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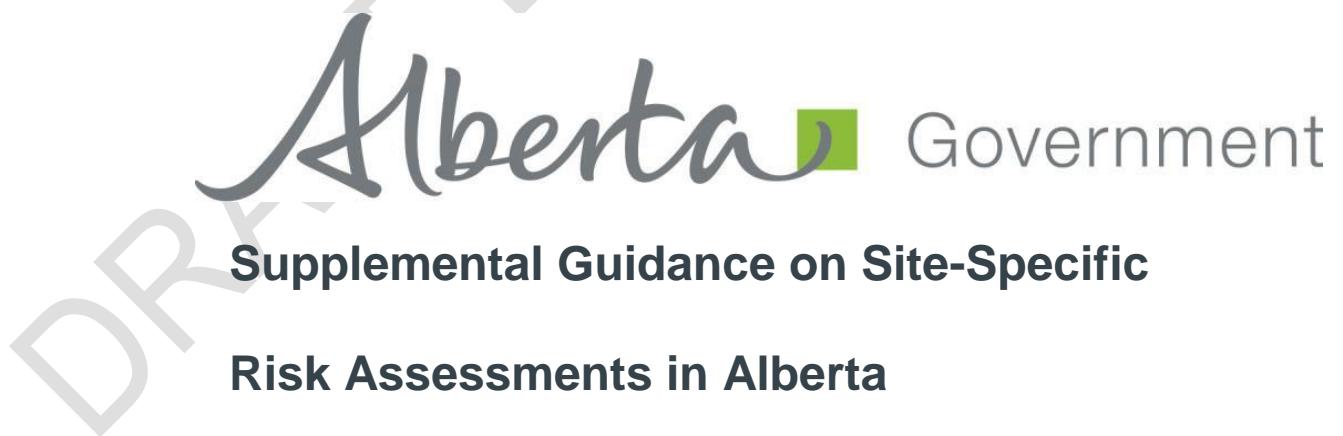
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Supplemental Guidance on Site-Specific

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Risk Assessments in Alberta

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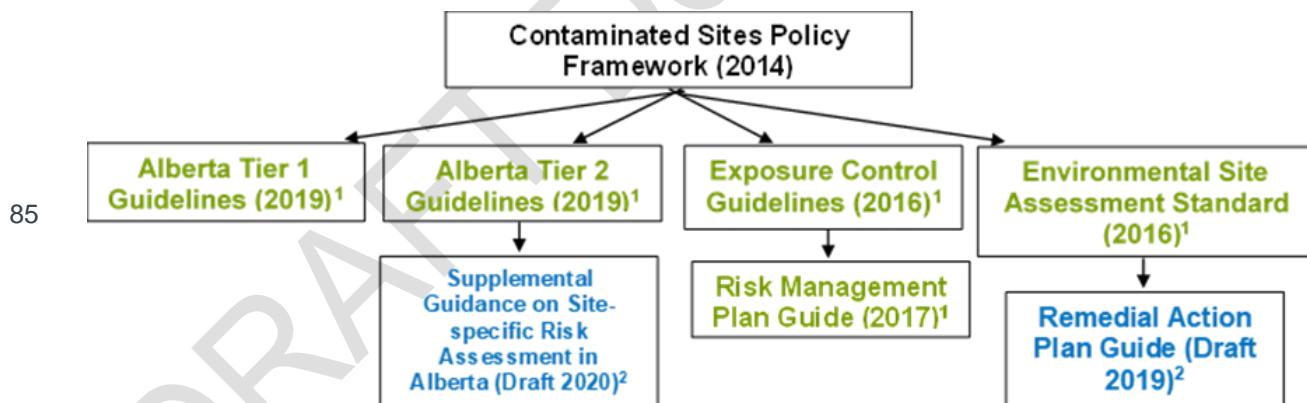
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69 Introduction

70 1.1 General

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

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



85 86 ¹Documents are incorporated into the *Remediation Regulation* by direct reference.

87 88 ²Documents are supplemental guidance to the primary reference that has been incorporated into
the *Remediation Regulation*.

89

90 1.2 Legislative Context

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

94 Whenever a release causes, has caused or may cause adverse effect, appropriate remedial
95 measures must be taken. Alberta's *Remediation Regulation* further clarifies the Duty to Take
96 Remedial Measures, as outlined in the *Environmental Protection and Enhancement Act*. Section
97 2 of the *Remediation Regulation* adopts the following documents under the *Alberta Contaminated*
98 *Sites Policy Framework* (ESRD, 2014) for this purpose;

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

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

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

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

117 1.3 Scope and Objectives

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

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

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

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

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

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

151 1.4 Organization of Document

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

- 155 • Section 2 – Relation to the Contaminated Sites Policy Framework

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

1.5 Relationship to other Alberta Policy and Guideline Documents

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

- 166 • Alberta Contaminated Sites Policy Framework (ESRD, 2014).
167 • Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta,
168 2019a).
169 • Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta,
170 2019b).
171 • Alberta Exposure Control Guide (Government of Alberta, 2016a).
172 • Alberta Risk Management Plan Guide (Government of Alberta, 2017b).

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

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175 2 Relation to the Contaminated Sites 176 Policy Framework

177 2.1 Alberta Contaminated Sites Policy Framework

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

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

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

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

199 2.2 Role of SSRA in the Management of 200 Contaminated Sites

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

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

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

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

216 2.3 Role of the Professional in an SSRA

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

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

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

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

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

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259 3 Scoping of Site-Specific Risk Assessment

260

3.1 Risk Assessment Goals

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

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

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

280

3.2 Complexity and Level of Effort

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

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

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

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

3.3 Data Collection Considerations

308 The information required to conduct a SSRA must include:

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

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

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

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

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

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

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

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

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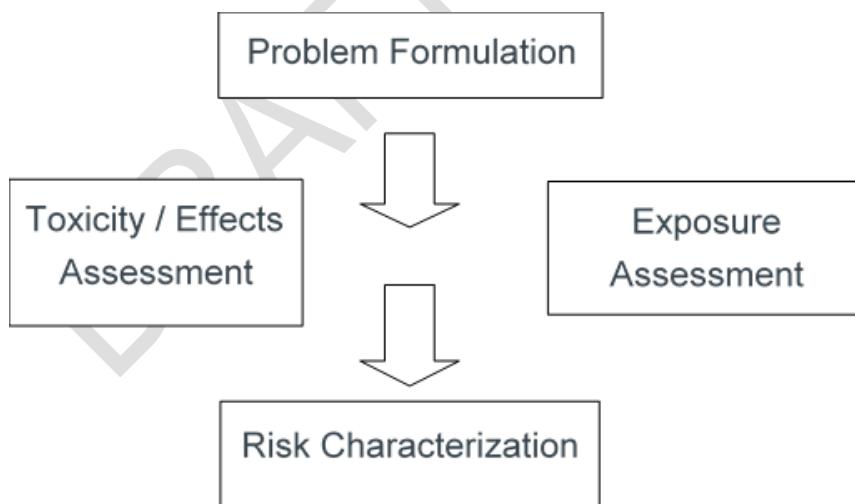
4 General Human Health and 354 Ecological Risk Assessment 355 Methods

356

4.1 Overview of HHERA Framework

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

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



370

Figure 4.1 HHERA Framework

371 **4.1.1 Problem Formulation**

372 Problem formulation is the first stage of any risk assessment and involves identification and
373 screening of the three main components of risk: COPCs, primary and sensitive/vulnerable
374 receptors (both human and/or ecological) and relevant exposure pathways of the site and its
375 setting. The goal of this stage is to focus the SSRA on those COPCs, pathways and receptors that
376 contribute to human health and ecological risk. An exposure pathway requires a COPC source, a
377 mechanism of chemical release to the transport medium, a transport pathway from the COPC
378 source to the receptor, and a route of intake at the receptor location. Ecological receptors are often
379 identified in terms of valued ecosystem components (CCME, 2020, Government of Canada,
380 2012a), which may not be limited to individual species but may include communities and
381 populations as well as ecological processes or functions. Ecological receptors must be selected to
382 be representative of all relevant trophic levels, and may require the identification of surrogates to
383 proceed through the risk assessment process. VECs can be defined for any relative “social,
384 economic or cultural importance— any particular species or group that is of special importance
385 would typically be included as a receptor of concern. These include domestic pets, livestock,
386 species of significance to Indigenous peoples, and species of commercial or recreational
387 importance. Such receptors may be subject to a different level of protection than other receptors of
388 concern” (CCME,2020, Government of Canada, 2012a).

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

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

- 400 • No COPCs present.
401 • No potential receptors present.
402 • No operative exposure pathways identified.

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

404 **4.1.2 Exposure Assessment**

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

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

423 **4.1.3 Toxicity / Effects Assessment**

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

433 **4.1.4 Risk Characterization**

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

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

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

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

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

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

459 4.2 Human Health Risk Assessment

460 4.2.1 General Guidance

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

464 General HHRA guidance includes the following:

- 465 • Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta,
466 2019a).
- 467 • Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta,
468 2019b).
- 469 • Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and
470 Groundwater Remediation Guidelines (Government of Alberta, 2017a).

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

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

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

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

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

512 **4.2.2 Human Health Protection Endpoints**

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

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

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

525 Both carcinogenic and non-carcinogenic effects must be assessed for COPC. See Section
526 4.2.3.2 for further discussion of the assessment of carcinogenic and non-carcinogenic endpoints.

527 **4.2.3 Chemical Classification and Toxicological Reference Values**

528 **4.2.3.1 Toxicological Reference Values Selection**

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

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

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

554 **4.2.3.2 Assessment of Carcinogenic versus Non-carcinogenic Endpoints**

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

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

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

571 **4.2.3.2.1 Endpoint Exceptions**

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

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

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

583 **4.2.3.3 Bioavailability and Relative Absorption Factors**

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

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

601 **4.2.3.4 Toxicity of Substances in the Absence of Published TRVs**

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

611 **4.2.4 Human Exposure Parameters**

612 Human exposure parameters (e.g., receptor characteristics, intake rates, time-activity patterns),
613 also referred to as exposure factors, are used to estimate contaminant intake or exposure dose,
614 and are available in various published sources. Values used in the development of the Tier 1
615 guidelines are tabulated in the Tier 1 Guidelines and Tier 2 Guidelines. These values are from
616 CCME (2006) and based on values published prior to that date by Health Canada. Health
617 Canada has subsequently updated a number of these exposure factors (Health Canada, 2012).
618 It is recommended that the most recent of the values published by Government of Alberta
619 (2019a) or if not available then Health Canada (2012) be used in a HHRA as part of SSRA.

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

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

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

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

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

639 **4.2.5 Fate and Transport Modelling and Exposure Estimation**

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

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

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

661 For example, Alberta Tier 1 residential guidelines typically only consider toddler and adult life
662 stages because these intake scenarios were critical to development of the Tier 1 Guidelines.
663 However, when conducting an SSRA these assumptions may not be appropriate and intake from
664 5 life stages, as noted by Health Canada (2010a, 2012) must be considered in the assessment.
665 Any deviation from these intake characteristics requires prior approval from the appropriate
666 Regulator or key reviewers.

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

- 669 • A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines
670 (CCME 2006).
- 671 • Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale
672 (CCME 2008).
- 673 • Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human
674 Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (Health Canada,
675 2012).
- 676 • Federal Contaminated Site Risk Assessment in Canada, Part V: Guidance on Human
677 Health Detailed Quantitative Risk Assessment for Chemicals (DQRA_{Chem}) (Health
678 Canada (2010a)).

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

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

694 4.3 Ecological Risk Assessment

695 4.3.1 General Guidance

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

700 Sources of general ERA guidance include the following:

- 701 • Alberta Tier 1 Soil and Groundwater Remediation Guidelines (Government of Alberta,
702 2019a).
- 703 • Alberta Tier 2 Soil and Groundwater Remediation Guidelines (Government of Alberta,
704 2019b).
- 705 • Guidance for Selecting Toxicity Reference Values for Alberta Tier 1 and Tier 2 Soil and
706 Groundwater Remediation Guidelines (Government of Alberta, 2017a).
- 707 • Protocol to Develop Alberta Water Quality Guidelines for Protection of Freshwater
708 Aquatic Life (AEP 1996).
- 709 • Environmental Quality Guidelines for Alberta Surface Waters (Government of Alberta
710 2018b).
- 711 • Canadian Council of Ministers of the Environment (CCME) Ecological Risk Assessment
712 Guidance (2020).
- 713 • Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance
714 (Government of Canada, 2012a).

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

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

4.3.2 Ecological Protection Endpoints

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

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

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

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

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

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

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

792 **4.3.3 Ecological Toxicological Reference Values (EcoTRVs)**

793 As with TRVs for HHRA, the starting point for EcoTRVs for ERA as part of a SSRA in Alberta will
794 be the values used in the derivation of the Tier 1 Guidelines. These are based on protocols
795 described in A Protocol for the Derivation of Environmental and Human Health Soil Quality
796 Guidelines (CCME 2006) or on *Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in*
797 *Soil: Scientific Rationale – Supporting Technical Document* (CCME 2008) for petroleum
798 hydrocarbons. *Protocols for Deriving Water Quality Guidelines for the Protection of Agricultural*
799 *Water Uses (Irrigation and Livestock Water)* (CCME1999b) and *A Protocol for the Derivation of*
800 *Water Quality Guidelines for the Protection of Aquatic Life* (CCME 2007) were used for
801 determining water quality guidelines.

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

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

Table 4.1: Recommended EcoTRVs where Tier 1 and/or Surface Water Quality Guidelines Exist

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

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

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

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

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

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

834 • Use of published TRVs. Examples include US EPA Ecological Soil Screening Levels
835 (Eco-SSLs) (US EPA, various dates), US EPA's ECOTOX database (US EPA, undated
836 [c]) and values published in Oak Ridge National Laboratory's Ecological Benchmark Tool
837 (ORNL, undated [online]).

838 • Derivation of literature-based TRVs using published toxicological data. Note that this
839 option may only be used for SSRA in Alberta if the derived TRVs have first been
840 published in the peer-reviewed literature and at the discretion of the appropriate
841 Regulator or key reviewers.

842 • Modifying existing guidelines to develop site-specific TRVs. This approach would be
843 similar to the approach recommended above for use when Tier 1 Guidelines are
844 available, but with the application of site-specific assumptions.

845 • Use of site-specific toxicity testing. Site-specific toxicity testing may be conducted using
846 the same methods and suite(s) of test organisms used in the development of Alberta Tier
847 1 or surface water quality guidelines (CCME 1999a, 1999b, 2006, 2007, 2008) or in
848 accordance with Government of Canada (2010a).

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

856 **4.3.4 Ecological Exposure Parameters**

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

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

- 864 • Values used in the development of Tier 1 Guidelines (CCME 1999b, 2006, 2007, 2008;
865 Government of Alberta 2019a).
- 866 • Federal Contaminated Sites Action Plan (FCSAP) Ecological Risk Assessment Guidance
867 – Module 3: Standardization of Wildlife Receptor Characteristics (Government of Canada
868 2012b).
- 869 • Wildlife Exposure Factors Handbook (US EPA, 1993)

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

872 **4.3.5 Fate and Transport Modelling and Exposure Estimation**

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

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

- 884 • A Protocol for the Derivation of Environmental and Human Health Soil Quality Guidelines
885 (CCME 2006).
- 886 • Canada-Wide Standard for Petroleum Hydrocarbons (PHC) in Soil: Scientific Rationale
887 (CCME 2008).
- 888 • Federal Contaminated Site Risk Assessment in Canada, Part I: Guidance on Human
889 Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (Health Canada,
890 2012).

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

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

907 **4.3.6 Lines of Evidence and Weight of Evidence Approaches**

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

918

919 5 Reporting Requirements

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

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

Table 5.1: Examples of Deficiencies in SSRA Reports

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

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

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

936

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937

6 Implementation of Site-Specific Risk 938 Assessment Results

939

6.1 Determining Requirement for Remediation

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

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

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

959

6.2 Identification of Risk Management/Exposure 960 Control Requirements

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

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

969 6.3 Site, Land and Water Use Restrictions

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

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

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

989 6.4 Regulatory Consultation and Review

990 The *Remediation Regulation* sets out regulatory tools that are available to the proponent when
991 assessing, managing risks at contaminated sites and seeking regulatory closure. The Alberta Tier
992 2 Guidelines set out a requirement for the proponent to seek acceptance of any SSRA by the
993 Regulator. Proponents conducting or planning to conduct assessment SSRAs for a contaminated
994 site are encouraged to consult with the appropriate Regulator or key reviewers at appropriate
995 stages of the project, and may be required to consult where prescribed by the Tier 2 Guidelines
996 and this document. The appropriate Regulator for contaminated sites is either AEP or the AER.
997 The reviewer may be AEP, AER, Alberta Health (AH) or Alberta Health Services (AHS).

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

1000 Limited Remediation Certificates and Tier 2 Compliance Letters prescribe AEP review of risk
1001 assessments where prepared in support of the applications (Government of Alberta, undated
1002 [online]). The *Limited Remediation Certificate Guide* (Government of Alberta 2019c) and the *Site-
1003 Based Remediation Certificate Guide* (Government of Alberta 2019d) specifically indicate that any
1004 Tier 2 risk assessments must have been submitted and reviewed prior to application for a
1005 certificate. Additionally, guidance for the preparation and submission of risk management plans
1006 under the Exposure Control option (Government of Alberta, 2016, 2017b) discuss the role of risk
1007 assessment in risk management plans and the review thereof.

1008 In addition to the above specific triggers, regulatory review by AEP or AER and/or AH or AHS
1009 may also be required for risk assessments conducted for other purposes such as spills and other
1010 public health or environmental concerns. In all cases, it is the responsibility of the submitting risk
1011 assessor to ensure that any risk assessment meets the requirements of the appropriate
1012 Regulator or key reviewers and that they are meeting all of the legal requirements in the
1013 legislative regime.

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1223 8 List of Acronyms

1224

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

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

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