulatory closure if the SSRA does not involve any assumptions that would necessitate ongoing risk management or land use restrictions.

7.2 Identification of Risk Management/Exposure Control Requirements

A potential outcome of an SSRA is that certain exposure pathways may require ongoing risk management, under Exposure Control, to achieve a level of risk that is acceptable. An estimated risk below the target level generally signifies that the site meets an equivalent level of protection as Tier 1 Guidelines. However, an estimated risk greater than a target level derived by comparing against the SSRO indicates that further investigation is necessary. Remediation or risk management may be required.

Where the SSRA is used in conjunction with risk management options, the results of the SSRA enable identification of the individual pathway(s) requiring management. This guides the selection and design of exposure control measures by estimating risks that may arise should the exposure control measures fail (Government of Alberta 2017b, as amended).

For Exposure Control, it is required that the risk assessment initially be conducted without the application of exposure control measures. It is the role of the RMP to demonstrate that proposed exposure control measures will adequately address identified risks. An updated SSRA with an additional scenario may be required to demonstrate the effectiveness of proposed risk management measures. The complexity of the initial and supplemental SSRAs may differ. For more information on risk management options please see the Alberta Risk Management Plan Guide and the Alberta Exposure Control Guide.

7.3 Site, Land, and Water Use Restrictions

The Tier 1 and 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. In Tier 1 Guidelines, this is accomplished using relatively conservative risk-based numerical guidelines that can be applied to most sites without condition or restriction. Tier 2 Guidelines provide the same level of protection as Tier 1 by incorporating site-specific data into the development of appropriate guidelines through guideline modification, pathway elimination or an SSRA. Contaminated sites remediated to Tier 1 Guidelines or Tier 2 Guidelines are eligible for regulatory closure.

Application of site-specific data or assumptions that restrict full options for land use under the appropriate land use category dictate the need for ongoing site management. In these cases, site management is necessary to ensure that the assumptions used to assess human and ecological risks or to develop SSROs remain valid. Ongoing site management requires land and/or water use restrictions, may involve other exposure control measures, and precludes regulatory closure. For more information on risk management options please see the Alberta Risk Management Plan Guide and the Alberta Exposure Control Guide.

An SSRA must clearly identify assumptions that determine if the site is eligible for regulatory closure under the Tier 2 Guideline options or where there are ongoing requirements for Exposure Control. For more information, see the Contaminated Sites Policy Framework and supporting documents.

7.4 Regulatory Consultation and Review

The *Remediation Regulation* sets out tools that are available under the regulation to the proponent when assessing a contaminated site, managing risks at contaminated sites, and seeking regulatory closure. The Tier 2 Guidelines set out a requirement for the proponent to seek acceptance of an SSRA by the appropriate regulator. Proponents conducting or planning to conduct SSRAs for a contaminated site are encouraged to consult with the appropriate regulator at appropriate stages of the project. The appropriate regulator for contaminated sites is either AEP or the AER. The regulator may contact AH, Alberta Health Services (AHS), or other relevant ministries or agencies for further input and consultation. Sometimes, a joint decision may be needed if there is an order(s) issued by other regulators (e.g., *Public Health Act*) on the site of interest.

For contaminated sites, several regulatory triggers exist for AEP or AER review of an SSRA. For example, review of SSRAs are necessary when submitting applications for:

- Site-based Remediation Certificates,
- Limited Remediation Certificates, and
- Tier 2 Compliance Letters.

The Limited Remediation Certificate Guide and the Site-Based Remediation Certificate Guide specifically indicate that any SSRAs must have been submitted, reviewed, and accepted by the appropriate regulator prior to application for either certificate.

Guidance for the preparation and submission of RMPs under Exposure Control discuss the use of an SSRA within a RMP and corresponding review.

In addition to the above specific triggers, regulatory review may be required by multiple agencies. Additional review by other agencies may be initiated by the appropriate reviewer and may include any of AEP, AER, AH or AHS to ensure that all public health and environmental concerns are addressed. It is the responsibility of the submitting professional to ensure that any SSRA meets the requirements of the appropriate regulator along with all legal requirements.

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9 List of Acronyms

AEP	Alberta Environment and Parks
AER	Alberta Energy Regulator
AF	Allocation Factor
AH	Alberta Health
AHS	Alberta Health Services
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CCME	Canadian Council of Ministers of the Environment
COPC	Contaminant of Potential Concern
CSM	Conceptual Site Model
DQRA	Detailed Quantitative Risk Assessment
EcoTRV	Ecological Toxicity Reference Value
EDI	Estimated Daily Intake
ESA	Environmental Site Assessment
EPA	Environmental Protection Agency
ERA	Ecological Risk Assessment
HHERA	Human Health and Ecological Risk Assessment
HHRA	Human Health Risk Assessment
HI	Hazard Index
HQ	Hazard Quotient
ILCR	Incremental Lifetime Cancer Risk
RfD	Reference Dose
RMP	Risk Management Plan
SSRA	Site-specific Risk Assessment
SSRO	Site-specific Remedial Objective
TDI	Tolerable Daily Intake
TLU	Traditional Land Use
TRV	Toxicity Reference Value
VEC	Valued Ecosystem Component
WoE	Weight of Evidence

10 Glossary

Adverse Effect: Impairment of or damage to the environment or human health. This is a limited scope from the *Environmental Protection and Enhancement Act* definition of adverse effect: “Impairment of or damage to the environment, human health or safety or property.” Safety and property are not addressed in the context of this document.

Age Dependent Adjustment Factors (ADAF): Default numeric modifiers to the cancer slope factor that account for the increased susceptibility to cancer from early-life exposures to linear carcinogens in the absence of chemical-specific data.

Allocation Factor (AF): The relative proportion which it is allowable for medium (soil or groundwater) to constitute in the RTDI from various environmental pathways (air, soil, food, water, consumer products).

Background Concentration: A representative ambient level for a contaminant in soil or water. Ambient concentrations may reflect natural geological variations in relatively undeveloped areas or the influence of generalized industrial or urban activity in a region.

Bioaccumulation: The accumulation over time of a substance and especially a contaminant in a living organism.

Bioaccumulation Factor (BAF): The quotient obtained by dividing the concentration of a substance in an organism (or specified tissue) by its concentration in a specified exposure medium for example: air, food, sediment, soil, water.

Bioconcentration Factor (BCF): Equivalent to an uptake factor, for the case where there is a change in concentration from one phase to another phase. For example, for water (only) it is the change in concentration between the abiotic exposure medium (water) and the organism.

Biomagnify: The process by which chemical concentrations in plants or animals increase relative to food from transfer through the food web (e.g., predators have greater concentrations of a particular chemical than their prey).

Contaminant: A substance that is present in an environmental medium in excess of natural background concentration.

Contaminant of Potential Concern (COPC): Any contaminant which may or may not be causing an adverse effect to human and ecological receptors at a site.

Ecological Risk Assessment (ERA): The process of evaluating the potential adverse effects on non-human organisms, populations, or communities in response to human-induced stressors. ERA applies a formal framework, analytical process, or model to estimate the effects of human actions on natural organisms, populations, or communities and interprets the significance of those effects in light of the uncertainties identified in each study component.

Ecological Toxicological Reference Values (EcoTRVs): See Toxicity Reference Value

Environmental Site Assessment (ESA): An ESA is implemented to determine whether soil or groundwater contains contaminates in excess of Alberta Tier 1 or Tier 2 guidelines. The ESA process may be conducted in phases, but the overall process must be thorough enough to characterize site conditions and to identify and delineate all areas of residual contamination on the site prior to being considered complete. Additional ESA information can be found in the AEP’s Environmental Site Assessment Standard.

Estimated Daily Intake (EDI): Total "background" exposure to a chemical experienced by most Canadians. Estimated daily intake arises from the low levels of contamination commonly found in air, water, food, soil, and consumer products (e.g., tobacco, paints, and medicines). Estimated daily intake of a chemical is determined through a multimedia exposure assessment.

Exposure Assessment: For any line of evidence, the component for a risk assessment that quantifies the degree to which an organism encounters a stressor.

Exposure Control: Alberta's Exposure Control Guide defines “exposure control” as risk management through use of site-specific exposure barriers and/or administrative controls on contaminated land. Source removal and control must occur before exposure control can commence.

Exposure Pathways: The routes through which a receptor of concern encounters contaminants of concern in environmental media (e.g., soil, water, air, sediment). Examples of exposure pathways include ingestion and inhalation.

Hazard Index (HI): For any line of evidence, the component for a risk assessment that characterizes the nature of effects elicited by each contaminant under an exposure condition that is relevant to each receptor of concern. HI is the sum of more than one HQ for multiple substances (generally via additivity) and/or multiple exposure pathways. The HI is calculated separately for chronic, sub-chronic, and shorter-term duration exposures. If the HI is less than 1.0, then the adverse effects are assumed not to be of concern. If the HI is greater than 1.0, then the adverse effects are assumed to be of concern, and that more precise or accurate evaluation of risks may be warranted to address uncertainty.

Hazard Quotient (HQ): Numerical ratio that divides an estimated environmental concentration or other exposure measure by a response benchmark. Typically, the response benchmark is a value assumed to be protective of the receptor of concern. A HQ is the ratio of estimated site-specific exposure to a single chemical from a site over a specified period to the estimated daily exposure level, at which no adverse health effects are likely to occur. HQ values above 1.0 indicate that an adverse effect is possible, and that more precise or accurate evaluation of risks may be warranted to address uncertainty.

Incremental Lifetime Cancer Risk (ILCR): The incremental increase in lifetime cancer risk, over and above the risks experienced by the general population due to background environmental exposures, associated with a specific project or activity.

Reference Concentration: An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

Residual Tolerable Daily Intake (RTDI): The dose of a chemical above the background exposure to which a person could be exposed without expected adverse effects. RTDI = TDI – EDI.

Site-Specific Remedial Objective (SSRO): The objective which determines allowable contaminant concentration concentrations in applicable media that do not result in unacceptable human or ecological risks. It is established for a specific site to be met by the implementation of a Remedial Action Plan and, if appropriate, ongoing risk management.

Tolerable daily intake (TDI): The level/rate of chemical exposure to which a person may be exposed with no expected adverse effects. A tolerable daily intake can only be determined for chemicals with threshold effects (i.e., non-carcinogens).

Toxicity Reference Value (TRV): An exposure concentration or dose of a contaminant of potential concern that is not expected to cause an unacceptable level of effect in a receptor of concern. As such, a toxicity reference value may consist of a TDI, tolerable concentration, risk specific concentration, risk specific dose, RfD, or Ecotoxicological benchmark for a chemical of potential concern.

Traditional Land Use (TLU): Traditional knowledge and land use, associated with Indigenous communities and populations, are key considerations in the assessment of human health risks. Firstly, Indigenous receptors may be at greater risk than the general population due to behavioural, cultural and lifestyle factors linked to environmental exposures (e.g., consumption of traditional foods), and as such, may be identified as vulnerable receptors. Information on food sources, consumption rates, activity patterns and other behavioural characteristics should be collected through community consultation and incorporated explicitly into the risk assessment.

Unit Risk (UR): The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water, or 1 µg/m3 in air. The interpretation of unit risk would be as follows: if unit risk = 2 × 10-6 per µg/L, 2 excess cancer cases (upper bound estimate) are expected to develop per 1,000,000 people if exposed daily for a lifetime to 1 µg of the chemical per liter of drinking water.

Valued Ecosystem Component (VEC): For the purposes of an ecological risk assessment (ERA), a component of the ecosystem that is potentially adversely affected, either directly or indirectly, by the contaminants at a site and that is identified by the risk assessor as one for which the ERA is to be designed to protect. A VEC can be any non-human individual organism, species, population, community, habitat, or ecosystem. A receptor of concern may be the same as a VEC, but it can also be a surrogate for the VEC or be a useful element in a line of evidence but not a VEC. For example, a VEC may be a wetland complex. Several receptors of concern may be selected to evaluate key attributes of this wetland (e.g., specific species at risk, diverse aquatic plant community, nutrient processing, water retention) and these would be evaluated to determine the potential direct and indirect risk of contaminants to the VEC. A VEC is identified as such through having one or more of the following qualities: • intrinsic ecological significance • importance to human populations • economic and or social value, and/or • ability to serve as a baseline from which effects of changes can be evaluated.

1 Appendix: Allocation Factor

For soil and groundwater remediation guidelines, Alberta has adopted the use of the allocation factor (AF) as described in *A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines* (CCME 2006). The use of allocation factors is included in the Tier 1 equations. In development of SSROs for an SSRA, the use of the AF as described in Alberta Tier 1 must be maintained.

This appendix clarifies the use of the AF in the development of soil and groundwater quality guidelines. It has been included to ensure that risk assessors apply the AF to the calculation of the SSRO consistent with how it is used in the calculation of Alberta Tier 1 Guidelines.

1.1 History of the Allocation Factor

In 1996, the *Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines* (CCME 1996) documented the concept of an AF. The AF was included in the risk assessment to ensure that the entire allowable residual risk associated with a substance release to the soil was not allocated to the individual substance release or connected with the single release location. In this way, room could be left to account for the wide variety of ways a person can be exposed to a substance that is independent of the site in question. From the 1996 Protocol:

To derive a guideline, it is necessary to ascribe some allowable proportion of the total chemical exposure to the soil medium. One approach is to base allowable contaminant apportionment to the various media in proportion to the distribution expected if the various media were in equilibrium in terms of contaminant intermedia distribution (Travis and Hattemer-Frey, 1989). This assumes that the air, water, soil, and food to which most Canadians are typically exposed exist in such equilibrium. However, much of the food consumed in Canada is imported or grown in areas distant from the residence (agricultural lands being an exception). Further, many Canadians consume water that has been treated and supplied by a municipal source. Canadians also spend a majority of time indoors where air is heated, cooled and often contaminated by emissions from various consumer products, building materials, and lifestyle activities. Therefore, environmental media are not likely to be in equilibrium. Apportionment of allowable exposure between media based on theoretical equilibria is therefore not appropriate.

The CCME Subcommittee on Environmental Quality Criteria for Contaminated Sites [SEQCCS] has proposed a simple, arbitrary, and practical solution to this problem which recognizes that ***no single medium should deplete the entire tolerable daily intake or even the entire residual tolerable daily intake (RTDI)****. The RTDI is the difference between the tolerable daily intake (TDI) and the estimated daily intake (EDI) (RTDI = TDI-EDI). With five primary media to which people are exposed (i.e., air, water, soil, food, and consumer products) the SEQCCS proposes that 20% of the residual acceptable daily intake be apportioned to each of these five media.*

The SEQCCS proposes to apportion only 20% of the RTDI to soils for the purpose of deriving soil remediation guidelines. This "Soil Allocation Factor" (SF) of 20% allows for 80% of the remaining tolerable increment exposure to be reserved for other media (i.e., food, air, water, and consumer products). Although this soil allocation factor has been arbitrarily established, the SEQCCS believes that soils contaminated at the guideline level will not cause the total exposure from all media (air, water, food, and contaminated soil), via all direct and indirect pathways (ingestion, inhalation, and dermal absorption), to exceed the TDI. The generic soil guidelines are calculated after considering the sum of the background soil exposure and the percentage (20%) of residual tolerable daily intake allocated to soil.

The protocol provided a simple explanation for the generic scenario. It did not provide guidance on what to do when one or more exposure pathways are not relevant to the COPC. It did, however, set out the following precedent:

- all 5 media must be considered,

- values should be calculated based on the RTDI AFTER considering all other routes of current exposure (e.g., an estimate of the EDI),
- regardless of the current EDI, there needs to be allocation for exposure to other media so that the entire risk tolerance is not associated with the local site in question,
- no single media should be apportioned the entire exposure residual tolerable daily intake, and
- the default AF is 0.2, based on uniform allocation to all 5 media.

The *Canada-Wide Standard for Petroleum Hydrocarbons in Soil* (PHC CWS) (CCME 2000) was developed by the CCME under the Harmonization Sub-Agreement on Standards. Alberta was a signatory to the Standard and thereby agreed to implement it in Alberta. The Standard provides a unique perspective on the AF. It represents an example where the AF could potentially be modified if enough information is available for each pathway of concern. From CCME (2000):

In the most general case discussed in the Protocol, a substance is considered to have the potential to be present in all media and therefore, on a default basis, an allocation of 20% of the RTDI is assigned to each of the 5 media. However, for specific substances, in this case PHCs, there may be properties that preclude the presence or limit the concentration in various media. When this is the case, both the issues of uncharacterized exposure and the potential creation of a new guideline are negated or mitigated. In such cases a greater proportion of the RTDI can be allocated to critical media, such as soil.

This document allows the regulator to assign a disproportionate amount of the SAF to specific media provided there is enough supporting evidence. It does not give clear details on how this is done. However, some principles that can be followed include the following:

- The risk assessor must consider all applicable exposure routes and media. The entire allocation cannot be assigned to the site in question if the receptor is potentially exposed through other routes (i.e., SAF ≠ 1).
- The risk assessor must consider existing and potential regulatory control or guidelines for a particular medium in deciding how to apportion to that medium.
- The risk assessor must consider uncharacterized exposure and range of exposure within a given medium in deciding the apportionment for that medium. Current estimated average or median exposure is not sufficient.
- Any media where there is or is potential for regulation or exposure control must be considered.

The AF may go in either direction using these principles. Exposure routes are not simply eliminated but an assessment must also be done on how important each pathway is for the contaminant in question and whether the fraction set aside for that pathway should be increased or decreased. For example, if there is a high potential for exposure through a specific medium not connected with the site or a high likelihood of regulatory control in that medium, a higher AF may be assigned. That would result in a lower AF assigned to the media in question.

In the 2006 CCME updated the *Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines.* In this update, CCME added the following clarification to the use of the Soil AF:

Depending on their physical and chemical properties, some soil contaminants may not normally be present in all four of the remaining media (air, water, food, and consumer products). For example, high molecular weight hydrocarbons exhibit very low solubility and volatility and, as a result, the contribution of air and water to overall human exposure may be insignificant. If defensible contaminant-specific evidence exists demonstrating that the contaminant does not occur in a given medium, the RTDI may be distributed amongst fewer media and the soil allocation factor may be increased from 20% to a value given by:

$$SAF = 100\% / (\text{number of applicable exposure media})$$

Under this method:

- Removal of a medium since the contaminant does not occur in the medium of interest. It is not based on aspects of the site or currently estimated exposure,
- The remaining allocation is distributed evenly between the remaining media, and,
- The document is silent on the more detailed procedure that was used in the 2000 Standard.

In 2008, the PHC CWS was updated. The AF was not considered in scope of the review and the original unaltered text quoted from 2000 can be found in this document. The PHC CWS does acknowledge the protocol update in 2006 but retains the original AFs. By doing so, they acknowledged the change in 2006 but maintained that it was consistent with the protocol to assign a disproportionate amount of the remaining RTDI to specific media provided it can be justified through a more detailed analysis of each exposure medium. However, because of the lack of specific guidance on how this is to be done, Tier 1 Guidelines have maintained the method as defined in CCME (2006) for estimation of AFs.

1.2 Description of the Allocation Factor and Relation to Other Terms

The AF is included in the Tier 1 Guideline equations for calculation of soil and groundwater quality guidelines. The AF is applied to the evaluation of all human health pathways except when it is necessary to calculate a drinking water quality guideline.

For the drinking water pathway, Alberta has adopted Health Canada as its primary reference source for drinking water quality guidelines. As a result, Alberta accepts the approach used by Health Canada for calculating the drinking water quality guideline (Health Canada 2010a). If there is no primary or secondary reference source available for the drinking water quality guideline, the consultant may follow this procedure in the development of a groundwater quality guideline that is protective of the drinking water pathway only.

For all other pathways, the AF must be included in the development of soil and groundwater quality objectives.

The AF is intended to ensure that the person who is exposed to a COPC from a particular site or location is protected regardless of present or future exposure through other day-to-day activities. This notion and the relationship between the AF and other parameters that have been mistakenly assumed to serve the same purpose as the AF is described further in *A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines* (CCME 2006).

1.3 Allocation Factor and Hazard Quotient

The HQ is the ratio between the potential exposure to a substance and the concentration at which an adverse effect might occur. The Tier 1 and Tier 2 Guidelines and the CCME (2006) protocol do not discuss the HQ. However, because the HQ in a preliminary quantitative risk assessment is often set at 0.2, the AF has often been misinterpreted as equivalent to the HQ. The statement by Health Canada that Alberta uses a HQ of 0.2 in risk assessments (*Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRAChem)* (Health Canada, 2010)) is incorrect and has encouraged this interpretation.

AEP assumes a HQ of 1 for all risk assessments except where it is necessary to use a HI to describe synergistic effects for multiple COPCs. In this instance the HI is set to 1. As the HQ is set to 1, it does not appear in the Tier 1 Guideline formula.

The HQ or HI is value is separate and distinct from the AF.

AEP maintains the CCME approach to the AF. The AF offers clarity about what is being protected and offers a definitive method on how the appropriate level of protection is to be evaluated. Although Health Canada allows for modification of the HQ with a more robust estimation of EDI, this does not apply to the AF. This estimate does not address how to appropriately allocate the RTDI among the potential routes of exposure. Specifically, the estimate of EDI does not address:

- protection of sensitive populations and populations that may receive higher than average exposure to sources from the 5 media given that the EDI is typically set on the average population exposure,
- assurance that non-reported exposures are accounted for,
- allowances for protection of exposure due to other media (e.g., guidance that may be developed for other media exposure), and
- allowance for persistence or bioaccumulation characteristics of the COPCs that may impact long-term exposure to some COPCs.

1.4 Allocation Factor and Background Concentration

The AF and background soil or groundwater concentration are two separate and distinct items serving separate functions. However, these are misinterpreted enough to justify further discussion.

Background concentration is a measure of average concentrations found in soil or groundwater. In many instances there is a COPC concentration that occurs naturally in soil or groundwater independent of the anthropogenic activity that resulted in the substance release(s). This concept is further described in the Tier 1 Guidelines.

Remediation below what would be considered background for the location of interest is not expected. For threshold substances, once the risk-based endpoint is estimated, the average background soil or groundwater concentration may be added back into the final calculated risk-based guideline. This is done within the Tier 1 formulae as described in Alberta Tier 1 and does not represent a SSRO. This will ensure that the final guideline does not result in remediation below the background soil or groundwater condition.

The AF represents the maximum portion of the RTDI that results from exposure to the site so that the final guideline “allows room” for current and future exposure to other media not connected with the site being assessed. The AF is determined independently of soil concentrations and has no relation to this term in the equation. Confusion of these terms results in critical errors in an SSRA.

1.5 Allocation Factor and EDI

The AF is sometimes mistakenly identified as the EDI. As noted in the definitions, the AF is calculated based on the RTDI and the EDI is used in determining the RTDI. These values are used for two separate functions in the equation and should not be assumed to be related. For further information on the difference between the AF and the EDI, see CCME (2006).

The EDI estimates the exposure to the COPC for the average individual from all activities. For threshold COPCs, it is subtracted from the TDI to ensure that the person is not currently exposed to more than what is considered a threshold exposure in their daily activities. This ensures that exposure to contaminated materials at the site, coupled with an average or median daily exposure from sources not connected with the site, cannot exceed the calculated TDI.

The AF specifies the amount of the RTDI that the person can be safely exposed to from the site affected by the substance release. It ensures that the entire RTDI cannot be allocated to a single substance release connected with the site, leaving room for exposure through other routes not connected with the substance release (unless the AF has been adjusted because exposure is not occurring elsewhere).

1.6 Application to SSRA

For an SSRA, the following will be applied to the review by the regulator:

- Background soil and groundwater values may be measured at the site, provided sufficient sampling locations are available that are representative of conditions before the substance release.
- EDI values that are listed in the Tier 1 Guidelines represent the primary reference sources for Alberta. Where available, these are used as generic inputs for risk modelling. Normally, these cannot be altered at the site-specific level unless there is a detailed human health study for the site or area in question that can document site-specific exposure. While this may be possible at the site level, it requires a detailed site-specific human health study to confirm the modification.
- The HQ is set to 1.
- AFs cannot be removed or set to 1 at the site-specific level and are not related to the HQ.
- Where AFs are available in the Tier 1 Guidelines, they must be adopted in the SSRA.
- Where AFs are not available in the Tier 1 Guidelines, an AF of 0.2 is adopted by default.
- If the AF is not available in the Tier 1 Guidelines, an AF may be recommended based on the same process as outlined in CCME (2006). For example, if the COPC is not sufficiently volatile, an AF of 0.25 can be recommended based on the remaining 4 media of concern. These modifications will require review before acceptance.
- AFs in the Tier 1 Guidelines cannot be modified. Where a detailed local survey is available that accounts for local consumer habits, it may be possible to modify the site AF based on this information.

1.7 References

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