Technical Guidance 7: Supplemental Guidance for Risk Assessments

May 2018

Stakeholder Comments / Recommendations	Ministry Response(s)
The reviewers request that this text (i.e. paragraph on sensitive receptors) be removed. The evaluation of these groups is difficult due to lack of recommended TRVs /exposure assumptions; this is likely why these subgroups are not included in numeric standards derivation. These subgroups cannot be accurately identified as being present or absent on a contaminated site and may not be distinguishable from the general population (e.g., we don't know if a residential building will have children presenting pica behaviors as occupants or if workers at an industrial/commercial building will become or are pregnant/vulnerable due to health status).	The ministry cannot remove the requirement to include sensitive receptors from HHRA. Health Canada PQRA states: *"Critical receptors in all […] subgroups should be identified and evaluated if it is anticipated that these groups could be exposed to on-site contaminants".* Similar language can be found in Health Canada DQRA: "*In identifying potential receptors, consideration should be given to potentially sensitive and/or unique receptors who may be exposed to increased levels of risk".*
The reviewers ask that the following text will be added to the section with regards to sensitive receptors, The Ministry does not expect these receptors to be evaluated on a typical contaminated site. However, this may be required on a site specific basis where the Ministry considers it to be warranted.	The ministry continues with the current policy for protection of human health, including sensitive receptors (see previous response).
The reviewers edited the comment box referring to acute exposures to reflect that workers are not tied to a specific land use – i.e. those regulated under Worksafe BC. Removed the word "sub-surface" as exposures for these receptors could occur in surface soils as well. The edit allows for the clarification that the ≥90 days exposure scenario is the defining factor for not requiring evaluation.	The reference to "sub-surface" was removed from the note box. The mention of utility, trench, and construction workers was retained, as these are the most common examples of receptors exposed acutely at contaminated sites.
Remove the reference to the Health Canada spreadsheet tool. This is no longer endorsed by CCME/HC – they cite numerous errata and do not take any responsibility. This section refers to specific guidance from Health Canada that is recommended to be used and is problematic to recommend a source no longer endorsed by Health Canada/CCME. Remove the reference to the soil vapour assessment documents from this section. The Part VII reference is also listed in soil vapour guidance section following. Redundant and mainly a characterization document that belongs in the soil	The link to the spreadsheet tool and vapour guidance was removed.

Stakeholder Comments / Recommendations	Ministry Response(s)
vapour section.	
Recommend addition of a comment box with the following text: The Table 7 list in the PQRA guidance lists PEFs for 44 individual PAHs. Protocol 30 refers to the CCME 2010 PAH soil quality document, which only lists 9 individual PAHs and, in Table 1, lists 8 of those CCME PAHs (benzo[g,h,i]perylene) is excluded from Table 1 of Protocol 30). This creates potential inconsistency about what should be evaluated. The comment box indicating that only those 8 PAHs identified in Table 1 of Protocol 30 need be evaluated using PEFs relative to benzo[a]pyrene addresses this inconsistency.	The following text was added in Protocol 30: *"Substances that do not meet the Protocol 30 criteria 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."*
Revise text where referring to the use of US EPA documents on exposure parameters. Previous wording suggested that all of these exposure scenarios/methods must be followed but this would result in inconsistency (e.g., inhalation of volatiles while showering and garden produce uptake not typically evaluated or required where no drinking water control is recommended). Clarify that these documents are recommended where warranted and needed, so as to not contradict Health Canada and Ministry policy.	The text has been revised to provide clarification.
Has the toddler lead TRV been used/published as endorsed by the MoE? The industrial standard only includes the adult receptor. For lead, we understand this is a risk-specific dose, not a tolerable daily intake or oral reference dose. Does MoE have TRVs for child and adult, or for adult only? If the toddler TRV in Wilson and Richardson (2013) is not formally endorsed by the ministry, suggest revising text to state that the MoE approved TRV is specific to adults as this could cause confusion with the adult TRV being used for assessing toddlers and under-predicting risk.	The lead TRVs in TG7 for toddler and adult are both endorsed by the ministry. The TG7 hyperlink is updated to guide towards the TRV derivation document.
Add the adjustment of target levels to the requirements for use in supplemental human health TRVs.	The adjustment of target levels were added to the requirements for use in supplemental human health TRVs.
Revise text. RAGs Part E Log K_{OW} values may be outdated for certain substances, with the US EPA providing Log K_{OW} s from more recent sources as well (e.g., US EPA's EPI Suite is used	The reference to RAGS E was removed as a K_{OW} source and added as the rationale for the K_{OW} less than 4.5 cut off value.

Stakeholder Comments / Recommendations	Ministry Response(s)
as a source of Log K_{OW} in ORNL's RAIS). Note: For some substances (e.g., high molecular weight PAHs with log K_{OW}'s greater than 5), RAGS Part E indicates such substances are "outside the effective predictive domain" of the models used in the guidance. This limitation increases the uncertainty in exposure intake calculations if the recommended equations are used. Is it expected that such substances will be evaluated, and uncertainties discussed in the uncertainty section? Or is the limitation of the models such that the calculations are of little value and therefore, dermal exposure via water for substances "outside the predictive domain" need not be evaluated quantitatively and they remain uncertain? Note: Consider including rationale for this distinction between less than 4.5 and equal to or greater than 4.5.	The ministry agrees that an upper bound K_{OW} may be relevant for the dermal exposure pathway, and may consider adding such a value in the future.
Further clarity is required re: dermal exposure to metals in groundwater. The guidance currently states that "If the log K_{OW} 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." The question remains, does this excluded metals, which do not have K_{OW} values?	Metals are excluded. Clarification regarding metals was added to the section in TG7.
Clarification is requested on the ministry expectations related to the note box that cautions practitioners about the use of Protocol 1.	The following text was added, *"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."*
Request to move the quantifiable risk-based standards, equations and default assumptions currently in Protocol 1 and the Tier 1 policy decisions into TG7 and/or draft Protocol 28.	The ministry is considering the revision of Protocol 1 in the future.
Request to revise a species at risk "frequenting or residing" into "residing" the site. Frequenting the site wouldn't necessarily result in inhalation exposures being a primary pathway. The description of resides	The text was not revised. Frequenting a contaminated site may result in a primary exposure pathway.

Stakeholder Comments / Recommendations	Ministry Response(s)
includes higher exposure scenarios for inhalation.	
Preferential use of EcoSSLs: From a practical point of view this will result in defaulting to the matrix numerical soil standards (i.e., toxicity to soil invertebrates and plants) for many substances (e.g., most metals) as the EcoSSLs are typically lower than the CSR standards for one or more of the ecological receptor groups (plants, invertebrates, birds, mammals) for which EcoSSLs have been developed.	The decision to give preference to the use of the EcoSSLs continues and was based on the knowledge that many small sites remediated to risk-based standards do not require a risk assessment scope that warrants a TRV selection process and to provide those sites with a conservative alternative.
Issue 4 of the Policy Decision Summary contains an error with respect to protection level for AL/PL (EC10 stated), corrected in FAQs (EC20 with rationale provided). A new reference needs to be listed there.	A new reference to Protocol 28 was provided in a new section named "Ecological Protection Goals".
Revise the note box referring to the use of *de novo* EcoTRVs in risk assessments with a reference to the Director's Approval Workbook - http://www2.gov.bc.ca/gov/content/environment/air-land-water/site-remediation/guidance-resources/approvals	The reference was added.
Insert a qualifier that not all sites warrant automatic eco-toxicity tests.	A qualifying sentence was added.
Overall Comment for the document – we recommend the insertion of a reference list rather than web-links to external sources that cannot be maintained by the Ministry: As web-links change or die, it may be more useful to have complete references to refer to (e.g., RAGS Part A, Volume 1 has a reference number of EPA/540/1-89/002).	Hyperlinking within guidance documents is the current practice within the ministry and the ministry strives to keep hyperlinks up to date. The ministry may consider a different format in the future.
Editorial changes provided in track changes	Where the suggestions provided greater clarity the changes were made.
The following text was added: *"Substances that do not meet the Protocol 30 criteria 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."* and, "*It is emphasized that Protocol 30 is limited to the classification*	The ministry added a note box with the following statement, "*The ministry does not currently require the inclusion of the potentially carcinogenic effects of lead in human health risk assessment.*" The following paragraph was clarified, "Recognizing that a carcinogenic substance may elicit both carcinogenic and non-carcinogenic effects,

Stakeholder Comments / Recommendations	Ministry Response(s)
of carcinogens, and should not be considered as a classification of TRVs."	both endpoints should be assessed in detailed human health risk assessments of such substances '*where suitable TRVs are available.' "*