

Appendix F
Draft Version 1.1 – September 13, 2007

Checklist for Review of Risk Assessment Reports

This checklist was developed at the request of the Roster Steering Committee’s Risk Assessment Subcommittee to guide Contaminated Sites Approved Professionals (CSAP) in their review of ‘low to moderate risk’ sites, as defined by a CSR Protocol, where the Contaminated Sites Regulation risk based standards for remediation are being applied. It has been assumed that the site investigation(s) that supplied the data for the risk assessment has/have been reviewed and approved by a Standards Assessment Approved Professional and further review of the quality of the site investigation report (e.g. to confirm that contaminant delineation has been achieved) is not warranted.

It is noted that a large amount of professional judgment is required to adequately evaluate whether or not a risk assessment has been appropriately completed. The checklist provided below is intended to assist a reviewer to determine if an acceptable approach has been used. Use of the checklist will assist in the assessment of the adequacy of existing data and whether or not a defensible approach has been developed. It is not intended that the checklist be used as the definitive decision-making tool (i.e., a reviewer should not add up the “yes” and “no” responses to determine the adequacy of the investigation).

Issue	Yes	No	Comments
PART 1: ECOLOGICAL RISK ASSESSMENT			
General Considerations			
Does the site meet the requirements of the high priority test and is therefore eligible for a CSAP recommendation under Protocol 6?			
Has the site been properly classified under Protocol 6 as eligible for self-review or peer-review, and if required has a peer reviewer signed the report?			
Has the site investigation report that			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
has supplied the risk assessment data been reviewed and approved by a qualified professional?			
In the site investigation upon which the ecological risk assessment was based, were sample media from all relevant habitats used to determine exposure concentrations?			
Have the objectives of the ecological risk assessment been stated?			
Has a general description of the property, surrounding area and AECs been included?			
Has the potential for off-site migration been evaluated?			
Have contaminant concentrations and degradation products over time been considered?			
<i>Terrestrial Receptors</i>			
Problem Formulation			
Data QA/QC – Does original laboratory data match tabulated data?			
Data QA/QC - Have summary statistics been developed and used properly?			
Have the contaminants of potential concern been identified based on appropriate standards, criteria, and			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
guidelines?			
Has an acceptable rationale been provided for screening out any contaminants that exceed the appropriate standards, criteria, or guidelines?			
Have contaminants of potential concern been screened for bioaccumulation and biomagnification? Does this screening identify high risk classification substances?			
Was a site-specific survey of potential receptors conducted?			
Have on/off-site receptors of potential concern been identified based on generally accepted practices (e.g. maximally exposed, rare/endangered species, valued by humans, available data etc.)?			
Have all reasonable exposure pathways been identified?			
If contaminants that biomagnify have been identified, have appropriate exposure pathways been identified?			
Has the Problem Formulation identified the current and potential future land use of the Site and surrounding area?			
Have assumptions associated with current and future land use been			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
identified (e.g. development scenario)?			
Has the Problem Formulation considered all relevant exposure scenarios (direct and indirect)?			
Has a conceptual exposure model showing the results of the Problem Formulation been included? Is it accurate?			
If the assessment of risk will be based on several lines of evidence, have the lines of evidence been identified and given weight in the Problem Formulation?			
Is there a clear statement of which contaminant-pathway-receptor combinations warrant further assessment?			
Is there a reasonable rationale if contaminant-pathway-receptor combinations are excluded from further assessment?			
Have the assessment and measurement endpoints for complete exposure pathways warranting further assessment been defined and are they consistent with generally accepted MOE policy?			
Exposure Assessment			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
Has each contaminant-pathway-receptor combination identified for further assessment in the Problem Formulation been assessed in the Exposure Assessment?			
Has each land use scenario been assessed in the Exposure Assessment?			
Have the most appropriate exposure media been used to characterize exposure?			
Are point estimates of exposure concentration based on reasonable concentrations with justification documented?			
Have appropriate receptor characteristics been selected and have they been tabulated?			
Have appropriate exposure equations been used?			
Are the tools used in the exposure assessment (fate and transport, food chain models, others outlined in DERA) appropriate for the nature of the site, level of investigation and route(s) of exposure?			
Have model assumptions been clearly stated or tabulated with references?			
Are the exposure results presented clearly and appropriately?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
Is an example exposure calculation included for each potentially significant exposure route in the risk assessment?			
Toxicity/Effects Assessment			
If site-specific toxicity testing has been conducted, did the test methods meet quality standards of an agency such as Environment Canada or ASTM?			
If site-specific toxicity testing was conducted, were the test concentrations representative of the concentration range determined by the DSI?			
If site-specific toxicity testing was conducted, were the tests selected appropriate for the site, media and ROC?			
If reference sites were used in the assessment, were their locations and contaminant concentrations acceptable?			
If ecological surveys (e.g. plant community, birds) were conducted, were methods sound, sampling locations appropriate and seasons appropriate?			
Are the point estimates of acceptable contaminant concentration (herein referred to as TRV) (eg. EC20,			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
LOAEL) appropriate for use in the current assessment and are they consistent with the exposure data?			
Have the TRVs been referenced?			
Are the TRVs consistent with measurement endpoints identified in Problem Formulation?			
Has the endpoint associated with each TRV been identified?			
Have the potential interactions of the COPCs been discussed?			
Risk Characterization			
If hazard quotients were calculated, was the HQ tabulated for each contaminant-receptor-pathway identified in the Problem Formulation?			
If the risk characterization is based on a weight of evidence approach, is the weight given to each line of evidence appropriate?			
Are the conclusions (i.e., risk characterization) consistent with the assessment endpoints and supported by the results?			
If summary statistics were used in the exposure assessment, were the implications of maximum			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
concentrations or hotspots stated?			
If site-specific, risk-based standards are proposed, are they supported by the data?			
Are uncertainties in the risk assessment predictions stated, including their implications on risk predictions?			
In the absence of CSR risk based standards for ecological receptors, have risks been categorized (e.g. low, medium, high) and are the categorizations appropriate for each COPC?			
<i>Aquatic Receptors</i>			
Problem Formulation			
Data QA/QC – Does original laboratory data match tabulated data?			
Data QA/QC - Have summary statistics been developed and used properly?			
Have the contaminants of potential concern been identified based on appropriate standards, criteria and guidelines?			
Has an acceptable rationale been provided for screening out any contaminants that exceed the appropriate standards, criteria, or guidelines?			
Have contaminants of potential concern			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
been screened for bioaccumulation and biomagnification?			
Was a site-specific survey of potential receptors conducted?			
Have on/off-site receptors of potential concern been identified based on generally accepted practices (eg. maximally exposed, rare/endangered species, valued by humans, available data etc.)?			
Have all reasonable exposure pathways been identified?			
If contaminants that biomagnify have been identified, have appropriate exposure pathways been identified?			
Has the Problem Formulation identified the current and potential future land use of the Site and surrounding area?			
Has an accurate conceptual exposure model showing the results of the Problem Formulation been included?			
If the assessment of risk will be based on several lines of evidence, have the lines of evidence been identified and given weight in the Problem Formulation?			
Is there a clear statement of which contaminant-pathway-receptor combinations warrant further			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
assessment?			
Is there a reasonable rationale if contaminant-pathway-receptor combinations are excluded from further assessment?			
Have the assessment and measurement endpoints for complete exposure pathways warranting further assessment been defined and are they consistent with generally accepted MOE policy?			
Exposure Assessment			
Has each contaminant-pathway-receptor combination identified for further assessment in the Problem Formulation been assessed in the Exposure Assessment?			
Have the most appropriate exposure media been used to characterize exposure (e.g. groundwater vs. surface water)?			
Are the point estimates of exposure concentration based on reasonable concentrations with justification documented?			
Have appropriate receptor characteristics been selected and have they been tabulated?			
Have appropriate exposure equations			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
been used?			
Are the tools used in the exposure assessment (fate and transport, food chain models, or others outlined in DERA) appropriate for the nature of the site, level of investigation and route(s) of exposure?			
Have model assumptions been clearly stated or tabulated with references?			
Are the exposure results presented clearly and appropriately?			
Is an example exposure calculation included for each potentially significant exposure route in the risk assessment?			
Toxicity/Effects Assessment			
If site-specific toxicity testing has been conducted, did the test methods meet the quality standards of an agency such as Environment Canada or ASTM?			
If site-specific toxicity testing was conducted, were the test concentrations representative of the concentration range determined by the DSI?			
If site-specific toxicity testing was conducted, were the tests selected appropriate for the site, contaminated media and ROC?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
If reference sites were used in the assessment, were their locations and contaminant concentrations acceptable?			
If ecological surveys (e.g. benthic invertebrates) were conducted, were methods sound, sampling locations appropriate and seasons appropriate?			
Are the point estimates of acceptable contaminant concentration (herein referred to as TRV) (eg. EC20, LOAEL) appropriate for use in the current assessment and are they consistent with the exposure data?			
Have the TRVs been referenced?			
Are the TRVs consistent with measurement endpoints identified in Problem Formulation?			
Has the endpoint associated with each TRV been identified?			
Have the potential interactions of the COPCs been discussed?			
Risk Characterization			
If hazard quotients were calculated, was the HQ tabulated for each contaminant-receptor-pathway identified in the Problem Formulation?			
If the risk characterization is based on a			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
weight of evidence approach, is the weight given to each line of evidence appropriate?			
Are the conclusions (i.e., risk characterization) consistent with the assessment endpoints and supported by the results?			
If summary statistics were used in the exposure assessment, were the implications of maximum concentrations or hotspots stated?			
If site-specific, risk-based standards are proposed, are they supported by the data?			
Are uncertainties in the risk assessment predictions stated, including their implications on risk predictions?			
In the absence of CSR risk-based standards for ecological receptors, have risks been categorized (e.g. low, medium, high) and are the categorizations appropriate for each COPC?			
PART 2: HUMAN HEALTH RISK ASSESSMENT			
General Considerations			
Does the site meet the requirements of the high priority test? and therefore			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
eligible for a CSAP recommendation under Protocol 6.			
Has the site been properly classified under Protocol 6 as eligible for self-review or peer-review, and if required has a peer reviewer signed the report?			
Have the site investigation and remediation confirmation (if applicable) report(s) that supplied the risk assessment data been reviewed and approved by a qualified professional?			
Did the site investigation(s) upon which the HHRA was based provide exposure concentrations for all relevant exposure routes?			
Have the objectives of the HHRA been stated?			
Has a general description of the property, surrounding area and AECs been included?			
Has the potential for off-site migration been evaluated?			
Have contaminant concentrations and degradation products over time been considered?			
Problem Formulation			
Data QA/QC – Does original laboratory			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
data match tabulated data?			
Data QA/QC - Have summary statistics been developed and used properly?			
Have the contaminants of potential concern been identified based on appropriate standards, criteria, and guidelines?			
Has an acceptable rationale been provided for screening out any contaminants that exceed the appropriate standards, criteria or guidelines?			
Have contaminants of potential concern been screened for bioaccumulation and biomagnification?			
Have all reasonable exposure pathways been identified?			
If contaminants that biomagnify have been identified, have appropriate exposure pathways been identified?			
Has the Problem Formulation identified the current and potential future land use of the Site and surrounding area?			
Have both current and future land use scenarios been considered? and were the assumptions made appropriate?			
Has the Problem Formulation considered all relevant exposure scenarios?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
Has a conceptual exposure model showing the results of the Problem Formulation been included? Is it accurate?			
Have the most sensitive on- and off-site receptors been evaluated?			
Have persons who may undertake excavation , maintenance or similar works at the Site been included as ROC?			
Are impacts likely in the top 1 metre of exposed soils?			
If hydrocarbons (or other volatiles) are present within 30 metres of buildings, has vapour intrusion been evaluated?			
If food is available from the site, was it properly evaluated?			
If contamination has the opportunity to impact the aquatic environment, have all aquatic pathways been evaluated (e.g., recreational use of water, consumption of biota)?			
If contamination has the opportunity to impact drinking water wells, has domestic water use been evaluated?			
Are impacts found in exposed surface soil? If so, are these impacts adequately delineated?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
Exposure Assessment			
Were exposure calculations conducted using the maximum measured on-site concentration(s)?			
If the maximum concentration was not used, was the selected statistic (mean, upper confidence limit of the mean, specified percentile value, etc.) appropriate and defensible given sample size and other factors?			
Have exposures to all relevant receptor age groups been identified (infant, toddler, child, teen, adult)?			
If all relevant receptor age groups have not been evaluated, has the most sensitive age group been identified?			
Were all receptor exposure characteristics drawn from accepted sources (i.e. followed the MOE hierarchy in Technical Guidance 7)?			
If an alternate source of receptor characteristics was used, was this because no Canadian data or value has been published?			
If alternate sources for exposure characteristics were used, was the source/citation clearly documented?			
If alternate sources for exposure			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
characteristics were used, are the assumptions used appropriate and adequately justified?			
Were assumptions regarding exposure duration and exposure frequency appropriate and adequately justified?			
Does the report include worked example calculations? Can those calculations be reproduced?			
Are all equations dimensionally consistent and are all units correct (i.e., are the dimensions and the units the same on both sides of the equal sign)?			
Have any models been used to predict environmental concentrations? If so, are these considered to be appropriate for the site? Are they considered to be acceptable by the MoE?			
Has soil vapour intrusion into buildings been modelled? Is the approach used considered acceptable by the MoE?			
If soil vapour or indoor air measurements were used, were they collected appropriately?			
In the case of petroleum hydrocarbons, has the MoE's surrogate approach for VPH and LEPH been adopted for quantification or exposure intakes?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
If bioavailability factors have been used, have they been applied to both the exposure terms and the toxicity terms?			
Were exposures amortized over an appropriate time period that is supported by the toxicity data?			
Toxicity Assessment			
Have all toxicity reference values used in the assessment been adopted by agencies recognized by the MoE?			
Have all toxicity reference values been selected according to the MoE's preferred hierarchical approach described in Technical Guidance 7?			
Are the toxicity reference values as specific to the route of concern as possible? Were the oral TRVs used for dermal exposure adjusted for absorbed dose?			
Were TRVs for both carcinogenic and non-carcinogenic effects considered and were the TRVs selected appropriate for the substances and exposure pathways being assessed?			
Did the toxicity values utilized correspond with the correct			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
isomer/speciation of the chemical identified on site?			
If alternative toxicity reference values have been selected, is adequate rationale provided? Did the selected value(s) have a large impact on the conclusions?			
In the case of petroleum hydrocarbons, has the MoE's approach been adopted for selection of toxicity reference values for surrogates?			
In the case of insufficient toxicity assessment, was the conclusion based on appropriate guidance?			
Risk Characterization			
Are the results of the risk assessment clear?			
Have any Hazard Quotients been reported to be greater than 1? If so, which chemicals and receptors?			
Have any Incremental Lifetime Cancer Risk Estimates been reported to be greater than 1×10^{-5} ? If so, which chemicals and receptors?			
Have worked examples of the risk calculations been provided?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
Have chemical interactions been adequately addressed?			
Are risks provided for current and future scenarios?			
Was the description and interpretation of the risk, unambiguous, appropriate, objective and well supported?			
Are the conclusions (i.e., risk characterization) consistent with the assessment endpoints and supported by the results?			
If summary statistics were used in the exposure assessment, were the implications of maximum concentrations or hotspots stated?			
If site-specific, risk-based standards are proposed, are they supported by the data?			
Were risks for any substances summed across multiple pathways, or were risks for more than one substance summed? If so, was rationale provided for additivity of risks, and is the approach taken appropriate?			
Sensitivity Analysis			
Are uncertainties in the risk assessment predictions stated explicitly, including their implications on risk predictions?			

Appendix F
Draft Version 1.1 – September 13, 2007

Issue	Yes	No	Comments
Were sources of uncertainty adequately characterized?			
PART 3: OVERALL SUMMARY			
Was the documentation of the risk assessment report adequate in addressing the ecological and human health risk arising from the contaminated site?			
Were all assumptions made explicit? Were the assumptions appropriate and supported with suitable data?			
Did the conduct of the risk assessment follow sound scientific principles?			
Is the risk assessment scientifically defensible and of sufficient quality?			
Does the risk assessment meet MoE written and verbal policies/guidance?			