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9 Appendix 1: Structure of a risk assessment report

9.1 Introduction

Health risk assessment reports should be clear and transparent in their development; stating the objective of the assessment, setting the scene (CSM summary), and clearly identifying the data sources and assumptions that the assessment has been based upon. A clear visual image of the site, contaminant source locations, potential exposed populations and exposure pathways present at the site should be conveyed, for example, site plans and schematic CSM diagrams. The risk assessment report should provide a systematic approach for characterising the nature and magnitude of the risks associated with environmental health hazards with justification for decisions made throughout the report provided at each stage.

9.2 General

The objectives of this section are to:

- provide guidance to consultants on how to report Tier 2 quantitative health risk assessments
- provide guidance to regulatory agencies/recipients reviewing risk assessment reports on what information to expect and the level of detail required based on individual situations.

Regulatory bodies should seek further information from consultants where reports:

- are not clear and transparent
- do not present a logical framework for the decisions and assumptions made in conducting the assessment.

9.3 Key principles

9.3.1 Overview

Quantitative health risk assessments should follow the guidance provided in Schedules B4 and B7 and should be divided into the five key steps listed below to ensure logical reporting of the assessment:

1. issues identification
2. data collection and evaluation (development of a CSM)
3. exposure assessment
4. toxicity assessment
5. risk characterisation (and development of site-specific target levels, if required).

The level of detail required in a risk assessment report should be appropriate to the complexity of the site and individual scenario requiring assessment. In order to make this judgment, the risk assessor and reviewer should consider:

- whether the objectives of the risk assessment have been clearly defined
- whether the CSM fully represents the site conditions and complexity
- whether the information obtained from the site assessment is robust and sufficiently characterises the current contamination status of the site, including contaminant source areas (refer to Schedule B2 for details on how to conduct an effective site assessment)
- whether the available data has been appropriately interpreted and full justification provided as to how the data has been used within the assessment — Schedule B2 also provides information on data assessment

- whether the exposure scenarios and settings selected adequately represent the relevant land uses and potentially exposed populations.

Interpretation of site data and selection of input data used in the risk modelling is paramount to the outcome of the risk assessment and requires professional judgement. In the selection of appropriate representative input data, the assessor should consider the CSM and make it clear how the input values and modelling strategy (for example, use of fate and transport models) relate to the CSM.

The risk assessment should also consider detection limits and their appropriateness in relation to the screening criteria and/or toxicity of a substance. The risk assessor should justify the reasoning behind the input values chosen for any risk assessment.

The report language should be objective and avoid the use of subjective terms such as 'heavy/medium/light contamination' which can lead to confusion. In many parts of the risk assessment, expert judgement is necessary. It should be made clear where this is the case, and all assumptions should be identified and explained.

Further information on what is required and what to include in the five-step process that comprises the fundamentals of the risk assessment are presented in the following sub-sections.

9.3.2 Issues identification

Issues identification should be part of the introductory section of the risk assessment. Information on the following should be provided:

- the nature of the problem (i.e. why this assessment is being carried out)
- the stakeholders (including off-site receptors where relevant) and their objectives (as far as possible)
- the objectives of the risk assessment (what the risk assessment is trying to determine)
- an outline of the risk management decisions that need to be made.

The relationship between the risk assessment and the risk management process should be made clear.

9.3.3 Data collection and evaluation (development of a conceptual site model)

The data collection section relies on a well-designed site assessment developed with an understanding of potential exposure pathways/routes associated with past and present land use in mind. It is assumed here that the site investigation itself is presented as a separate document (or report section) which need not be repeated in the risk assessment though the raw data relied on in the risk assessment should be included as an appendix.

The data collection section should include the following:

- identification of the data used in the risk assessment
- consideration of the data quality objectives and whether these are met by the data available
- identification of any significant data gaps.

The data evaluation section should include:

- summary of the CSM
- selection of and justification for Tier 1 screening criteria
- explanation of any fate and transport modelling used (e.g. groundwater fate and transport to estimate groundwater quality at an off-site receptor for comparison with drinking water standards)

- identification of any need for site zoning to consider specific source areas separately (e.g. hotspots, or areas where different land uses apply)
- explanation of the basis on which the site results are screened (e.g. comparison of 95% UCL of each zone to the screening criteria)
- Tier 1 screening
- identification of and justification for contaminants of concern for Tier 2 assessment
- identification of critical exposed populations (including off-site receptors where relevant) and pathways for Tier 2 assessment
- identification of and justification for any insignificant exceedences of screening criteria that will not be assessed at Tier 2.

9.3.4 Exposure assessment

This section should include a clear discussion on the exposure scenarios likely to occur at the site, and whether the site-specific situation fits into the exposure scenarios characterised in Schedule B7. If these scenarios are not applicable or representative of the exposure scenario under assessment, an explanation together with behavioural and lifestyle assumptions and site assumptions should be provided within the report.

Software and mathematical algorithms used to calculate the contaminant intake should be referenced. It is only necessary to present equations if the risk assessment uses a method that is not published in full (for example, if amendments to algorithms are made). An explanation of why the model or approach selected is appropriate should be given.

All input variables should be presented and justified. Use of default assumptions should be justified.

All reasonable efforts should be employed to validate exposure models (model uncertainty) with field data (for example, soil vapour data to inform outputs from the model developed by Johnson and Ettinger (US EPA 2004a)) where possible.

9.3.5 Toxicity assessment

In the hazard identification, a brief summary of the potential adverse effects of the contaminants of concern should be given. The summary should concentrate on the potential effects that are relevant to the contaminant in the context of the site and the exposure scenarios. Lengthy reviews of toxicology are not generally required. Clear presentation and referencing for physical and chemical properties is also required.

Dose–response assessment involves selection of appropriate toxicity reference values. If toxicity reference values used are adopted from the relevant Schedule B7 appendix, then no additional explanation is required and a reference is sufficient. If toxicity reference values are selected for substances not included in Schedule B7, then explanation and justification of a similar order to that presented in Schedule B7 should be given.

9.3.6 Risk characterisation

9.3.6.1 Overview

This section needs to present the quantitative estimates of risk calculated through modelling and should provide an evaluation of the overall quality of the assessment and the degree of confidence the risk assessor has in the estimates of risk and conclusions drawn.

Risk characterisation should include a summary of key issues and conclusions, as well as describing the likelihood of adverse health effects. The summary should include a description of the assumptions

made when conducting the risk assessment, together with the limitations and uncertainties associated with the risk assessment. The detailed risk calculations or model outputs should be presented in a manner that enables the calculations to be verified.

The conclusions should be presented in language that can be understood by non-specialists. The significance of the quantitative risk estimates should be explained in the context of the objectives of the project and the risk management decisions that need to be made.

9.3.6.2 Uncertainty

Uncertainty analysis should identify sources of uncertainty in the risk assessment and quantify them as far as possible. A tabular presentation such as that given in enHealth (2004), Table 16, is considered likely to be suitable for many circumstances. The uncertainty analysis should be specific to the assessment undertaken; a generic appraisal of the uncertainties inherent in all risk assessments is not sufficient. The uncertainty analysis should identify the impact that the uncertainty may have on the outcome (using the sensitivity analysis where possible) and identify those uncertainties that are not included in the sensitivity analysis.

9.3.6.3 Sensitivity analysis

A sensitivity analysis should present the key quantifiable uncertainties and provide plausible ranges for each. The effect on the model outcome should be stated for each uncertainty (or set of related uncertainties). Commentary on the significance of uncertainties and variability should be given. A tabular format may be appropriate; an example is provided below.

Table 9. Example format for presentation of sensitivity analysis results

Variable	Range		Risk outcome		Sensitivity level / Comment
	Min	Max	Min	Max	

RfD	reference dose
RI	risk index
RQ	risk quotient
SA	skin area
SA EPA	South Australia Environment Protection Agency
SBRC	Solubility Bioavailability Research Consortium
SD	standard deviation
TC	tolerable concentration in air
TBT	tributyltin
TCA	trichlorethane
TCE	trichloroethene
TDI	tolerable daily intake
TEF	toxicity equivalence factor
TPH	total petroleum hydrocarbons
TPHCWG	Total Petroleum Hydrocarbon Criteria Working Group
TRV	toxicity reference value
UCL	upper confidence limit
URF	unit risk factor
US EPA	United States Environmental Protection Agency
US NOAA	United States National Oceanic and Atmospheric Administration
WHO	World Health Organization