Protocol 20 – Detailed Ecological Risk Assessment Requirements (Version 1 Draft 7)

General Comments Related to Protocol 20 sections

Section/Issue	Comments	Stakeholder Recommendation	Ministry Response
3.0 Detailed Ecological risk assessment checklist	**Reference to Technical Guidance 7** In Section 3.0 of the Draft Protocol 20, it is stated that the risk assessment "must follow the risk assessment methodology, procedures and guidance in Technical Guidance." It is not clear why the reader is referred to Technical Guidance 7 as more comprehensive risk assessment methodology, procedures and guidance are provided in the Detailed Ecological Risk Assessment (DERA) in British Columbia Technical Guidance, which is referenced much later in Draft Protocol 20. The methodology, procedures and guidance provided in DERA are more complete and reflect the current state of the science. In addition, there may be confusion regarding acceptable practice as some recommendations in Technical Guidance 7 conflict with the guidance provided in DERA (e.g. DERA specifically states that TRVs derived by Oak Ridge National Laboratory should be considered preliminary while Technical Guidance 7 refers to Oaks Ridge as a preferred source for TRVs).	It is suggested that the ecological risk assessment guidance provided in Technical Guidance 7 either be removed or aligned with DERA to avoid confusion among practitioners.	Technical Guidance 7 is the ministry RA guidance and the Science Advisory Board DERA guidance document is external to the ministry. If there are differences between the Technical Guidance 7 and DERA guidance, the ministry usually gives preference to Technical Guidance 7. However both these documents are guidance only, and if acceptable rationale is provided alternative methods and approaches can be used. The wording for the Technical Guidance 7 reference was changed from "must follow" to "expected to follow".
	Reference to Ministry Ecological Risk Assessment Policy Summary Question 4.5 asks "Did the level of protection used in the DERA meet that specified in the ministry ecological risk assessment policy decision summary for the appropriate land use or media?" The MOE policy decision summary was related to Protocol 1 – Tier I (preliminary) Ecological Risk Assessment Guidance.	Since the policy decision summary is dated and the issue of acceptable level of effect was addressed more recently in DERA, it would be preferable to reference DERA.	Similar to the previous response, the ministry usually gives preference to Technical Guidance 7, unless acceptable rationale is provided.
	Clarify bioaccumulation definition Q 1.15 [previous version numbering] asks "if	Some clear direction from the MOE in terms of definitions and requirement for ERA would be helpful in assisting with	This question was deleted from the protocol as it is a subset of the question on relevant exposure pathway

	contaminants that bioaccumulate / biomagnify" have been identified. These two words have two different meanings in toxicology and risk assessment: the former referring to the accumulation of contaminants most often from water and diet and include all contaminants, the later referring to higher body residues with trophic transfer. There is considerable uncertainty within the BC risk assessment community regarding requirements for ecological risk assessments when it comes to contaminants that bioaccumulate (e.g. metals in general) versus those that biomagnify (e.g. selenium, methyl mercury). Also: Tissue ingestion is relevant whenever tissue ingestion contributes to total dose, not just for substances that may be bioaccumulative	CSAP Society reviews.	identification.
	Clarify when HQ exceedance is acceptable Q 5.4 asks "If an ecological hazard quotient exceeded one, but the level of risk was considered acceptable, was a rationale provided". I have some concern with the lack of a definition of acceptable risk. DERA provides narrative description of risk (negligible, low, moderate and high), however it is not clear what is acceptable. Although the concept is tied to some extent to the measurement and assessment endpoints, there is considerable uncertainty that a HQ of 2 that is determined to be negligible would be considered so by all, or even most, practitioners especially in light of the fact that the acceptable HQ for human health must be less than 1.0.		The acceptability of a DERA HQ which exceeds the 1.0 benchmark will be left to the professional judgement of the risk assessor. The ministry expects the risk assessor to consider the inherent conservatism, risk and uncertainty of the factors used to derive the HQ value and fully document their rationale related to the acceptability of the risk estimate.

Section V Professional Statements and Signatures	**Section V Professional Statements and Signatures** The three statements in Section V are vague and do not add to the quality of the review. For	It is anticipated that the review of the detailed ecological risk assessment will be signed and stamped by a CSAP. This should be considered sufficient evidence that the reviewer knows how to conduct a detailed ecological risk	The risk assessor may be a non-Approved Professional risk assessment specialist. We are responding to the requirement of CSR section 63 which requires risk assessors to certify they have demonstrable experience in

	example, the statement "the detailed ecological risk assessment upon which this checklist is based has been performed in accordance with approved methodology, procedures, guidance and standard professional practice" is vague in identifying which jurisdiction has approved the methodology and under what circumstances it should be used. Also "Most RAs will have more than one contributor...[provide a] bigger space?"	assessment is taking their review role seriously and has the necessary experience conducting investigations of this type. If any of these elements are missing, the approved professional could be in violation of their code of ethics from their professional regulating body.	remediation of the type of contamination found at the site. A reference to section 63 was added to the section. Instructions added: If multiple signatories add additional Part 3 forms as needed. NOTE: All signatories to Part 3 are jointly and equally responsible for all risk assessment aspects of the Detailed Ecological Risk Assessment.
Specific I Comments Related to Protocol 20 Questions			
Question 1.1	Add question: Does the investigator identify who the major participants are in the investigation and state their qualifications?	Add this question from CSAP Society guidance	Question added with edits: Does the DERA identify who the major participants are in the risk assessment and state their qualifications?
	Add question: Does the report or cover letter provide reliance of the report to the Ministry (and the Approved Professional if submitted for a Protocol 6 review)?	Add this question from CSAP Society guidance	Suggested new question was not added as the issue is addressed by adding the signature block section.
Question 1.2	Add question: Does the investigator describe how the method(s) of investigation and the findings of the previous stages(s) were used to design and carry out the current study?	Add this question from CSAP Society guidance	Question added with edits: Does the DERA describe how the method(s) of assessment and the findings of any previous investigation(s) were used to design and carry out the current assessment?
Question 1.3	Add question: Does the investigator describe the extent to which the previous investigations were/were not relied upon?	Add this question from CSAP Society guidance	Question added with edits: Does the DERA describe the extent to which any previous assessment(s) were/were not relied upon?
Question 1.4	Add question: If there were any MOE pre-approvals, is the documentation attached to the risk assessment?	Add this question from CSAP Society guidance	Question added with edits: If ministry preapprovals apply to the DERA, has all required preapproval documentation been provided with the risk assessment?
Question 1.5	Add question: Does the report make it clear what conditions were required (if any) for the instrument being applied for (e.g., Schedule B conditions for a Certificate of Compliance)?	Add this question from CSAP Society guidance	Question added

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Question 2.6	Add question: Have the contaminants of potential concern been identified?	Add this question from CSAP Society guidance	Question added with minor edits: Were potential contaminants of concern identified?
Question 2.8	Add question: Have all relevant exposure scenarios (direct and indirect) been identified and considered?	Add this question from CSAP Society guidance	Question added with edits: Were all relevant exposure pathways (direct and indirect) identified and considered?
Question 2.11	Modify question: Has an [acceptable] rationale been provided for excluding any contaminants from the risk assessment that exceed the appropriate standards, criteria, or guidelines? [Has a rationale been provided for excluding unscheduled substances that are site-related?] [modification of the BCMOE question in brackets]	Modify question to add "acceptable" to rationale requirement. Add requirement for excluding site related unscheduled substances.	Determining the acceptability of the rationale for excluding contaminants is the responsibility of the risk assessment reviewer (either ministry or Approved Professional); therefore the 'acceptable' qualifier is not required. There is no legal requirement to provide rationale for excluding non-prescribed substances under the CSR; however, additional requirements regarding the control of such substances as pollution at a site may be imposed under the *Environmental Management Act*.
Question 2.12	Modify question: Has a qualified biologist conducted a site-specific survey of potential receptors (terrestrial and/or aquatic)?	Qualify with: If site-specific information are unavailable or limited.	The question was simplified to: "Did a qualified biologist visit and assess the site?" If there are unusual circumstances where a biologist would not visit the site, these must be documented in the comments section.
	Delete question: If lines of evidence are established are they composed of single or closely related measurement endpoints only, i.e., they do not mix weakly related endpoints such as amphipod toxicity and algae toxicity?	Delete and modify the related weight of evidence question	The question was deleted and the following modified weight of evidence question 2.19 was adopted: Were future contaminant concentrations and potential contaminant degradation products considered?
Question 2.18	Modify question: If the assessment of risk will be based on several lines of evidence, has the lines of evidence been identified and assigned magnitude of effect categories and weightings in the Problem formulation prior to data analysis?	Modify to: If the assessment of risk will be based on several lines of evidence, has the approach been described for evaluating individual lines of evidence and integrating findings across lines of evidence?	The modified question was adopted and further edited: If the assessment of risk was based on several lines of evidence, was the approach used to evaluate individual lines of evidence and to integrate findings across lines of evidence documented?
Question 3.2	Add question: Has the investigator evaluated each applicable land use scenario (current and	Add this question from CSAP Society guidance	Question added

	future)?		
	Add question: Have the most appropriate exposure media (soil, groundwater, sediment, vapour, etc) within or adjacent to the legal parcel being risk assessed been used to characterise exposure?	Add this question from CSAP Society guidance	Suggested new question was not added as determining the appropriateness of the selected exposure media is the responsibility of the risk assessment reviewer.
Question 3.3	Add question: Are point estimates of exposure concentrations reasonable and is supporting rationale documented?	Add this question from CSAP Society guidance	The following modified version of the question was adopted: Was supporting rationale provided for methods used to estimate exposure point contaminant concentration(s)?
	Add question: Have appropriate receptor characteristics been selected and documented?	Add this question from CSAP Society guidance	Suggested new question was not added as determining the appropriateness of the selected receptor characteristics is the responsibility of the risk assessment reviewer.
	Add question: Where field data were collected, are the environmental media adequately characterized to represent exposure to each receptor/receptor group?	Add this question from CSAP Society guidance	Suggested new question was not added as determining the adequacy of the media characterization is the responsibility of the risk assessment reviewer.
Question 3.4	Modify: Are the exposure model equations provided and referenced?	Modify to: If a fate and transport model or other exposure model has been used, are the model equations provided and referenced?	Modified question adopted: If a fate and transport model or other exposure model was used, were model equations provided and referenced?
	Add question: Are the tools used in the exposure assessment appropriate for the nature of the site, level of investigation and route(s) of exposure?	Add this question from CSAP Society guidance	Suggested question was not added as determining the adequacy of exposure assessment tools is the responsibility of the risk assessment reviewer.
Question 3.5	Modify question: Has a worked calculation of the exposure model been provided for each exposure route in the risk assessment?	Modify to: If an exposure model has been used, have equations, along with the input data, been provided to support an independent QA check for each exposure route in the risk assessment?	Modified question adopted: If an exposure model was used, were equations and the input data provided to support an independent quality assurance check for each exposure route in the risk assessment?
Question 4.2	Modify question: Has a rationale for the selection of the toxicity reference values (TRVs) been provided?	Modify to: If TRVs are used, has a rationale for the selection and/or development of the toxicity reference values (TRVs) been provided?	Modified question adopted: If toxicity reference values (TRVs) were used, was a rationale for the selection and/or development of the TRVs provided?
Question 4.3	Modify: Have the TRVs been referenced?	Modify to: If TRVs are used, have the TRVs been referenced? If developed	Modified question adopted: If TRVs were used, was the source of the TRVs

		de novo, is the derivation process documented?	referenced? If TRVs were developed *de novo*, was their derivation documented?
	Add question: If dose-response or concentration-response relationships are used to estimate actual risks rather than to develop hazard quotients, have those relationships been developed or applied using sound scientific rationale?	Add this question from CSAP Society guidance	Suggested new question was not added as the issue is addressed by question 5.3
Question 4.6	Modify question: If reference sites were used in the risk assessment, has a rationale for their locations been provided which includes consideration of contaminant concentrations and important controlling factors for any biological endpoint (e.g. grain size, depth, etc.)?	Modify to: If risks were evaluated relative to references sites or reference conditions, has rationale for selection of reference sites or reference data been provided, and have important confounding variables (e.g., texture, pH, grain size, depth etc.) been addressed and considered?	The modified question was adopted and further edited: If risks were evaluated relative to a reference site(s) or reference condition(s), was rationale for the selection of the reference site(s) or reference condition(s) provided? Were confounding variables (e.g. soil: texture, pH, grain size, depth etc.) addressed and considered in the evaluation?
Question 4.7	Add question: If site-specific toxicity testing was conducted, did the test methods meet quality standards of an agency such as Environment Canada or ASTM?	Add this question from CSAP Society guidance	Question added: If site-specific toxicity testing was conducted, did the test method(s) used meet the quality standards of Environment Canada, ASTM or another recognized government agency?
	Add question: If site-specific toxicity testing was conducted, was the toxicity testing program pre-	Add this question	Suggested new question was not added as the preapproval requirement is
	approved reviewed by BC Ministry of the Environment and, if so, was supporting documentation provided?		covered in question1.4
Question 4.8	Modify question: If site-specific toxicity tests were conducted, did the concentrations used include the high exposure zone of the site?	Modify to: If site specific toxicity testing was conducted, were concentrations used representative of the concentrations ranges determined by the DSI?	A modified version of the question was adopted: If site-specific toxicity tests were conducted, did the tests include samples from the most contaminated area(s) of the site?
	Add question: If site-specific toxicity testing was conducted, were the tests selected appropriate for the site, media and receptor of concern?	Add this question	Suggested new question was not added as determining the appropriateness of the toxicity tests is the responsibility of the risk assessment reviewer.
	Add question: Were the uncertainties associated with the hazard quotient documented?	Add this question	Suggested new question was not added as issue is addressed by the more general uncertainty question 5.7
Question 5.5	Modify question: Have risks for all open	Modify to: Have risks for all open	The original question was retained as

	contaminant of concern-receptor-pathway combinations from the problem formulation been assessed and categorized as acceptable or unacceptable?	contaminant of concern-receptor-pathway combinations from the problem formulation been described? Have both risks and uncertainties been sufficiently characterized so that a decision about their acceptability can be made by risk managers (if so, is a rationale provided)?	the ministry believes the onus lies with the risk assessor conducting the assessment to determine and definitively state if the risk/hazard determined in their risk assessment is or is not acceptable.
	Add question: If the risk characterization is based on a weight of evidence approach, is the approach for characterizing risks based on the integrations of lines of evidence appropriate?	Add this question	Suggested new question was not added as determining the appropriateness of the approach for characterizing risks based on the integration of lines of evidence is the responsibility of the risk assessment reviewer.
Question 5.8	Modify question: If changes were made to preliminary weightings (e.g., during problem formulation) in a weight of evidence evaluation, was a rationale provided?	Modify to: Is the weight of evidence evaluation consistent with the approach laid out during problem formulation?	A modified version of the question was adopted: If a weight of evidence evaluation was completed, were the weight of evidence conclusions determined in a manner consistent with the approach laid out in the problem formulation?
	Delete question: If summary statistics were used in the exposure assessment, were the implications of maximum concentrations and hotspots above the assessed exposure concentrations discussed?	Delete question	Question deleted as similar to question 3.3
	Delete question: If alternate TRVs (i.e., other than those recommended in Technical Guidance 7, “Supplemental Guidance for Risk Assessments”) were used did the selected value(s) have a large impact on the conclusions and was this discussed?	Delete question	Question deleted as ministry preapproval is required to modify TRVs and this issue is covered by question 1.4