Supplemental Guidance for Risk Assessments

This document provides Qualified Professionals guidance on the performance of human health and ecological risk assessments for contaminated sites in British Columbia (BC). It supplements existing provisions under the Environmental Management Act (the Act) and Contaminated Sites Regulation (the Regulation), and is subject to change as risk assessment methodology, protocols, policy and guidance are updated.

Screening level risk assessment
Protocol 13, “Screening Level Risk Assessment” (SLRA) is intended to evaluate whether contamination at a specific site meets or exceeds benchmark screening criteria for human health and the environment. The SLRA process involves a simple default assessment of key exposure pathways and receptors.

Contaminated sites that meet SLRA benchmark screening criteria are considered to satisfy the Regulation’s risk-based standards. No further risk assessment or remediation is required at such sites as long as site conditions do not change. Ongoing environmental monitoring to ensure maintenance of site conditions may be necessary at SLRA assessed sites.

The use of SLRA is subject to the following precluding conditions: 1) certain contaminated media (vapours, surface water, and sediments) may not be risk assessed in SLRA, 2) certain contaminants of concern (inorganic substances in acidic soil or groundwater, bioaccumulative substances, and mobile NAPL or DNAPL) cannot be evaluated by SLRA. Furthermore, Director’s approval is required for use of SLRA at high risk sites.

Detailed human health risk assessment
General guidance
Detailed human health risk assessments under the Act should include all applicable human receptors known, or reasonably inferred, to be present at a site under current and future use, including sensitive or exposed human receptor subgroups such as:

a) susceptible age groups (e.g. children and the aged),

b) hypersensitive individuals (e.g. pregnant women, PICA children, etc.),

c) vulnerable individuals known to suffer compromised health impacts (e.g. chemical hypersensitivity, impaired pulmonary function, immunodeficiency, etc.), and

d) uniquely exposed individuals (e.g. subsistence consumers).

Further, provision of rationale for site-specific inclusion or exclusion of sensitive receptors is expected in all detailed human health risk assessments.
Acute and subchronic exposures to contaminants by utility, trench, and construction workers do not need to be assessed in human health risk assessments carried out under the Regulation. Worker health and safety is the responsibility of WorkSafeBC under the *Workers Compensation Act* and the Occupational Health and Safety Regulation. WorkSafeBC requirements must be met at contaminated sites. Operative chronic (>90 days) occupational exposure pathways need to be included in risk assessments completed under the Regulation.

**Deterministic risk assessment**

**General guidance**

For human health deterministic risk assessment, the ministry recommends use of the following Health Canada, Federal Contaminated Site Risk Assessment in Canada, guidance:

- **Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012)**,
- **Part II: Health Canada Toxicological Reference Values (TRVs), Version 2.0 (2010)**,
- **Part V: Guidance on Complex Human Health Detailed Quantitative Risk Assessment for Chemicals (DQRA\_CHEM) (2010)**,
- **Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment for Chemicals (DQRA\_RAD) (2010)**,
- **Supplemental Guidance on Human Health Risk for Country Foods (HHRA Foods) (2010)**,
- **Supplemental Guidance on Human Health Risk Assessment of Contaminated Sediments: Direct Contact Pathway (2017)**, and
- **Supplemental Guidance: Checklist for Peer Review of Detailed Human Health Risk Assessments (HHRA) (2010)**.

Furthermore, the ministry strongly recommends use of the critical human receptors, physiological parameters, exposure routes, exposure scenario assumptions and associated toxicological equations provided in Health Canada, *Federal Contaminated Site Risk Assessment in Canada Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012)* guidance:

- Table 2. Problem Formulation Checklist,
- Table 3. Recommended Human Receptors and Their Characteristics for Preliminary Quantitative Risk Assessments,
- Table 4. Exposure Duration and Frequency Assumptions for Preliminary Quantitative Risk Assessments,
- Table 5. Recommended General Equations Dose Estimation,
- Table 7. Potency Equivalence Factors for Carcinogenic Polycyclic Aromatic Hydrocarbons, and
- Table 8. Toxic Equivalency Factors for Dioxins, Furans, and Certain Polychlorinated Biphenyls.

The ministry also recommends use of the absorption factors provided in *Part II: Health Canada Toxicological Reference Values (TRVs), Version 2.0 (2010)*:

- Table 3. Dermal Relative Absorption Factors (RAF\_dermal) of Selected Substances.

Other Health Canada documents than those listed above may be used if adequate rationale is provided.

In cases where ministry protocols and policy contradict the guidance documents listed above, ministry protocols and policy take precedence over the guidance. In these circumstances contact the ministry for further advice.
**Exposure parameters**
For exposure parameters, equations and scenarios not contained in Health Canada guidance, the ministry recommends use of the following U.S. Environmental Protection Agency (US EPA) guidance where warranted:

- **Supplement to RAGS, Volume 1, Part A: Community Involvement in Superfund Risk Assessments (1999)**,
- **Guidelines for Carcinogen Risk Assessment**,
- **Guidelines for Reproductive Toxicity Risk Assessment**,
- **Guidelines for Neurotoxicity Risk Assessment**,
- **Guidelines for Developmental Toxicity Risk Assessment**,
- **Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures**,
- **A Framework for Assessing Health Risk of Environmental Exposures to Children**,
- **Exposure Factors Handbook**, and
- **Child-Specific Exposure Factors Handbook**.

**Soil vapour assessment**
For risk assessment of exposures to soil vapours, the ministry recommends use of the following protocol and guidance:

- **Ministry of Environment. Protocol 22, “Application of Vapour Attenuation Factors to Characterize or Risk Manage Vapour Contamination”**, 
- **Ministry of Environment. Technical Guidance 4, “Vapour Investigation and Remediation”**, 
- **Health Canada. Federal Contaminated Sites Risk Assessment in Canada: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites**, and
- **Science Advisory Board for Contaminated Sites in British Columbia: Report on Screening Level Risk Assessment, SLRA Level 1 and SLRA Level 2**.

**Carcinogenic classification**
“Carcinogenic substance” means any chemical classified as carcinogenic in accordance with **Protocol 30, “Classifying Substances as Carcinogenic”**. Evaluation of both non-carcinogenic and carcinogenic effects related to exposure to contamination at a site is necessary for human health risk assessments carried out under the Regulation. For carcinogenic substances that elicit both carcinogenic and non-carcinogenic effects, both endpoints should be assessed in human health risk assessments where suitable TRVs are available. However, it should be carefully considered which route(s) of exposure are relevant for each endpoint.

Substances that are not classified as carcinogenic under Protocol 30 do not require the evaluation of carcinogenic effects in risk assessment, even though slope factors and/or potency estimates may be provided by other agencies. Note that Protocol 30 is limited to the classification of carcinogens, and should not be considered as a classification of TRVs.
The ministry does not currently require the inclusion of the potentially carcinogenic effects of lead in human health risk assessment.

**Source and selection of human health toxicity reference values**

Toxicity Reference Values (TRVs) include: Acceptable Daily Intake (ADI), Tolerable Daily Intake (TDI), Reference Dose (RfD), Reference Concentration (RfC), Risk-Specific Dose (RsD), Benchmark Dose (BMD), Minimum Risk Level (MRL), Cancer Slope Factor (CSF), and Cancer Unit Risk (UR), among others.

The ministry acknowledges that TRVs from Canadian agencies generally incorporate Canadian, as opposed to foreign, policy assumptions and values. Further, the ministry also recognizes that Canadian agency TRVs are widely used within Canada for public health and environmental decision making outside of the contaminated sites field, and that use of Canadian TRVs will generally provide for greater consistency between contaminated sites risk assessments and other risk assessments conducted on food, water and air. However, TRVs published by the US EPA are subject to more frequent peer review and updating. In addition, US EPA TRVs have been used by the ministry in setting most of the numerical standards of the Regulation.

In consideration of the above, the ministry recommends the following hierarchy of TRV sources:

1. BC Ministry of Environment derived and approved TRVs, including TRVs for:
   - Sodium ion,
   - Chloride ion, and
   - Lead (toddler and adult)
2. US EPA: Integrated Risk Information System (IRIS) toxicity reference values in human health risk assessment, for all but the following:
   - Chlorinated dioxins and furans
   - PCBs

For the above substances and classes of substances, the ministry recommends use of the most recently published or publicly available Health Canada TRVs.

3. Health Canada: Toxicological Reference Values (TRVs) and Chemical-Specific Factors, Version 2.0.
4. UN World Health Organization: International Programme on Chemical Safety, INCHEM.

**Supplemental agency sources for human health TRVs**

Where US EPA, Health Canada or World Health Organization TRVs are lacking for a substance, use of human health TRVs from the following supplemental sources may be considered:

- US Agency for Toxic Substances and Disease Registry: ATSDR Toxic Substances Portal,
- California Environmental Protection Agency: Toxic Criteria Database,
- Netherlands National Institute of Public Health and the Environment: Re-evaluation of Human Toxicological Maximum Permissible Risk Levels,
- US EPA: Regional Screening Levels,
- Oak Ridge National Laboratory: Risk Assessment Information System, and
- Other TRVs published by Canadian or US government agencies.

The selection of a TRV from one of the supplemental agency sources listed above is expected to be based on the following criteria:

a) existence of a comprehensive and contemporary published toxicological assessment on which the TRV is based,

b) the extent of supporting rationale and documentation pertaining to the scientific derivation of the TRV, and
c) the extent and rigor of scientific peer review provided for the TRV.

The rationale for the selection of a supplemental TRV should be fully...
documented in any human health risk assessment report in which the supplemental TRV is used.

Supplemental TRVs may require adjustments in exposure assumptions and/or target risk levels before they can be used in the risk assessment of a contaminated site. Such adjustments should be documented in any human health risk assessment report in which they have been used.

Use of de novo derived human health TRVs
In the case where no credible human health TRV can be found, a de novo TRV may be derived based on the scientific literature related to the toxicity of the substance.

The use of de novo TRVs in risk assessments submitted in support of contaminated sites applications under Protocol 6 must be approved by a Director prior to use.

Hazard index and additive risks
A hazard index needs to be calculated for:

a) each substance over all operable exposure pathways (regardless of whether substance concentrations exceed the numerical standards in all exposure media), unless toxicity is pathway specific, and

b) each group of substances sharing a mechanism of toxicity and a target organ, including structurally related substances (e.g. carcinogenic PAHs, PCBs, PCDDs and PCDFs).

Probabilistic risk assessment

General guidance
Probabilistic human health risk assessment methods can often provide better information on the variability and uncertainty of risks. The ministry recommends the following US EPA risk assessment guidance be used for conducting probabilistic risk assessment:

- Guiding Principles for Monte Carlo Analysis.

When probabilistic methods are used, the ministry expects the rationale for the selection of input parameter distributions and their applicability to BC to be fully documented.

Policy decisions

Dermal exposure from contaminated water
Human health risk assessments of the dermal exposure pathway for receptors coming into contact with contaminated surface or groundwater should determine the log octanol-water coefficient (log Kow) value for all contaminants of concern present in the surface or groundwater that exceed the applicable numerical water standards in the Regulation. Log Kow values as published by the US EPA are recommended for use. In accordance with Risk Assessment Guidance for Superfund (RAGS): Part E, Supplemental Guidance for Dermal Risk Assessment, if the log Kow for a contaminant of concern is less than 4.5, the dermal exposure pathway for receptors arising from contact with surface or groundwater with respect to that substance need not be evaluated. However, if the log Kow for a contaminant of concern is greater than or equal to 4.5, the dermal exposure pathway for contact with surface or groundwater with respect to that substance is expected to be evaluated in the human health risk assessment. The dermal exposure pathway from water for metals does not require evaluation.

Future drinking water use
If the future drinking water exposure pathway is considered incomplete or inoperative (e.g. a community water supply is present as an alternate drinking water source, all site impacted drinking water wells have been decommissioned, or the risk management
approach for the site is ongoing prohibition of use of site impacted water as drinking water), risk calculations and associated risk estimates for the future drinking water pathway need not be included in the risk assessment for the site. However, where risk calculations and estimates are not provided the statement “future drinking water risks were not calculated” and full documentation of the rationale by which the future drinking water pathway was determined to be incomplete or inoperative should be included in the human health risk assessment report.

Further requirements for determining the current and future groundwater use for drinking water are provided in Protocol 21, “Water Use Determination”.

### Detailed ecological risk assessment

#### General guidance

The primary goal of ecological risk assessment and/or ecological risk management is to ensure the continued presence, or successful re-introduction, of a biologically diverse, functional, self-sustaining, and interdependent community or ecosystem as an essential component of the remediation of contaminated sites as appropriate to the land use.

The following ministry protocols and technical guidance apply to the performance of ecological risk assessments for contaminated sites in BC:

- **Protocol 1, “Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia”**, 
- **Protocol 20, “Detailed Ecological Risk Assessment”**, 
- **Tier 1 “Ecological Risk Assessment Policy Decision Summary”**, 
- **Technical Guidance 15, “Concentration Limits for the Protection of Aquatic Receiving Environments”**, 
- **Technical Guidance 19, “Assessing and Managing Contaminated Sediments”**, and 
- **Contaminated Sites Q&As**

Portions of **Tier 1 Guidance (Protocol 1)** are considered outdated and not representative of current risk assessment practices in British Columbia. It is expected that Protocol 1 will be used in conjunction with, and in consideration of: the **Tier 1 Ecological Risk Assessment Policy Decision Summary, Protocol 13 Screening Level Risk Assessment** and/or **Protocol 20 Detailed Ecological Risk Assessment Requirements**. Where inconsistencies exist between these later documents and Protocol 1, it is expected that precedence will be given to the most recent document.

Any ecological risk assessment report submitted in support of a recommendation to issue a contaminated sites legal instrument must be accompanied by either a Protocol 13 or a Protocol 20 checklist. Where an operable exposure pathway in Protocol 13 is further evaluated under Protocol 20 both checklists are required.

The ministry also recommends consideration of the following guidance:

- **Science Advisory Board for Contaminated Sites in British Columbia: Detailed Ecological Risk Assessment (DERA) in British Columbia Technical Guidance (2008)**.

### Ecological receptors

Despite the primary focus on assessing impacts and effects at the community or population level in ecological risk assessment, assessment at the individual organism level may be required in some circumstances, e.g. when individuals of rare and endangered species protected under the Canadian Federal **Species at Risk Act** and **BC Wildlife Act** are present. In addition, the assessment of habitat considered critical to support rare and endangered species or individuals may be required.

### Exposure pathways

Exposure pathways to be evaluated in ecological risk assessment are usually limited to direct contact and/or ingestion. The inhalation pathway of exposure is not usually
evaluated for ecological receptors, unless site-specific conditions indicate that this pathway is the primary route of exposure for a population of a species, or if an individual of a rare and endangered species frequents or resides (e.g. burrows, hibernates, etc.) at the site.

**Exposure parameters**
For relevant ecological exposure parameters, the ministry recommends use of the following sources:

- US EPA: [Wildlife Exposure Factors Handbook](#),
- California Environmental Protection Agency: [CalEcotox Database](#),
- US Geological Survey: [Wildlife and Contaminants Online](#),
- Environment Canada: [FCSAP Ecological Risk Assessment Guidance, Standardization of Wildlife Receptor Characteristics (March 2012)](#), and
- California Department of Toxic Substances Control: [Guidance for Ecological Risk Assessments (EcoNOTES)](#).

Relevant information from other jurisdictions and pertinent peer reviewed scientific literature may be used to supplement the above sources of ecological exposure parameters if the rationale for the selection of supplemental ecological exposure parameters is included in the ecological risk assessment.

**Ecotoxicity profiles**
For detailed ecological risk assessment, toxicity profiles are commonly provided for each contaminant evaluated. At a minimum, such ecological toxicity profiles should include the following information:

a) toxic effects expected from exposure,
b) the sensitivities of the different receptor groups exposed, and
c) the range of toxicities reported in the scientific literature for similar species to those present at the site under assessment.

These toxicity profiles form the basis for the selection of appropriate ecological benchmarks to be used in the ecotoxicity assessment component of the ecological risk assessment.

**Ecological benchmarks**
For the purpose of deriving Hazard Quotients (HQs), the Estimated Environmental Concentration (EEC) should be compared to Ecological Toxicity Reference Values (EcoTRVs). The ministry supports the use of EcoTRVs based on contaminant intake, dose, tissue residues, and concentrations in environmental media to which an organism is exposed.

For estimating risks to ecological receptors the use of effects levels such as Effective Dose, Lethal Dose, Effective Concentration or Lethal Concentration, for x percent of exposed organisms (i.e. EDx, LDx, ECx or LCx values, respectively) is preferred. The use of No Observed (Adverse) Effect Levels (NO(A)ELs), No Observed (Adverse) Effect Concentrations (NO(A)ECs), Lowest Observed (Adverse) Effect Levels (LO(A)ELs), or Lowest Observed (Adverse) Effect Concentrations (LO(A)ECs) and similarly derived benchmarks that are dependent on experimental design are not recommended, unless no alternative benchmark can be found for a site.

The types of ecological effect endpoints that need to be addressed at the population level for non-endangered species include acute (e.g., toxicity and lethality) and chronic processes (e.g., reproductive, growth and maintenance, and critical developmental). Carcinogenicity is not usually selected as a chronic ecological effect endpoint unless the rate of cancer incidence is sufficient to threaten survival at the population level. If a particular organism warrants protection at the level of the individual (e.g., an individual of a rare and endangered species) an appropriate chronic effect endpoint and effect level for the individual, rather than the population, should
be considered if data is available and adequate for assessment.

***Source and selection of EcoTRVs***
The ministry recommends preferential use of the US EPA ecological soil screening levels (**EcoSSLs**) as terrestrial EcoTRVs, and use of the BC Ministry of Environment **Water Quality Guidelines** (i.e. the selected TRV used for guideline derivation as specified in the Technical Appendix for a substance) as aquatic EcoTRVs.

***Supplemental agency sources for Eco TRVs***
Where EcoTRVs from the preferred sources are lacking for a substance, use of EcoTRVs from the following supplemental sources may be considered:

- US EPA: **ECOTOX Database**, 
- Oak Ridge National Laboratory: **The Risk Assessment Information System (RAIS), Ecological Benchmark Tool**, 
- California Environmental Protection Agency: **CalEcotox Database**, 
- US EPA, Region 9: **Biological Technical Assistance Group (BTAG) Recommended Toxicity Reference Values for Mammals**, 
- Centre d’Expertise en Analyse Environnementale du Québec: **Valeurs de Référence pur les Récepteurs Terrestres**, 
- Canadian Council of Ministers of the Environment (CCME): **Scientific Criteria Documents**, and 
- CCME: **Canadian Tissue Residue Guidelines for the Protection of Wildlife Consumers of Aquatic Biota**.

The most stringent of the applicable EcoTRVs from the supplemental agency sources listed above should be used in the ecological risk assessment unless it can be shown that an alternate value is more appropriate based on:

- a) the existence of a more comprehensive and contemporary published scientific assessment, 
- b) enhanced relevance (study design, exposure route, etc.) to the site, 
- c) enhanced scientific credibility, or 
- d) greater extent of supporting rationale and documentation.

Selected EcoTRVs should be accompanied by a citation and documentation of the ecological effect endpoint upon which the value is based.

***Use of de novo derived EcoTRVs***
Where no credible ecological benchmark or EcoTRV can be found, a **de novo** EcoTRV may be derived based on:

- a) the scientific literature related to the ecotoxicity of the substance, or 
- b) ecotoxicological experimental data obtained for the substance on a site specific basis (e.g., *in-situ* bioassay data obtained for a site).

The ministry recommends consideration of the following guidance:

- US EPA: **Guidance for Developing Ecological Soil Screening Levels (Eco-SSLs), Eco-SSL Standard Operating Procedure #6: Derivation of Wildlife Toxicity Reference Value (TRV) (June 2007)**, and 
- Environment Canada: **FCSAP Supplemental Guidance for Ecological Risk Assessment, Selection or Development of Site-Specific Toxicity Reference Values (June 2010)**.

The use of arbitrary uncertainty factors (UFs) in **de novo** EcoTRV derivation is discouraged. However, if data are limited and/or extrapolations are required among taxonomic groups, incorporation of an UF may be warranted.
The use of de novo EcoTRVs in risk assessments submitted in support of contaminated sites applications under Protocol 6 must be approved by a Director prior to use. Previously approved de novo EcoTRVs can be consulted in the Director’s workbook; however, where previously approved information is used at a different site a new application for a Director’s decision must be made, demonstrating the relevance and applicability of the information to the site.

**Ecological protection goals**

Ecological risks are acceptable if the effects levels at the site are less than or equal to the specified effects level for the particular land use applicable at the site, as stated in Protocol 28, “Standards Derivation Methods”.

**Hazard index**

A hazard index needs to be calculated for each substance that exceeds a numerical standard in one or more media at the site, including all relevant exposure media regardless of whether substance concentrations exceed the numerical standards in all exposure media.

**Toxicity testing**

If toxicity testing is considered for use as a line of evidence in ecological risk assessment, the ministry recommends toxicity test methods established by the following agencies:

- Environment Canada: [Biological Test Method Series](https://www.ec.gc.ca/psw-eng.aspx),
- US EPA, OCSPP Harmonized Test Guidelines,
- American Society for Testing and Materials (ATSM): [Environmental Toxicology Standards](https://www.astm.org/),
- International Organization for Standardization (ISO): [TC 147/SC 5 – Biological Methods](https://www.iso.org/).  

In selecting appropriate toxicity tests from the above-mentioned agencies, the following criteria should be considered:

a) relevance of the test species to species present at the site,

b) sensitivity of the test species to the contaminant(s) of concern,

c) relevance of the test exposure duration,

d) appropriateness of the test effect endpoints to the mechanism of toxicity of the contaminant(s) of concern, and

e) the extent and representativeness of site phylogenetic diversity when batteries of toxicity tests are used.

In addition to the above agencies’ ecological toxicity tests, the toxicity test methods provided in the following guidance documents are also recommended for use:

- Environment Canada: [FCSAP Supplemental Guidance for Ecological Risk Assessment. Toxicity Test Selection and Interpretation. (March 2010)](https://www.ec.gc.ca/psw-eng.aspx), and

**Weight-of-evidence**

For use of the weight-of-evidence approach in ecological risk assessment the following guidance is recommended:

Requirements for human health and ecological risk assessment reports

Procedure 10, “Requirements for Service Application Resubmissions, Withdrawals and Amendments” provides direction regarding expectations for human health and ecological risk assessment reports submitted for review under the Regulation. It is recommended that this procedure be followed to prevent errors and omissions that may deny or delay approval of applications for contaminated sites legal instruments.

Performance verification plans

Administrative Guidance 14, “Performance Verification Plans, Contingency Plans and Operations and Maintenance Plans” describes the plans required to support risk-based remediation involving risk controls, when plans are required, and how they should be prepared, implemented and used.

A performance verification plan must be included in applications for contaminated sites legal instruments that rely on risk controls to meet risk-based standards (based on a screening level or detailed risk assessment).

Approval under protocol 6

Protocol 6, “Eligibility of Applications for Review by Approved Professionals”, requires Director’s approval of certain risk assessment methodologies before a recommendation by an Approved Professional for a risk-based contaminated sites legal instrument can be made. The ministry’s application form and instructions for obtaining a Director’s approval can be found on the ministry’s Site Remediation website.

For more information, please direct inquiries to site@gov.bc.ca.

Revision history

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