

Exposure draft

Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction

This guidance manual was commissioned by the Department of the Environment and Energy and prepared by Hydrobiology and ToxConsult Pty Ltd. The manual was revised following peer review.



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The national assessment of chemicals associated with coal seam gas extraction in Australia was commissioned by the Department of the Environment and Energy and prepared in collaboration with NICNAS and CSIRO

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Abbreviations

General abbreviations	Description
AICS	Australian Inventory of Chemical Substances
ASC NEPM	National Environmental Protection (Assessment of Site Contamination) Measure
CAS RN	Chemical Abstracts Services Registry Number
CoPC	Chemicals of Potential Concern
CSG	Coal Seam Gas
DoEE	Australian Government Department of the Environment and Energy
DTA	Direct Toxicity Assessment
EC	Effect concentration
EDC	Endocrine disrupting chemical
EUSES	European Union System for Evaluation of Substances
HPV	US EPA High Production Volume chemical
HQ	Hazard Quotient
IESC	Independent Expert Scientific Committee on Coal Seam Gas and Large Coal Mining Development
IMAP	Inventory Multi-tiered Assessment and Prioritisation
IUPAC	International Union of Pure and Applied Chemistry
K_d	Soil–water partitioning coefficient
K_{oc}	Organic carbon normalised solids–water partitioning coefficient
K_{ow}	<i>n</i> -octanol–water partitioning coefficient
LC	Lethal concentration
LOEC	Lowest Observable Effects Concentration
MATC	Maximum Acceptable Toxicant Concentration
MNES	Matters of National Environmental Significance
MoE	Margin of Exposure
NEC	No Effect Concentration
NEPM	National Environmental Protection Measure
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effects Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative, and toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration

General abbreviations	Description
PPE	Personal Protective Equipment
Q	Quantity
QSAR	Quantitative Structure Activity Relationships
REACH	Registration, evaluation, authorisation and restriction of chemical substances
RQ	Risk Quotient
SMILES	Simplified Molecular Input Line Entry System
TIA	Toxicity Identification Assessment
TRV	Toxicity Reference Value
US EPA	United States Environmental Protection Agency
UVCB	Chemical substances of <u>u</u> nknown or <u>v</u> ariable <u>c</u> omposition, including complex reaction products and <u>b</u> iological materials

Glossary

Term	Description
Accidental release	The release of a chemical to the environment outside of intended use which includes transport accidents, leaks and spills.
Acute toxicity	A lethal or adverse sub-lethal effect that occurs as the result of a short exposure, relative to the organism's life span. The Australian and New Zealand water quality guidelines (ANZECC and ARMCANZ 2000a) define acute exposure as being between 24 and 96 hours duration for multi-celled organisms and being between 24 and 72 hours duration for single-celled organisms. In mammalian toxicity, an acute exposure is typically considered to be <14 days.
Absorption	The process by which a chemical that, after contact with the exchange boundary (e.g. skin, lungs, gut), penetrates the exchange boundary and enters the circulatory system. The amount absorbed may be the same or less than the applied dose.
Adsorption	The reversible adhesion of an extremely thin layer of molecules to a particle surface. This process can bind methane and carbon dioxide, for example, to coal particles.
Adverse effect	Change in the morphology, physiology, growth, development, reproduction, mortality or morbidity of an organism, population or system, that results in an impairment of capacity, or an increase in susceptibility to other influences.
Aeolian deposition	Aeolian deposition occurs when contaminants in the soil compartment become airborne in dust (as particulates) and are transported to a secondary site. This transport may result in exposure to the aquatic compartment.
Ambient air	The external air environment. It does not include the air environment inside buildings or structures. Definition as per the National Environmental Protection (Ambient Air Quality) Measure.
Analogue	A chemical compound that is structurally similar to another but differs slightly in composition (as in the replacement of one atom by an atom of a different element or in the presence of a particular functional group).
Benchmark dose (BMD)	A dose or concentration that produces a predetermined change in response rate of an adverse effect (called the benchmark response or BMR) compared to background. The BMD, or statistical lower confidence limit on the dose or concentration at the BMD (BMDL), is frequently used as a point of departure for deriving a toxicity reference value for a substance.
Bioaccumulation, Bioconcentration, Biomagnification	Bioaccumulation describes a process by which chemicals are taken up by a plant or animal either directly through exposure to a contaminated medium (soil, sediment, water) or by consuming food or water containing the chemical. Related terms are bioconcentration in which chemicals are absorbed by an animal or plant to levels higher than the surrounding environment; and biomagnification, in which chemical concentrations in plants or animals increase from transfer through the food web (e.g., predators have greater concentrations of a particular chemical than their prey (US EPA 2015a)).

Term	Description
Bioavailable	The fraction of the total of a chemical in the surrounding environment that can be taken up by organisms. The environment may include water, sediment, soil, suspended particles, and food items.
Bounding estimate	A bounding estimate captures the highest possible exposure, or theoretical upper bound, for a given exposure pathway. Bounding estimates are useful for rapid screening estimates of risk and use the highest possible exposure, the highest intake rates, highest exposure frequency and distribution; and average adult body weights for estimates.
Breakdown product	A chemical derived from a parent molecule that has been altered by, for example, heat, light, chemical reaction, or by enzymes or catalysts.
Calibration	Model refinement to achieve a desired degree of correspondence between model simulations of the hydrogeologic framework, hydraulic properties and boundary conditions and observations of the groundwater flow system.
Cancer Slope Factor (CSF)	Cancer slope factors and unit risks are used to estimate the risk of cancer associated with exposure to a carcinogenic or potentially carcinogenic substance. A cancer slope factor is an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent by ingestion. This estimate, usually expressed in units of proportion (of a population) affected per mg of substance/kg body weight-day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100.
Carcinogenicity	An adverse health effect involving the conversion of normal cells to neoplastic cells (abnormal cells showing growth which is more rapid and not coordinated with the growth of other cells) and the further development of neoplastic cells into a tumour.
Central tendency estimates	A central tendency estimate represents the “average” or “typical individual” in a population, usually near the median or 50 th percentile of the population distribution. The arithmetic mean uses average values derived using all data in the population distribution. For example, a median exposure or a median dose corresponds to the 50 th percentile of exposure or dose values. Central tendency estimates are most useful when data are in a log normal distribution.
Chain of custody	A formally documented continuity of possession, and proof of integrity of evidence collected, which establishes each person in possession of the evidence.
Chronic toxicity	A biological response to exposure to a toxicant that takes a prolonged period to appear and persists for a prolonged period. Chronic toxicity is an adverse effect that occurs as the result of exposure to a chemical for a substantial proportion of the organism’s life span (for the purpose of this manual termed ‘long term chronic’ toxicity) or an adverse sub-lethal effect on a sensitive life stage (for the purpose of the manual termed ‘sub-chronic’ toxicity). A substantial proportion of an organism’s lifetime would typically be greater than 10%.
Coal Seam Gas (CSG)	A form of natural gas (generally 95 to 97% pure methane, CH ₄) typically extracted from permeable coal seams at depths of 300 to

Term	Description
	1000 m. Also called coal seam methane (CSM) or coalbed methane (CBM).
Conservative, conservatism	An assessment aimed at deliberately overestimating the potential risks to humans and the environment.
Contaminant	Biological (e.g. bacterial and viral pathogens) and chemical (see toxicants) introductions capable of producing an adverse effect on a biological system, seriously changing structure or function or leading to death.
Default values	When specific data are unavailable, the risk assessor usually relies on modelling or other means of calculating the exposure amounts and fluxes. Such exposure models and calculations may, in turn, need to make extensive use of default values to estimate the various model inputs where direct measurements are absent. Default data can be sourced from international sources, Australian databases and regional sources.
Degradation	Transformation resulting in the removal of a contaminant from a compartment. Transformation can occur in aquatic and soil compartments via various mechanisms including biodegradation, geoattenuation in aquifers and aquitards, photolysis and hydrolysis.
Dilution	The process of making a substance less concentrated by adding water. This can lower the concentrations of ions, toxins and other substances.
Direct Toxicity Assessment (DTA)	Direct toxicity assessment (DTA), or Whole-of-Effluent Toxicity (WET) testing, involves the assessment of the adverse impacts of complex mixtures of compounds, ranging from concentrated industrial effluents to natural waters, on aquatic organisms. DTA enables a greater understanding of potential impacts of mixtures on aquatic organisms and can be used to develop environmental protection measures such as dilution levels for mixtures being discharged into aquatic ecosystems. It is often used in conjunction with Toxicity Identification Assessment (DTA).
Drilling fluids	Water and chemicals that are pumped down the wellbore to lubricate the drill bit, to carry rock cuttings back up to the surface, to control pressure and for other specific purposes. Also known as drilling muds.
Ecotoxicity	The inherent potential or capacity of an agent such as a chemical, mixture, or substance to cause adverse effects in a living organism. Toxic (harm from chemicals) effects on plants and animals, populations, or communities (US EPA 2015a).
Effect concentration (EC _x)	EC _x refers to the concentrations that cause 'x' per cent of individuals to experience a given effect or the concentration which, on average, causes an 'x' per cent effect (EC _x). For example EC ₁₀ is a toxicant concentration that would cause a 10% reduction in a measure such as fecundity or growth.
Endpoint	A measurable ecological characteristic chosen as the assessment endpoint that is related to valued characteristics and a measure of biological effects (eg, death, reproduction, growth) of particular species. Endpoints can include measures of exposure as well as measures of effects or no effect.
Endocrine disrupting chemical (EDC)	An exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects

Term	Description
	in an organism, its progeny, or its (sub)population. Endocrine disrupting chemicals interfere with an organism's endocrine system and produce adverse developmental, reproductive, neurological, and / or immune effects in both humans and wildlife.
Environmental compartment	Environmental compartments (soil, surface water, groundwater, sediments, air) into which a chemical has been, will be or could be released.
Environmental fate	The life cycle of a chemical or biological pollutant after release into the environment.
European Union System for Evaluation of Substances (EUSES)	EUSES is a decision-support system for the evaluation of the risks of substances to humans and the environment. The system is based on the EU Technical Guidance Documents (TGDs; EC-TGD, 2003) for the risk assessment of new and existing substances and biocides and the EUSES software package as implemented in the ECHA <u>Chemical Safety Assessment Reporting tool</u> (Chesar, available at: https://chesar.echa.europa.eu).
Existing chemical	An industrial chemical not defined as a new chemical under the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> . Existing chemicals are naturally occurring chemicals and those listed in the Australian Inventory of Chemical Substances (AICS).
Exposure Assessment	Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure assessment includes processes such as determining emissions, release points, chemical transport pathways, rates of movement through specified environmental medium, and estimates of an agent's transformation or degradation (attenuation) rate. Exposure assessment provides an estimate of the concentrations or doses within an environmental compartment that a (sub)population may be exposed to.
Exposure pathways	In a risk assessment, exposure pathways are means by which hazardous substances move through the environment from a source to a point of contact with organisms / ecosystem / habitat (environment) and / or people (human health).
Flowback water	The initial flow of water returned to a well after fracture stimulation and prior to production. This is the fluid that flows back, or is pumped back, to the surface following hydraulic fracturing but prior to gas production. Some of this water is returned fracturing fluid and some is natural 'formation water' (often salty water that is naturally present in the coal seam).
Formation water	Naturally occurring groundwater that is within or surrounding the coal, rock or other target formations.
Genotoxicity	An adverse health effect on the genome (genetic structure) of an organism.
Geogenic chemical	A naturally occurring chemical originating, for example, from geological formations.
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or sub(population) is exposed to that agent.
Hazard assessment	Assessment of the possible adverse effects if an organism, system, or sub(population) was exposed. Includes hazard identification and hazard characterisation.

Term	Description
Hazard identification	The identification of the adverse effects which an agent has an inherent capacity to cause.
Hazard Index (HI)	The hazard index is the sum of the hazard quotients derived for a chemical.
Hazard quotient (HQ)	Hazard quotients are calculated by dividing exposure estimates (i.e. predicted environmental concentration or PEC) by the acute and chronic ecotoxicity values (i.e. predicted no effect concentration or PNEC). The term risk quotient is used in this manual.
High-end estimate	A high end estimate means above the 90 th percentile of the population distribution, but not higher than the individual in the population who has the highest exposure. For example, a high-end exposure estimate is a plausible estimate of the individual exposure for those organisms at the upper end of an exposure distribution. High end estimates are often used to describe reasonable maximum, reasonable worst-case, or maximum exposures and are generally more realistic than bounding estimates. They generally involve a combination of high and central tendency data.
Homologue	A compound belonging to a series of compounds differing from each other by a repeating unit, such as a methylene group, a peptide residue, etc.
Hydraulic fracturing	Also known as 'fracking', 'fracing' or 'fracture stimulation' or 'stimulation'; Stimulation of hydrocarbon (oil and gas) bearing geological formations to enhance the flow of hydrocarbons and other fluids towards the well. The process involves the injection of fluids, gas, proppant and other additives under high pressure into a geological formation to create a network of small fractures radiating outwards from the well through which the gas, and any associated water, can flow.
Hydraulic fracturing fluid	A fluid injected into a well under pressure to create or expand fractures in a target geological formation (to enhance production of natural gas and / or oil). It consists of a primary carrier fluid (usually water), a proppant and one or more additional chemicals to modify the fluid properties.
Infiltration	Passage of water through the soil surface and into the soil. Infiltration occurs when contaminants in soil, for instance through spillage or storage dam leaks, leach through the soil profile towards groundwater.
Intended release	The release of a chemical to the environment through designed use including hydraulic fracturing processes, irrigation or dust suppression.
Irritation / corrosivity	An adverse health effect to the dermal (skin) membrane.
Isomer	An isomer is a molecule with the same chemical formula as another molecule, but with a different chemical structure. That is, isomers contain the same number of atoms of each element, but have different arrangements of their atoms.
Lethal concentration (LCx)	LCx refers to the concentrations that are lethal to a certain percentage 'x' of the individuals. For example, LC ₁₀ is the toxicant concentration that is expected to be lethal to 10% of a group of organisms under specified conditions.

Term	Description
Low concern	<p>A chemical of low human health hazard. Chemicals of low concern are considered to have a low likelihood of causing adverse human health effects should an exposure occur.</p> <p>A chemical that is considered unlikely to cause harm to humans or the environment based on its intrinsic properties (that is, low hazard); or a chemical where the probability that the chemical will cause harm is low based on its assessed use, volume of use, potential release mechanisms, likely transport-fate pathways, and relevant receptors (low risk).</p>
Margin of Exposure (MoE)	Ratio of the Point of Departure (PoD) (e.g. no-observed-adverse-effect level (NOAEL) for the critical (most sensitive) effect to the theoretical, predicted, or estimated exposure dose or concentration.
Maximum Acceptable Toxicant Concentration (MATC)	The maximum acceptable toxicant concentration (MATC) is a value that is calculated through aquatic toxicity tests to help set water quality regulations for the protection of aquatic life. Using the results of a partial life-cycle chronic toxicity test, the MATC is reported as the geometric mean between the No Observed Effect Concentration (NOEC) and the lowest observed effect concentration (LOEC).
Matters of National Environmental Significance (MNES)	Under the <i>Environment Protection and Biodiversity Conservation Act 1999</i> (EPBC Act), actions that have, or are likely to have, a significant impact on a matter of national environmental significance require approval from the Australian Government Minister for the Environment.
Mechanistic study	A study designed to understand the fundamental processes involved in or responsible for an action, reaction or other natural phenomenon.
Metabolism	All chemical reactions involved in maintaining the living state of the cells and the organism.
Monte Carlo analysis	Computational methodology to estimate the most probable outcome from a simulation model with uncertain inputs by generating multiple simulation runs from sampling input parameters based on known probability distributions.
Neurotoxicity	An adverse health effect on the nervous system of an organism.
New chemical	A chemical which is an AICS-listed industrial chemical for which its introduction is subject to a condition of use under Section 13 of the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> , or an industrial chemical not listed as an industrial chemical on the AICS, and in the case of a synthetic polymer: a chemical that is a new synthetic polymer but does not include: a reaction intermediate, or an incidentally-produced chemical.
No Effect Concentration	The concentration of a toxicant that has no adverse effect on a species. The NEC is a model-based measure of toxicity that can be determined by statistical analysis (for example, by using Bayesian or parametric methods).
No Observed Adverse Effect Level (NOAEL)	The highest exposure level at which there are no biologically significant increases in the frequency or severity of adverse effect between the exposed population and its appropriate control. Some effects may be produced at this level, but they are not considered adverse or precursors of adverse effects. The NOAEL is frequently used as a point of departure for deriving a toxicity reference value

Term	Description
	for a substance.
Partitioning	<p>Distribution of a solute, S, between two immiscible solvents (such as aqueous and organic phases) is an equilibrium condition that is described by the following equation:</p> $S_{aq} \rightleftharpoons S_{org}$ <p>The equilibrium constant for this equilibrium condition is:</p> $K = [S_{org}] / [S_{aq}]$ <p>where [Sorg] and [Saq] are the solute concentrations in the organic and aqueous phases, respectively, and the equilibrium constant, K, is called the partition or distribution coefficient.</p>
Partitioning coefficient (K _{ow} , K _{oc})	<p>K_{ow} describes the ratio of a chemical's concentration in the octanol phase to its concentration in the aqueous phase of a two-phase octanol-water system, often used as a measure of hydrophobicity. For example, chemicals with a high log K_{oc} will partition to soil rather than remain in the water compartment whereas highly water soluble chemicals with a low K_{ow} are more likely to remain in the water compartment.</p>
Point of Departure (PoD)	<p>A point on a dose-response curve that is defined by the available data and close to the range of observed data points, from which extrapolation techniques (e.g. linearised extrapolation and / or application of safety/uncertainty factors) are used to estimate a toxicity reference value.</p>
Pore water	<p>The water occupying the spaces between sediment or other soil or rock particles.</p>
Produced water	<p>The fluid that returns to the surface during the production phase of a well that contains both fracturing fluid and saline water from the rock formation.</p>
Potential concern	<p>These chemicals have the potential to cause adverse effects if they are released from coal seam gas operations. Specific risk management measures may be necessary to ensure that chemicals of potential concern do not harm the environment. For deterministic environmental risk assessment purposes, chemicals of potential concern have a RQ ≥ 1 and < 10.</p>
Potentially high concern	<p>These chemicals are likely to cause adverse effects if they are released to the environment from coal seam gas operations. Specific risk management measures are likely to be required to ensure that chemicals of potentially high concern do not harm works, the public, and / or the environment. For deterministic environmental risk assessment purposes, chemicals of potentially high concern have RQ ≥ 10.</p>
Predicted environmental concentration (PEC)	<p>Chemical concentration in a given environmental component (soil water, groundwater, surface water) that has been calculated by means of exposure models for a given exposure scenario.</p>
Predicted no effect concentration (PNEC)	<p>The concentration of a chemical that marks the limit at or below which no adverse effects of exposure in an ecosystem are measured.</p>
Quantitative structure activity relationship (QSAR)	<p>Quantitative structure activity relationship models are regression or classification models used in the chemical and biological sciences and engineering. In QSAR modelling, the predictors consist of physico-chemical properties or theoretical molecular descriptors of chemicals, and the response variables could be a biological activity of the chemicals. QSAR models first summarise</p>

Term	Description
	a supposed relationship between chemical structures and biological activity in a data-set of chemicals. Second, QSAR models predict the activities of new chemicals.
Receptor	Human health risk assessment: the receptor is often used to designate people who may be exposed to an environmental hazard, and to whom the risk assessment would be directed. It can also refer to the system or organs within the human organism adversely impacted by the toxicity. Environmental risk assessment: an entity which may be adversely affected by release of a chemical to the environment. This may include any organism, the habitat that supports the organism, or a broader ecosystem.
Repeat dose toxicity	Repeat dose toxicity comprises the adverse effects occurring in experimental animals as a result of repeated daily dosing with, or exposure to, a chemical for a part of their life span.
Reproductive toxicity	An adverse health effect on the reproductive system (sexual function, fertility and developmental effects) of an organism.
Risk	Risk is generally defined as the effect of uncertainty on objectives, resulting in a deviation from expected; and is often characterised by reference to potential events and consequences, or a combination of these. For the purposes of this guidance manual chemical risk is defined as the combination of the seriousness and the likelihood of an adverse effect in an organism, (sub)population, or system, caused under specified circumstances by exposure to an agent or agents.
Risk assessment (chemicals)	Estimation of the risk to a given organism, (sub)population, or system, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target organism. Chemical risk assessment includes a range of processes such as hazard identification, hazard assessment, exposure assessment, risk characterisation, and risk communication and management.
Risk characterisation (chemicals)	The process of estimating the likelihood and consequence of adverse effects due to an actual or predicted exposure to an agent. Risk characterisation may include risk estimation, which involves the quantification of that likelihood based on temporal or spatial frequency probability.
Risk characterisation ratio (chemicals)	Calculated by dividing the predicted environmental concentrations (PEC) by the predicted no-effect concentrations (PNEC). These are then used to decide if risks are adequately controlled for each environmental sphere and for each human population known to be or likely to be exposed.
Risk management (chemicals)	A decision making process that entails weighing political, social, economic, financial and engineering information against risk-related information to develop and select appropriate risk reduction measures, often referred to as “risk controls”, in response to identified risks.
Risk quotient	Calculated by dividing exposure estimates (i.e. predicted environmental concentration or PEC) by the acute and chronic ecotoxicity values (i.e. predicted no effect concentration or PNEC) (i.e., $RQ = PEC/PNEC$). In mammalian toxicity, a risk quotient refers to the ratio of an estimated exposure (e.g. daily intake of a

Term	Description
	chemical) to a toxicity reference value (e.g. tolerable daily intake) for threshold exposure ($RQ = \text{Exposure}/\text{TRV}$). Used in deterministic approaches that assume exposure will occur. "Risk quotient" is used throughout this manual and replaces the slightly older term "hazard quotients".
Risk reduction / risk minimisation	Risk control measures taken to avoid or minimise identified risks.
Run-off	The proportion of precipitation that is not absorbed by soil and thus flows across the surface. Run-off may occur during a rainfall event resulting in the transport of contaminants in the soil compartment to a secondary site in the soil compartment or into an aquatic compartment.
Screening Assessment	Undertaken to identify the level of concern associated with a chemical by investigating available data.
Sedimentation	The tendency for particles in suspension to settle out of the fluid in which they are entrained, and come to rest against a barrier. This is due to their motion through the fluid in response to the forces acting on them: these forces can be due to gravity, centrifugal acceleration or electromagnetism.
Sensitisation	An allergic response following skin or airways contact with the tested chemical.
Sensitivity testing	Any systematic, common sense technique used to understand how risk estimates and, in particular, risk-based decisions depend on variability and uncertainty in the factors contributing to risk. Sensitivity analysis identifies what is "driving" the risk estimates and ranks important sources of variability and uncertainty.
Stressor	A stressor is any physical, chemical, or biological entity that can induce an adverse response. Stressors may adversely affect specific natural resources or entire ecosystems, including plants and animals, as well as the environment with which they interact (US EPA 2014a).
Sub-chronic toxicity	Sub-chronic toxicity is an adverse sub-lethal effect on a sensitive life stage of a test organism. See definition for "chronic toxicity".
Tenement	A prospecting licence, exploration licence, retention licence, mining lease, general purpose lease or a miscellaneous licence granted or acquired under state or Commonwealth legislation and includes the specified piece of land in respect of which the mining tenement is so granted.
Toxic	An agent's inherent ability to cause an adverse biological effect if inhaled, ingested, or absorbed through the skin
Toxicant	A chemical capable of producing an adverse effect in a biological system at concentrations that might be encountered in the environment, seriously injuring structure or function or resulting in death.
Toxicity	The degree to which an agent may cause an adverse biological effect.
Toxicity Identification Assessment (TIA)	Toxicity Identification Assessment (TIA) techniques are used to identify chemicals causing toxicity in complex mixtures. Toxicity Identification Assessments can help target chemical risk reduction measures by identifying chemicals for elimination from a mixture. TIA uses toxicity tests in combination with chemical and physical

Term	Description
	manipulations of a mixture to identify the chemical(s) causing elevated toxicity. It is often used in conjunction with Direct Toxicity Assessment (DTA) techniques.
Toxicokinetics	The study of the absorption, distribution, metabolism and elimination of toxic compounds in the living organism.
Uncertainty	That which is unknown.
Unit risk factor (URF)	Cancer slope factors and unit risk factors are used to estimate the risk of cancer associated with exposure to a carcinogenic or potentially carcinogenic substance. A unit risk factor is an upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water or 1 µg/m ³ in air. The interpretation of unit risk for a substance in drinking water would be as follows: if unit risk = 2×10^{-6} per 1 µg/L, two excess cancer cases (upper bound estimate) are expected to develop per 1 000 000 people if exposed daily for a lifetime to 1 µg of the substance in 1 litre of drinking water.
Volatilisation	The process by which contaminants partition to air from the surface of soils or water bodies in which contaminants are present (such as storage dams holding wastewater and drilling fluids, rivers and wetlands, or the soil). The likelihood and extent of a chemical volatilising from soil and water is determined by individual chemical properties and environmental factors.

Summary

Chemical risk assessment is a structured process that estimates the potential impact or consequence of a hazard to an entity (e.g. people, communities or environments) under a specific set of conditions and over a given time frame. This guidance manual sets out a framework to assess the risks to human health and the environment associated with the use of chemicals for drilling and hydraulic fracturing in coal seam gas extraction in Australia. This includes chemicals associated with drilling activities, cementing and well completion, perforation propellants, acid clean out and pre-wetting chemicals, hydraulic fracturing, and fluid management activities, including produced water and waste fluids. It also includes naturally occurring geogenic chemicals mobilised by drilling or hydraulic fracturing and found in drilling fluids and drilling muds, flowback and produced water, brines, and treated water.

The manual draws on experience gained as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, commissioned by the Australian Government in June 2012 (DoEE 2017b, 2017c and 2017d; Mallants et al. 2017a and 2017b; NICNAS 2017a, 2017b, 2017c, and 2017d), as well as other national and international risk assessment methods.

The general risk assessment framework presented in this manual is designed to support a series of distinct stages in the chemical risk assessment process. These stages are:

- assessment planning and problem formulation (to plan the risk assessment process; and to establish the aim, objectives, outcomes of the risk assessments)
- data gathering and evaluation (including model construction)
- exposure assessment (to characterise the nature of exposure, including operational scenarios, points of release, transport-fate pathways, receptors, etc.)
- screening and validation processes (to determine chemicals known to be of low concern, and identify chemicals for further hazard and risk assessment)
- hazard assessment (to quantify and characterise the hazardous effects associated with each substance)
- risk assessment (to quantify and characterise the risks associated with the use of each substance)
- risk communication and management (to communicate risk assessment results, and to monitor, control, and review risk management processes over time).

The framework includes a tiered approach to risk assessment where assumptions are progressively refined and additional data collected if necessary to reduce uncertainty in the risk assessment conclusions. Documentation and communicating risks throughout the risk assessment is critical and supports the development of management and mitigation measures. Information and methods used, assumptions made, and uncertainties should be transparently reported for all phases.

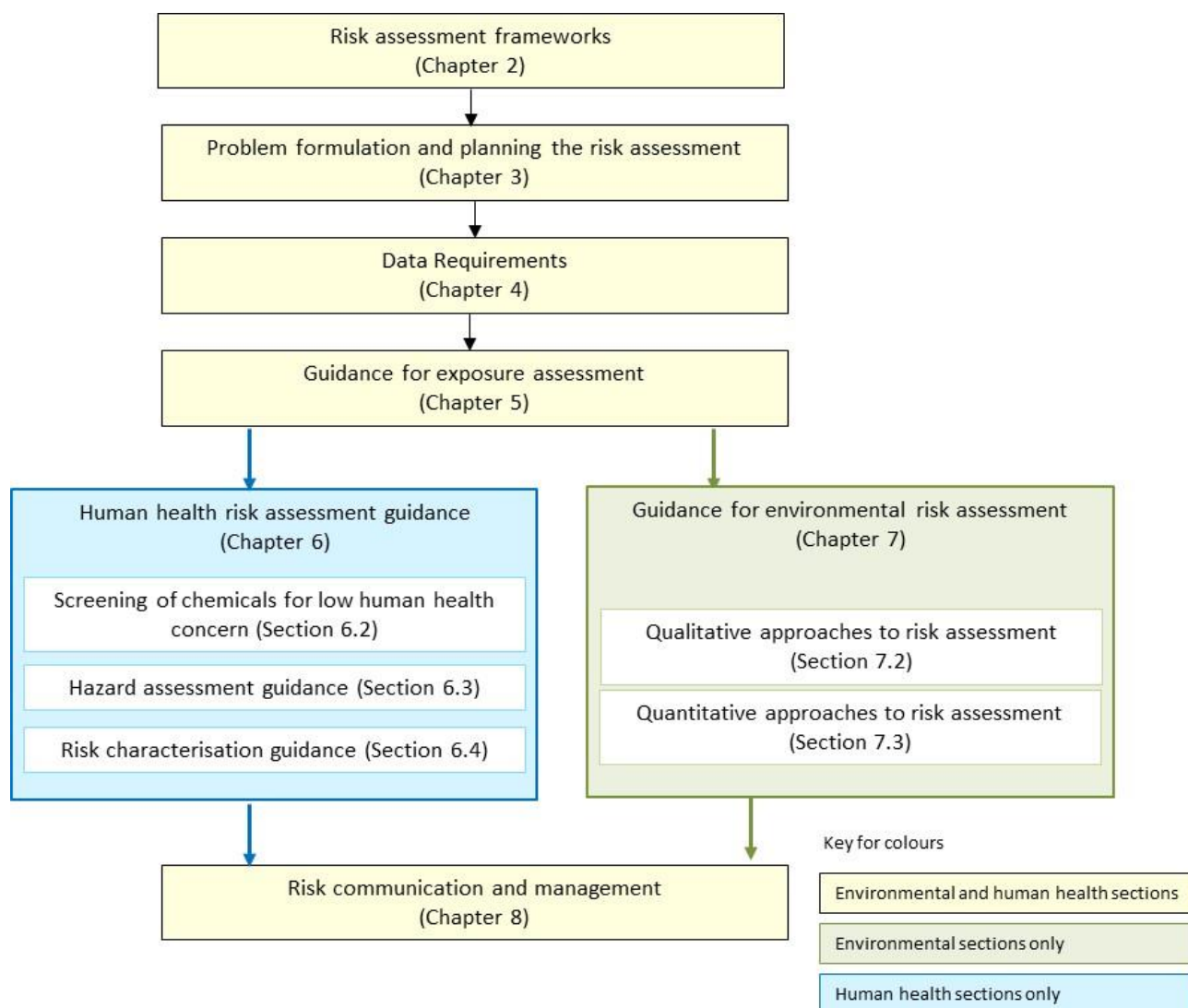
The risk assessment guidance documents referred to within this manual include:

- Environmental Risk Assessment Guidance Manual – for industrial chemicals (EPHC 2009a)

- Environmental Risk Assessment Guidance Manual – for agricultural and veterinary chemicals (EPHC 2009b)
- Environmental Health Risk Assessment – Guidelines for assessing human health risks from environmental hazards (enHealth 2012a).

This manual complements and draws on information and guidance from NEPM (2013)¹, ANZECC and ARMCANZ (2000a)², and AS/NZS HB 203:2012 (2012), OECD (2015c), and US EPA (2015b), which should be referred to as necessary.

Some elements of the guidance set out in this manual apply to both human health risk assessment and environmental risk assessment while other elements apply only to one or the other. Figure S.1 shows how the guidance can be used to assess human health or environmental risks. Each phase of assessment is described in the relevant section in the manual and in appendices. This information is intended to guide and inform the risk assessment process – each assessment needs to be tailored to the specific chemicals and scenarios being assessed.



¹ *National Environment Protection (Assessment of Site Contamination) Measure 1999*, as amended and in force on 16 May 2013.

² *Australian and New Zealand Guidelines for Fresh and Marine Water Quality 2000*, National Water Management Strategy (Document 4, volume 1, 2, and 3).

Figure S.1 Sections in this coal seam gas manual for guidance on undertaking an environmental and human health chemical risk assessment

1 Introduction

1.1 Coal seam gas extraction in Australia

Coal seam gas is the name given to any naturally occurring gas held underground in coal formations ('coal seams') by groundwater pressure and the weight of the rocks and soil above (APPEA 2017; GA 2017; DoE 2014a). Coal seam gas consists primarily of methane – a colourless and odourless gas found in coal deposits formed over millions of years from fallen trees and other plant matter (AP LNG 2017a; DoE 2014a; Miyazaki 2005). Coal seam gas is typically found in coal formations 300 to 1 300 m below ground level (APPEA 2017). Coal seam gas is also referred to as 'natural gas' or 'coal bed methane' (CBM).

Coal seam gas collects inside the coal seams. The coal seams are also generally filled with water and the pressure of this water and the rocks above holds the gas in a thin film on the surfaces of the coal particles and in the microscopic spaces in between the coal particles. The natural cracks in the coal can also contain gas, and can be filled with groundwater. At the microscopic level, coal has a large internal surface area and can store up to seven times as much gas as a conventional natural gas reservoir of equal rock volume (DoEE 2017a; DoE 2014a; Nuccio 2000). When the water pressure is reduced, gas is released from the coal particles. It can then flow through the natural cracks in the coal seam, and any induced fractures, to a gas extraction well. The gas and water can then be separated and the gas piped to compression plants for transportation via gas transmission pipelines (DoEE 2017a).

Liquefied natural gas – often referred to as "LNG" – is natural gas, such as coal seam gas, that has been cooled and converted to liquid. At -161°C, liquefied natural gas has about 1/600th the volume of room temperature natural gas, making it easier to store, pipe, and transport around Australia and overseas (Arrow Energy 2016). Coal seam gas is used for a variety of purposes including electricity generation, heating, cooking, and for a wide variety of industrial purposes (Arrow Energy 2016). It is also used to make fertilisers, plastics, and many chemicals and is exported to consumers overseas (APPEA 2017).

Coal seam gas is generally classed as an unconventional gas because it requires more advanced technology to extract than other more conventional natural gases. Other examples of unconventional gas include shale gas and gas from tight (impermeable) rocks and sands. In some cases, hydraulic stimulation is required to improve gas flow. Hydraulic stimulation – hydraulic fracturing or 'fracking' – is used to stimulate gas flows and extract coal seam gas at commercially viable rates. Not all coal seam gas extraction operations in Australia involve hydraulic fracturing (DoE 2014a).

Hydraulic fracturing is the process of injecting water, proppants, and other chemicals under high pressure into a coal seam to widen the existing natural fractures in the coal and to create new ones. A proppant, such as sand, is mixed with the injected fluid or gel and is carried into the fracture where it props the fractures open once the fracture treatment is complete and the pressure is released (DoEE 2017a). This allows the gas and water to flow at a faster rate, aiding the removal of water and the extraction of coal seam gas.

1.2 Chemicals associated with coal seam gas extraction

1.2.1 Drilling Chemicals

Coal seam gas extraction involves the drilling and installation of coal seam gas extraction wells. In Australia, single vertical gas production wells are commonly used to extract coal seam gas and water. Drilling multiple wells from a single drilling site, combined with

horizontal “directional” drilling technology and hydraulic fracturing, is common internationally, particularly in Canada and the USA (DoE 2014b). Coal seam gas wells are generally drilled using rotary or percussion techniques, which require the use of drilling fluids – “muds”.

Drilling fluids are used to cool and lubricate the drill bit, help float the cuttings back up to the surface, minimise drilling fluid loss, prevent clay swelling, and maintain annulus integrity and well bore stability. The drilling fluids in Australia are typically water-based, comprising water, organic polymers or clay additives such as bentonite (added to increase viscosity, inhibit clay and shale swelling and sticking, and flocculate drilled solids (DoE 2014b; Zvomuya et al. 2008). Biocides are also used in coal seam gas drilling fluids and muds (AECOM 2017). Drilling fluids and muds are, increasingly, being recycled and used in other drilling operations. Drilling cuttings and used drilling fluids and muds are often disposed of in buried pits, or through spraying techniques. Other disposal techniques include landfill and, in some cases, as hazardous waste (AECOM 2017).

1.2.2 *Cementing and monitoring chemicals*

Once the well bore has been drilled, casings and other infrastructure are inserted into the well and cemented into place. Chemicals are used in drilling cement, but usually end up bound in the cement matrix. Once the well is drilled and the casing, production tubing, and other infrastructure have been installed and cemented, extensive geophysical and other monitoring is undertaken to ensure that the well has been properly constructed, and to more fully characterise the surrounding underground geology and hydrology. The well is also pressure-tested to confirm well construction and integrity. Chemicals such as chemical tracers and mildly radioactive isotopes may also be used for monitoring purposes.

1.2.3 *Perforation chemicals*

Once the gas well has been fully tested, if hydraulic fracturing is required, small holes approximately 5 to 15 mm in diameter are made through the casing and cement at the depth of the coal seam target zone (DoE 2014a). These perforations are usually created using small explosive shape charges, which may leave minute undetonated traces of high explosive propellant or detonation products. Once the perforations are made and the well is connected with the target zone, the well is regarded as completed.

1.2.4 *Hydraulic fracturing chemicals*

Well clean-out, formation pre-wetting, and hydraulic stimulation are then carried out, all of which may involve the use of chemicals. Hydraulic fracturing involves the injection of fluids and proppant into the well under pressure to initiate fracturing in the coal seam and to keep the fractures open so that gas and water can flow to the well. Injection takes from tens of minutes to a few hours (AECOM 2017; Johnson et al. 2010; Taleghani 2009). The fluids are only injected into the target coal measure (a coal seam of a particular geological age) and not the formations above or below the target coal measure. This is achieved through accurate subsurface characterisation so that perforation and subsequent injection only occurs within the targeted coal seam. Some fracture treatments are, however, designed to produce a fracture that grows vertically through several adjacent thin coal seams because stimulating each seam individually would not be cost-effective (DoE 2014a).

Water makes up the majority of the fracturing fluid, with the next largest component being the proppant. Proppant is typically sand but can also be quartz, nut shells, ceramics or bauxite (DoE 2014a; Beckwith 2010). Some hydraulic fracturing fluids consist of a gel mixed with the water to increase viscosity or a friction-reducing additive. Viscosity is a measure of a fluid's resistance to flow. The main difference between fracturing with water – “slickwater”, which is water with a friction-reducing additive – and a water-gel mixture is that the increase in viscosity from the addition of gel allows more proppant to be carried into the fractures. Most operators in Australia use water-gel mixtures (DoE 2014a; APLNG 2017b; Golder Associates

2010). The most common gelling agents are natural polymers such as guar gum derived from the pods of the guar bean (Economides and Martin 2007). A range of other chemicals are used including acid, friction reducers, biocides, stabilisers, pH buffers and breakers (DoE 2014a). The fluid composition and volumes change during injection and are tailored to suit the site-specific condition at each well (DoE 2014a). For this reason, the exact amounts of chemicals used at each site may vary. For example, fracturing with gel can require a volume of around 1.2 % of additives, compared to water fracturing, which typically contains a 0.1 % volume of additives (DoE 2014a; AP LNG 2017b). In other situations, three or more percent may be required (AECOM 2017; NICNAS 2017a).

1.2.5 *Flowback water and produced water: anthropogenic and geogenic chemicals*

After hydraulic fracturing has been completed, government regulation requires a larger volume of fluid to be recovered from a well than was injected – generally around 150% (DoE 2014a; Golder Associates 2010). This recovered fluid (the initial fluid recovered after hydraulic fracturing is known as ‘flowback water’, and the fluid subsequently removed from the well is known as ‘produced water’) is a mixture of fluid injected for hydraulic fracturing and fluids occurring naturally in the coal seam. Because flowback and produced water contains a mixture of the injected chemicals (flowback water is estimated to contain between 20 and 60% of the injected chemicals) and chemicals that occur naturally in that rock formation (‘geogenic chemicals’), it must be properly contained and managed (AECOM 2017; DoE 2014a). Most of the remaining chemicals from the fracturing fluid are likely to be extracted in the produced water over the production life of the well. However, a proportion of injected fluid and chemicals may be retained in the coal seam because some chemicals adsorb onto the surface of the coal (DoE 2014a; Rogers et al. 2007). Some fractures also close shortly after being created and are cut off from the rest of the fracture network (DoE 2014a; Economides and Martin 2007). It is possible that some chemicals will be retained in these isolated fractures.

1.2.6 *Flowback and produced water storage; water treatment chemicals*

The flowback water and produced water are often piped from the well to large ponds where they are held prior to being treated to manage the chemicals present in the water. In some cases, particularly in the drier coal seams south of Sydney, the produced water is held in small tanks at or near the well, then collected and trucked to water treatment plants. The various water treatment techniques used to treat and manage flowback and produced water also involve the use of chemicals. The brines produced by reverse osmosis (RO) water treatment also comprise concentrated chemicals such as salts, metals, and metalloids, and must be properly contained and managed.

Summary descriptions of coal seam gas well construction techniques and hydraulic fracturing processes are provided in various reviews (see, for example, AECOM 2017; DoE 2014a and 2014b).

1.3 *Chemical risk assessment guidance for the coal seam gas industry in Australia*

Risk assessment is the part of the risk management process that estimates the potential impact, or consequence, of a hazard to people, communities or environments under a specific set of conditions and over a given time frame (LPSPD 2008; AS/NZS ISO 13000:2009 (2009); AS/NZS HB 203:2012 (2012)). Risk assessment and risk management are inherently about the management of unplanned events. The process of assessing and

managing these risks is aimed at ensuring that the risks arising from unplanned events are acceptable.

The Australian Government commissioned the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* in June 2012 (Mallants et al. 2017a and 2017b; DoEE 2017b, 2017c, and 2017d; NICNAS 2017a, 2017b, 2017c, and 2017d). This project developed a consistent approach to the assessment of the risks to human health and the environment from surface handling of chemicals used for drilling and hydraulic fracturing in coal seam gas extraction (DoEE 2017c and 2017d; NICNAS 2017d). The Department also commissioned deeper groundwater hazard screening research on the potential movement through the environment of chemicals remaining underground after hydraulic fracturing (Mallants et al. 2017c). This manual complements the risk assessment and research reports by providing guidance on the processes for assessing risks to human health and the environment from chemicals associated with coal seam gas operations in Australia.

The dedicated chemical risk assessment framework described in this guidance manual applies to exploration, pilot, development, operational, and production processes in Australia's coal seam gas industry. This includes specific points of release and exposures in coal seam gas operations that may differ from other industries. The manual refers to and draws from several risk assessment guidance documents, including the industrial chemicals and agricultural and veterinary chemicals guidance manuals (EPHC 2009a; EPHC 2009b), enHealth (2012a), the *National Environment Protection (Assessment of Site Contamination) Measure 1999* and its associated Schedules, as amended in May 2013 (NEPM 2013), the Australian and New Zealand Water Quality Guidelines (ANZECC and ARMCANZ 2000a), and Australian/New Zealand Standards (AS/NZS 2009; AS/NZS 2012); and other risk assessment sources and tools such as the OECD guidelines (OECD 2015c), the US EPA Toolbox (US EPA 2015b), the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, and the emerging national standard for environmental risk management of industrial chemicals.

1.4 Purpose

The purpose of this manual is to guide best practice human health and environmental risk assessment, focusing on chemicals associated with coal seam gas extraction in Australia. This includes chemicals associated with drilling activities, cementing and well completion, perforation propellants, acid clean out and pre-wetting chemicals, hydraulic fracturing, and fluid management activities, including produced and waste fluids. It also includes naturally occurring geogenic chemicals mobilised by drilling or hydraulic fracturing and found in drilling fluids and drilling muds, flowback and produced water, brines, and treated water.

The guidance manual is designed to assist evaluation of risks posed by chemical transport, storage, use, and disposal associated with coal seam gas operations. The manual builds on experience gained from risk assessment methods used for the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia*, although it also refers to other national and international risk assessment methods. The manual includes information on data requirements, methods and tools to use in assessing chemicals. This guide is not prescriptive and each assessment should be tailored to the specific chemicals and scenarios assessed.

1.5 How to use the manual

The following chapters guide assessors on:

- general concepts in chemical risk assessment (Section 2.1)

- this manual's framework for chemical risk assessments for the environment and human health (Section 2.2)
- planning a risk assessment and problem formulation for the assessment (Chapter 3)
- the data requirements for chemical risk assessments for human health and the environment (Chapter 4)
- how exposures are assessed for human health and the environment in the context of chemicals used in coal seam gas extraction (Chapter 5)
- human health risk assessment (Chapter 6) including:
 - screening for chemicals of low concern (Section 6.2)
 - assessing human health hazards (Section 6.3)
 - characterising human health risk (Section 6.4)
- environmental risk assessment guidance (Chapter 7) including:
 - screening for chemicals of low concern (Section 7.2)
 - assessing human environmental hazards (Chapters 4 and 7)
 - characterising environmental risk (Chapter 7)
- managing and communicating risk (Chapter 8).

Due to differing methods, some sections are only relevant to either human health or environmental risk assessment, while other sections are relevant to both. Figure 1.1 provides an overview of the risk assessment framework and guidance on the relevant sections within this document. Checklists for each step of the risk assessment can be found at the end of each chapter and at Appendix B. Appendix A includes an example list of coal seam gas water quality monitoring parameters. Appendix C lists the equations used in this manual. Suggested content for a chemical risk sheet is outlined in Appendix D.

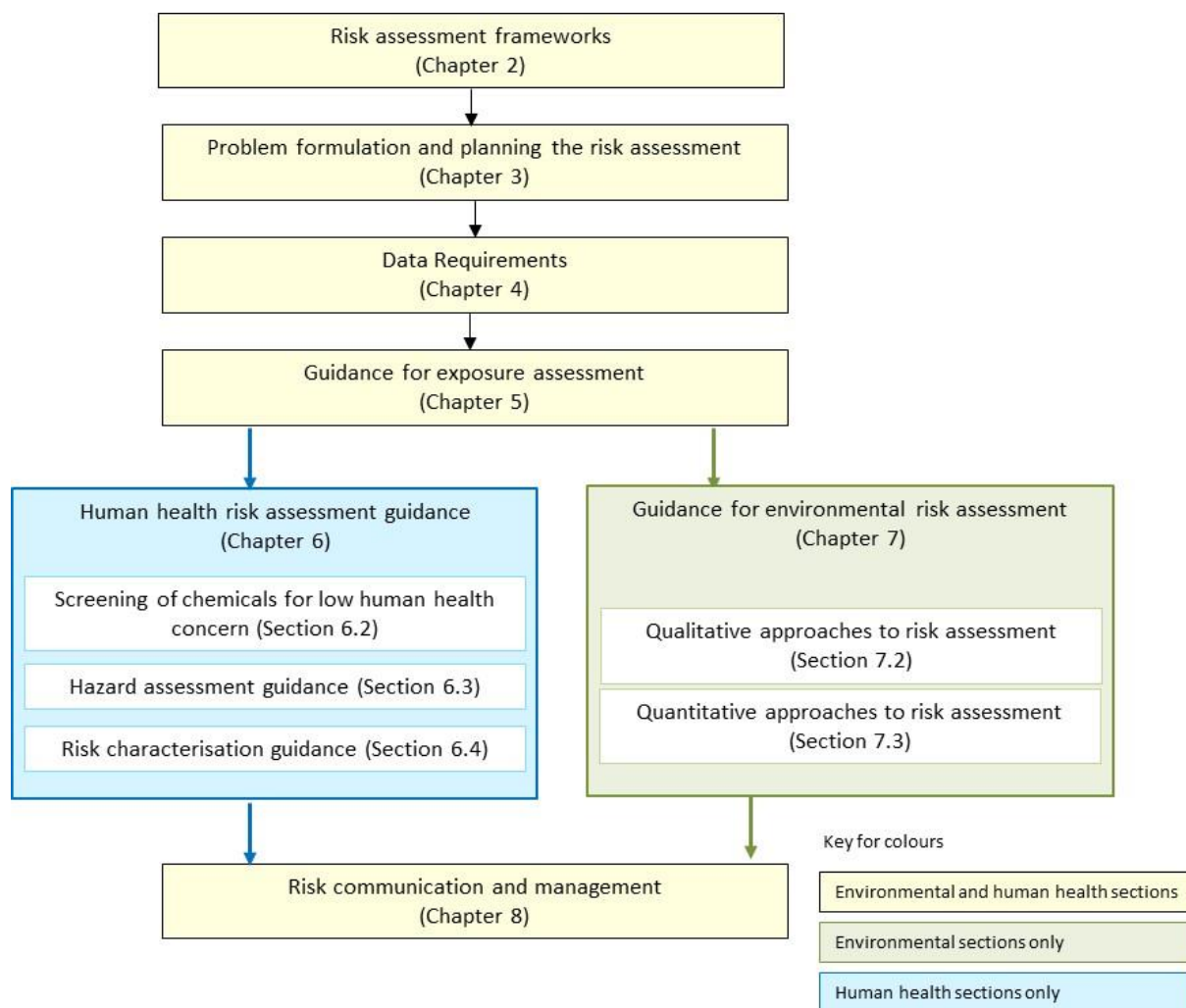


Figure 1.1 Guidance manual sections to follow when assessing environmental and / or human health risks.

2 Risk Assessment Frameworks

2.1 General concepts in chemical risk assessment

2.1.1 What is risk assessment?

Most activities people undertake have some level of risk – that is, a potential for harm. To assist in decision-making about whether some activities should be permitted, a formalised system of assessing and managing risks has been developed.

Risk is generally defined as the effect of uncertainty on objectives, resulting in a deviation from expected (AS/NZS ISO 13000:2009 (2009)). Risk is often characterised by reference to potential events or scenarios, and consequences, or a combination of these (AS/NZS ISO 13000:2009 (2009)). Risk management is the term applied to identifying, assessing, mitigating, controlling and communicating risks – that is, the whole process. Risk assessment is the technical and scientific part of the process where an estimate of the size of a risk is developed. As such, risk assessment is the systematic scientific evaluation of potentially adverse effects resulting from exposure to a hazardous agent or situation, and often requires the integration of both quantitative as well as qualitative scientific information (DoEE 2016a).

Risk assessment is the part of risk management that estimates the potential impact, or consequence, of a hazard to the environment, people or communities under a specific set of conditions and over a given time frame (EU 2003; AS/NZS 13000:2009). AS/NZS ISO 31000: 2009 notes that risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of that occurrence³. For the purposes of this guidance manual chemical risk is defined as the probability of adverse effects caused under specified circumstances by an agent in an organism, a (sub)population, or an ecological system. It is based on the hazard of a chemical and its level of exposure for a specific use and location (DoE 2016a). Risk is analysed during the chemical risk assessment process and can be represented simplistically (DoEE 2016a and 2016b) as:

$$Risk = function(hazard \times exposure) \quad [Equation 1]$$

A chemical risk assessment involves an assessment of a chemical's hazard (a property intrinsic to the chemical, often derived from a series of laboratory tests) and an assessment of exposure (the degree to which people or the environment are exposed to the chemical). Hazard assessment identifies the sort of "harm" the substance may cause. An exposure assessment then looks at how much of a chemical might be present (such as its volume or concentration) and how people or the environment might come into contact with it (such as from its transport, storage, use and disposal). A chemical risk assessment considers the likelihood of the harm occurring under defined conditions of exposure. The consideration of human and environmental exposure to the chemical differentiates "risk" assessment from "hazard" assessment, and promotes effective risk mitigation.

³ For example, in the context of water quality management in Australia and New Zealand, "risk" is typically defined as: 'the joint interaction of both the likelihood and consequence of an event having a negative or adverse impact. Estimates of risk may be expressed in absolute or relative terms. Absolute risk is the excess risk due to exposure. Relative risk is the ratio of the risk in the exposed population to the risk in the unexposed population' (Batley et al. 2017; Warne et al. 2016; ANZECC and ARMCANZ 2000a).

Chemical risk assessments traditionally (van Leeuwen 2007) include:

1. Problem formulation: Specifies what the activity being assessed involves, the regulatory environment that applies, what needs to be protected from harm and clarifies the scope and complexity of the assessment.
2. Data gathering and evaluation (including model construction).
3. Risk analysis:
 - Chemical identification:** identifies the chemical that is relevant for the situation being assessed;
 - Hazard characterisation:** Determines the adverse effects (harm) to receptors that could be caused by exposure to a chemical stressor (also called dose-response or hazard assessment). The hazard identification step is often incorporated as part of an effects assessment step, especially in ecological risk assessment;
 - Exposure assessment:** Determines the fate of the chemical stressor and the potential (or existing) exposure of receptors to the stressor;
 - Risk Characterisation:** The risk is estimated by combining the exposure and hazard assessments to determine the seriousness of potential harm.
4. Risk communication and management: Management and communication of risk identified in the assessment.

2.1.2 National and International Guidance for Chemical Risk Assessment

There are several risk assessment guidance documents which have been developed in an Australian context, for differing industrial settings, which provide relevant guidance for undertaking chemical risk assessments within the coal seam gas industry. The three main guidance documents referenced in this manual are:

- *Environmental Risk Assessment Guidance Manual – for industrial chemicals* (EPHC 2009a)
- *Environmental Risk Assessment Guidance Manual – for agricultural and veterinary chemicals* (EPHC 2009b)
- *Environmental Health Risk Assessment – Guidelines for assessing human health risks from environmental hazards* (enHealth 2012a).

Other guidelines and tools referred to in this manual including:

- *IESC Information Guidelines* (IESC 2015)
- *National Environment Protection (Assessment of Site Contamination) Measure 1999* (ASC NEPM 2013)
- *Australian and New Zealand Guidelines for Fresh and Marine Water Quality*⁴ (ANZECC and ARMCANZ 2000a) and *Australian Drinking Water Guidelines* (NHMRC 2016)

⁴ For further information see [accessed 23/10/2017]: <http://www.agriculture.gov.au/water/quality/nwqms>.

- *The National Harmonised Regulatory Framework for Natural Gas from Coal Seams* (SCER 2013)
- *Risk management – Principles and guidelines*. Australian/New Zealand Standards (AS/NZS ISO 31000:2009) (AS/NZS ISO 2009)
- *Managing environment-related risk*. Australian/New Zealand Standard (AS/NZS Handbook HB 203:2012) (AS/NZS 2012)
- United States Environmental Protection Agency (US EPA 2015b), Organisation for Economic Co-operation and Development (OECD 2015c), and Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework through NICNAS.

2.1.3 When to undertake chemical risk assessments in the coal seam gas industry

Chemical risk assessments should be undertaken for products, processes, situations and activities where there is a plausible case that there could be adverse consequences for the human population (human health risk assessment) and / or for the environment (environmental risk assessment) arising from the use of a chemical. Examples of situations where chemical risk assessments should be undertaken in the coal seam gas industry include:

- introduction of a new drilling, cementing, or hydraulic fracturing chemical under the *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) administered by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
- introduction of an existing chemical, listed on the Australian Inventory of Chemical Substances (AICS)⁵, as a drilling, cementing, or hydraulic fracturing chemical, which has been previously assessed by NICNAS for other uses but not for these particular uses
- assessment of risks or impacts associated with a coal seam gas development proposal
- assessment of pollution impacts at existing facilities, particularly contaminated sites⁶
- changes in operational procedures, particularly where chemical quantities and concentrations increase significantly, or where impacts on human health and environmental factors may result
- storage, use, re-use, or disposal of drilling, cementing, or hydraulic fracturing waste, including cuttings, recycled or spent fluids, wastewater or treated wastewater (for example, for irrigation or release into the environment through spraying or burying).

2.1.4 Approaches to risk assessment

Risk assessments are informed by problem formulation and depend largely on the availability of data. Approaches to risk assessment include:

⁵ Australian Inventory of Chemical Substances (AICS), accessible via <https://www.nicnas.gov.au/chemicals-on-AICS>.

⁶ Where a site may have already been contaminated from previous exposure to chemicals used in CSG activities, a framework is provided in National Environment Protection (Assessment of Site Contamination) Measure 1999, (NEPM 2013) for undertaking a risk assessment for human health and ecological receptors on contaminated land.

- qualitative (i.e. by categorising hazards and by describing risks in terms of 'high', 'medium' or 'low'), through assessment of data on chemical fate, toxicity, potential for bioaccumulation etc., based on expert judgement
- quantitative, resulting in a numerical measure of risk on some defined scale, often expressed in terms of Margins of Exposure (MoE) and / or risk quotients (RQ), and take uncertainty and / or various safety factors into account.

Deterministic or probabilistic approaches may be used:

- deterministic approaches follow known rules (e.g. fixed procedures) and use a point estimate of exposure and a point estimate of effects to predict potential risks (US EPA 2015b)
- probabilistic approaches account for uncertainty in predicting risk by deriving probabilistic estimates of risk. These approaches use an observed range or statistical distribution of estimates of exposure and a range or statistical distribution of estimate of effects to predict potential risks (US EPA 2015b).

The lack of comprehensive data sets will, in general, mean that it is unlikely there will be enough information to undertake a probabilistic chemical risk assessment without needing to make significant assumptions. This may result in little additional information being available for decision-makers while increasing the difficulty of explaining results to stakeholders. See enHealth (2012a):

Before the use of Monte Carlo is commenced for any situation being assessed, the assessor should check with the relevant regulator or government authority about whether such use is considered appropriate. Most regulators are likely to discourage the use of this technique, in the main due to the difficulty in explaining it to the affected community and the lack of robust probability distributions for parameters of interest.

Probabilistic methods are however often used to generate Species Sensitivity Distributions (SSDs), which can be used to develop Predicted No Effect Concentrations (PNECs) and water quality guideline values, where there is sufficient information (Batley et al. 2017; Traas and van Leeuwen 2007; ANZECC and ARMCANZ 2000a).

2.1.5 Designing a risk assessment

Chemical risk assessments in the coal seam gas industry are usually undertaken:

- as part of a planning process when a new development is proposed
- to investigate risks from historical activities
- when the chemicals used are being changed
- when changes are proposed for the procedures used in handling chemicals; or
- as part of the requirements under an environment protection licence / permit.

These risk assessments are conducted with available information. In most of these situations information will be incomplete. This can be because some information cannot be known until a facility is in place and operating or because activities occurred some time ago and there is no documentation outlining exactly what occurred. It is normal practice that assumptions about some aspects of the assessment will be needed and risk assessors have approaches to help identify relevant values for such assumptions. Chemical risk assessments, therefore, always need to acknowledge uncertainty and describe the assumptions being made and the evidence supporting them (enHealth 2012a). Communicating the risk assessors' approach to

identifying and managing uncertainty can be as important to the process, and to stakeholders, as the actual assessment.

The design of a risk assessment program should (enHealth 2012a):

- be based on an appropriate understanding of the situation being assessed
- consider realistic exposure scenarios
- consider the regulatory environment that applies (and the relevant requirements)
- use realistic assumptions or ‘default’ values (in the absence of definitive measurements or predictions)
- consider interactions between components, including aspects that may not be formally included within the assessment
- describe the responses of the human population or receiving environment
- capture direct and indirect impacts; and
- be inherently “bespoke” in nature, and specific to the locations, processes, and hazards being assessed.

The limitations and assumptions of the assessment need to be clearly communicated (enHealth 2012a).

2.1.5.1 Evaluating risk assessment methods

Given inherent uncertainty in any risk assessment, it is important to evaluate the method of risk assessment using criteria such as those below (enHealth 2012a):

- the logical soundness of the method (e.g. its justification based on theoretical arguments or scientific knowledge, and the validity of the underlying methodological assumptions)
- completeness (e.g. whether it can address all aspects of the problem and the degree to which it excludes issues because they are hard to accommodate)
- precision and accuracy (e.g. reflected in the confidence level associated with the results or the biases resulting from undue weight being given to specific considerations and the sensitivity of results to untested or untestable assumptions)
- acceptability (e.g. compatibility with existing processes; whether it is viewed as rational and fair; the level of understanding for all parties affected by it; and the confidence and familiarity of those who will use it)
- practicality (e.g. the level of expertise, time and input data required); and
- effectiveness (e.g. usefulness of results; range of applicability across different risks and problem areas; and effectiveness and efficiency of linkage with other types of methods).

2.2 Risk assessment framework for coal seam gas

For the purposes of this guidance manual, the term ‘chemical’ includes existing and new chemicals or substances used in coal seam gas operations. This includes chemicals associated with drilling activities, cementing and well completion, perforation propellants, acid clean out and pre-wetting chemicals, hydraulic fracturing, and fluid management

activities, including produced and waste fluids⁷. It also includes naturally occurring geogenic chemicals mobilised by drilling or hydraulic fracturing and found in drilling fluids and drilling muds, flowback and produced water, brines, and treated water.

The overall framework for risk assessments of chemicals used in coal seam gas operations is illustrated in Figure 2.1. The human health and environmental risk assessments fall within this framework, although there are some differences, particularly for the hazard and risk characterisation phases. The process for the human health and environment risk assessments are further outlined in sections 2.2.1 and 2.2.2, respectively.

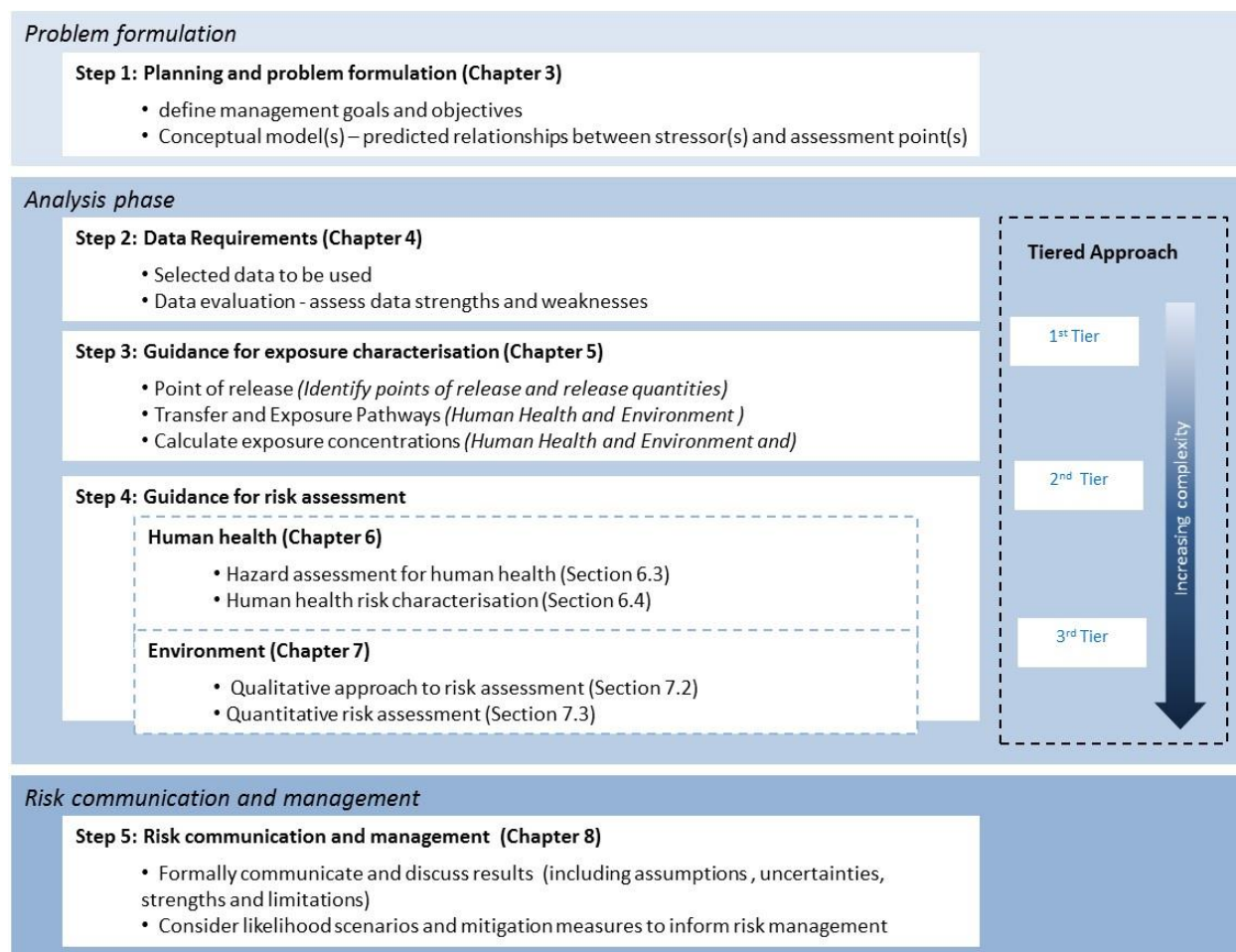


Figure 2.1 Overview of the chemical risk guidance manual for environment and human health risk assessment guidance

The framework for undertaking coal seam gas chemical risk assessments includes:

Problem Formulation:

- planning and problem formulation applies to both the human health and environmental risk assessments. It requires defining the bounds of the risk assessment to ensure it can inform risk management decisions (Chapter 3). This phase includes engaging with

⁷ Waste fluids can include used drilling fluids / muds, including cuttings, flowback water (the fluid that flows back, or is pumped back, to surface following hydraulic fracturing but prior to gas production), and produced water (water that is pumped out of the coal seams to release the natural gas during the production phase).

stakeholders and assessing regulatory requirements, defining assessment endpoints, developing conceptual models and formulating an analysis plan. It also includes:

- description and analysis of the regulatory environment, covering Commonwealth, state, and local government requirements, both for the coal seam gas project and for the scope of the risk assessment
- a conceptual site model, based on what is known of the site prior to the project commencing
- specifics about coal seam gas extraction at the site
- details about the location, geology, hydrogeology, relevant receptors; and any potentially affected communities or sub-populations
- stakeholders who should be consulted during risk assessment
- questions to be answered by the risk assessment

The Risk Analysis Phase:

- data requirements (Chapter 4) provides guidance on identifying data required to delineate hazards and exposure and determine the uncertainties, strength / weakness of the data
- exposure assessment (Chapter 5) provides guidance on the sources of chemicals and their distribution in the environment based on the activities involved in coal seam gas extraction, and potential or actual pathways for exposure of receptors (human and environmental receptors)
- hazard assessment examines the capacity of a chemical to cause adverse effects to human health and / or the environment. The hazard assessments are separated into different chapters for human health (Section 6.3) and the environment (Section 7.2.2)
- risk characterisation integrates the exposure assessment and hazard assessment into an overall risk estimate for human health (Section 6.4) and the environment (Section 7.3).

Risk communication and management:

- assessed risks should be communicated clearly and succinctly, by communicating the results of the risk assessment and through risk sheets or dossiers, which describe the hazards and risks associated with each individual chemical (Appendix E)
- social, economic, political and legal issues should be considered in making decisions about risk management (Chapter 7)
- iteratively monitoring and reviewing throughout the risk assessment is a critical aspect of the process (Figure 2.1). It is essential to re-visit the problem formulation to consider if further assessment is required as a result of additional data, the results of sensitivity and uncertainty analyses, or if chemical use or processes change.

This manual provides guidance on approaches and available tools for assessing the risks of handling of chemicals associated with coal seam gas extraction. Iterative consideration may be necessary at some steps, depending on problem formulation, available data, and assessment outcomes. The risk assessor must always check whether the guidance is

appropriate for the scenarios and circumstances being assessed, and that it meets any relevant regulatory requirements.

2.2.1 Human health risk assessment framework

A human health risk assessment for potential exposure of the public, or workers, to chemicals associated with coal seam gas extraction should be consistent with the guidelines for assessing human health risks from environmental hazards (enHealth 2012a). The exposure and risk equations articulated in enHealth (2012a; 2012b), the *National Environment Protection (Assessment of Contamination) Measure* (NEPM 2013) and the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (Mallants 2017a and 2017b; DoEE 2017b, 2017c, and 2017d; NICNAS 2017a, 2017b, 2017c, and 2017d) should be used in the human health risk assessment and may be appropriately modified, if required, for the circumstances being addressed.

Figure 2.2 illustrates the main components of the human health risk assessment framework and summarises the components of the assessment that are addressed in the subsequent chapters of this manual.

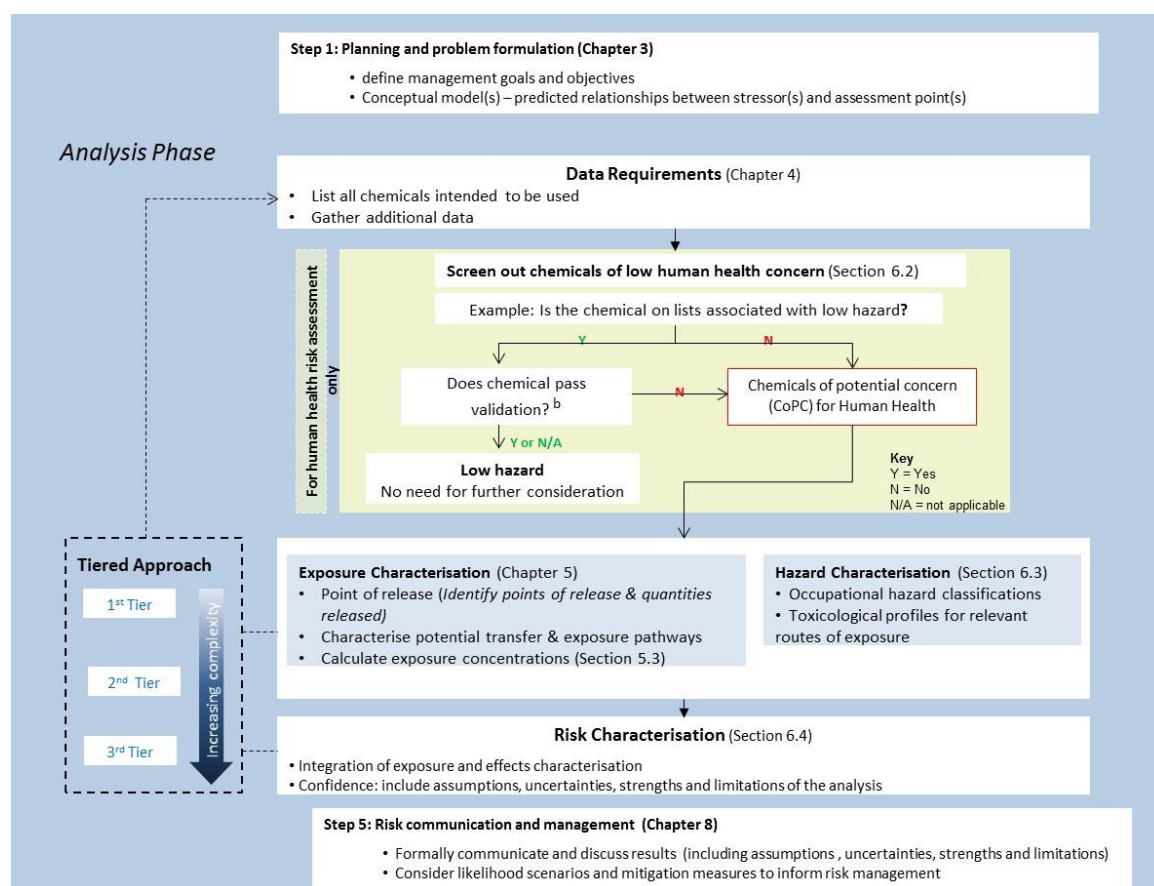


Figure 2.2 Overview of the chemical risk guidance manual for human health risk assessment guidance

^a The described screening approach is specific to the human health risk assessment (see Section 6.2)

^b It is suggested a tiered approach to risk assessment is used, which may involve stepwise refinement of assumptions and collection of additional data in order to reduce uncertainty in the risk assessment conclusions. (see Section 2.2.3)

2.2.2 Environmental risk assessment framework

The framework for environmental risk assessment was influenced by principles of the US EPA Framework for ecological risk assessment (US EPA 2015b, 2017a and 2017b). The diagram below (Figure 2.3) illustrates its main components and summarises the components of the assessment that are addressed in the subsequent chapters of this manual. It is suggested that a tiered approach to risk assessment is used, which may involve stepwise refinement of assumptions and collection of additional data to reduce uncertainty in the risk assessment and its conclusions. This may occur at any of the steps of risk assessment (see Section 2.2.3).

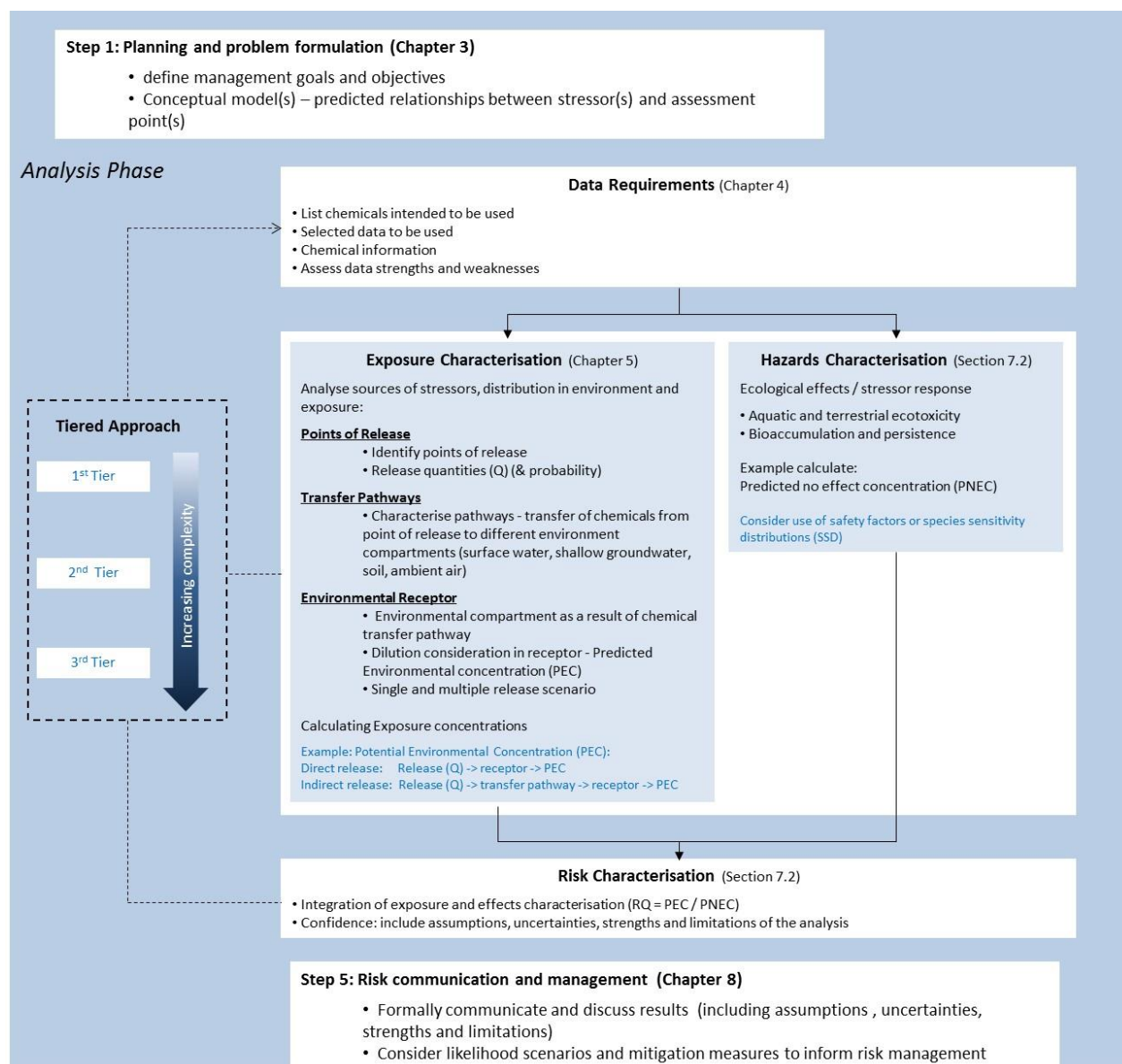


Figure 2.3 Overview of the chemical risk guidance manual for environment risk assessment guidance

2.2.3 Tiered approaches for human health and environmental risk assessments

Tiered approaches to chemical risk assessment are common. Such approaches progress from more conservative to more detailed assumptions, with the requirement for additional data at each successive tier. Tiered approaches can also be used to assess risks at differing

spatial scales, ranging from broad spatial scales to site-specific risks. One advantage of a tiered approach is that the cost and complexity of the risk assessment can be calibrated to the degree of risk. While there is often no clear *a priori* point of delineation between the various tiers, a tiered approach allows the problem under consideration to be assessed at an appropriate levels of complexity (enHealth 2012a).

Figure 2.4 provides an overview of a tiered approach to chemical risk assessment. This tiered approach involves steady refinement of exposure assessments. This is achieved by moving from simple to more sophisticated methods and models with increasing precision and realism to represent chemical quantities, points of release, transfer pathways and environmental receptors. Assessment at higher tiers occurs only if the risk is deemed unacceptable in the lower tier assessment. This flexible approach is preferred to ensure that the cost and complexity of assessments is proportionate to risk.

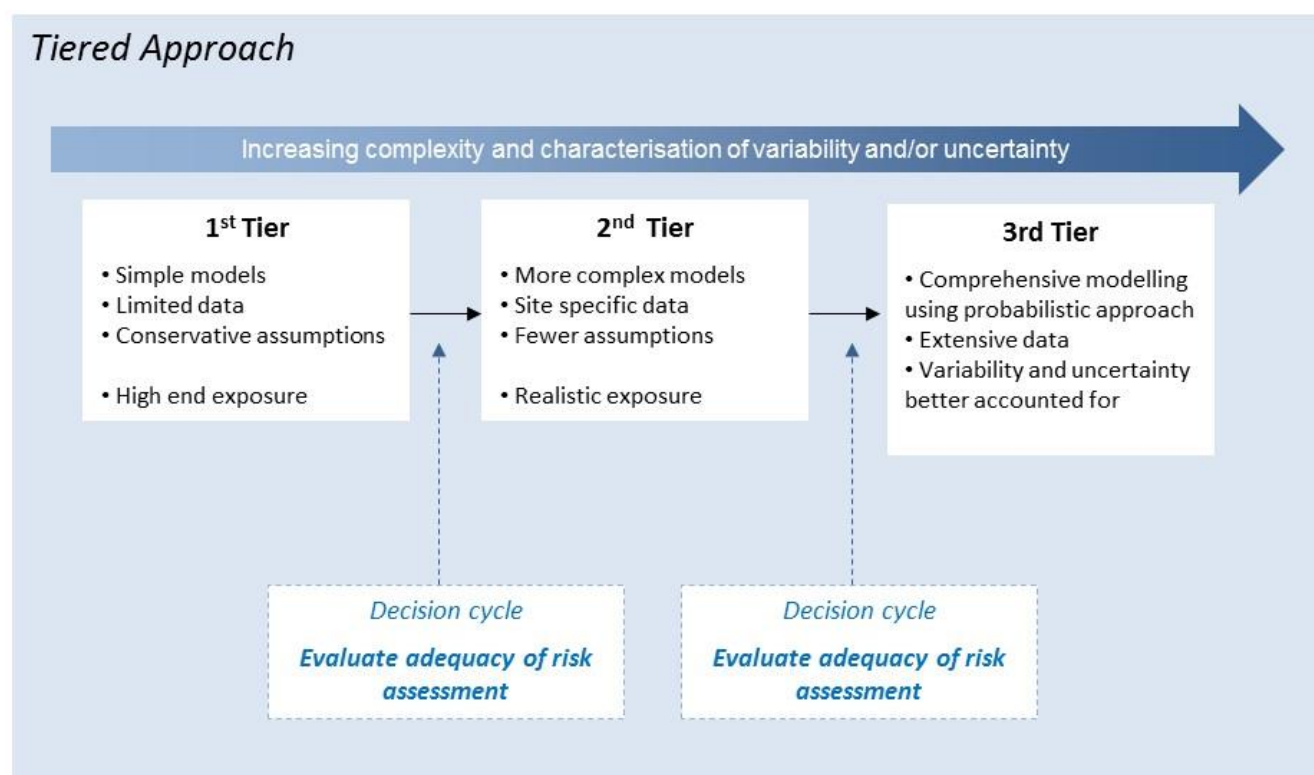


Figure 2.4 Tiered approach for chemical risk assessments

Using a tiered approach to risk characterisation can increase the level of complexity from a relatively simple deterministic approach through to a potentially more complex probabilistic approach (EPHC 2009a and 2009b; enHealth 2012a; US EPA 2015b). An initial assessment using basic tools (for example, using published information about coal seam gas chemicals, results from previous national and international regulatory risk assessments, existing guideline values, simple exposure calculations, and conservative assumptions) can be conducted as a Tier 1 assessment. Depending on the risk assessment outcome and levels of uncertainty, the assessor can then determine whether the results of the Tier 1 assessment warrant further evaluation. This is done through further tiers, with refinements of the input data and exposure assumptions (e.g. by including site-specific data) or by using more advanced models (such as probabilistic models that use distributions of data in place of point estimates).

The number and complexity of risk assessment tiers should be tailored to the circumstance of each individual project or application. The World Health Organisation (Meek et al. 2011)

and enHealth (2012a) include guidance depicting four tiers of progressively more complex assessment (that is, Tier 0 to Tier 3)⁸. The US EPA (2015b) promotes an iterative and flexible risk assessment approach where deterministic and probabilistic approaches can be used in combination and do not have to be conducted sequentially. Other guidelines commonly use an iterative and flexible approach to risk assessment. For example, tiered risk assessment is integral to the national guidance on *Environmental Health Risk Assessment in Australia* provided in enHealth (2012a). The Australian Government also provides guidance on tiered risk assessment in its manuals for assessment of industrial chemicals (EPHC 2009a), agricultural and veterinary chemicals (EPHC 2009b) and contaminated sites (NEPM 2013).

2.2.4 Recommended approach for chemicals associated with coal seam gas extraction

A tiered approach is recommended for assessments of chemicals associated with coal seam gas extraction in Australia, so that the cost and complexity of the assessments are proportionate to risk. This approach entails increasing levels of complexity and a commensurate refinement of assumptions and the inclusion of additional, more site-specific data. The chemical risk assessment will generally progress from an initial check to identify chemicals previously assessed by national or international regulators and considered to be of low hazard and therefore low concern (initial check), to a relatively simple deterministic approach (Tier 1) and, in some cases, through to a more detailed deterministic approach (Tier 2), with decision cycles at each step. A Tier 1, or screening, assessment may in some instances be sufficient to demonstrate that a risk is either acceptably low or very high and therefore unacceptable. More detailed assessment is more often required for risks in the middle or “grey” zone that lies in between. For chemicals with very high Tier 1 risk quotients (greater than 10), or that are present at very high concentrations (in the order of one thousand to ten thousand times higher than guideline levels), refining the risk assessment is unlikely to bring the risk to an acceptable level – more robust risk management measures, such as elimination, may be more appropriate.

For chemicals associated with coal seam gas extraction, chemical risk assessment approaches with two or fewer tiers would be acceptable in a wide range of circumstances. Generally, only a Tier 1 and Tier 2 assessment will be required for chemicals associated with coal seam gas extraction, with any further refinements of models, data, and assumptions built iteratively into the Tier 2 risk assessment. For the purposes of this guidance manual, the recommended chemical risk assessments tiers comprise:

- An initial check to identify chemicals previously assessed by national or international regulators and considered to be of low hazard, and therefore low risk, for human health and the environment
- Tier 1: screening risk assessment
- Tier 2: detailed risk assessment.

Further tiers of progressively more detailed assessment (Tier 3: refined or probabilistic assessments) may be challenging due to their extensive data requirements.

The assessment detail, measured data and modelling requirements, and assessment scale at each tier are described below. The information requirements for this approach are briefly outlined below (further details are available in DoEE 2017b, 2017c, and 2017d):

- **Initial Check:** For both the human health and environmental risk assessment, an initial check is suggested to identify chemicals previously assessed by national or

⁸ See, for example, Figure 1 in Meek et al. (2011: S4) and Figure 5 in enHealth (2012a: 13).

international regulators and considered to be of low hazard, and therefore low risk, for human health *and* the environment. For human health risk assessment, this check identifies chemicals reliably found in other national or international chemical risk assessments to be of low hazard and therefore of low concern for human health.

- The *National assessment of chemicals associated with coal seam gas extraction in Australia* includes an initial check to identify chemicals previously assessed by international regulators and considered to be of low hazard, and therefore low risk, for human health (NICNAS 2017b).
- **Tier 1 (screening):** Tier 1 assessments use simple models and equations to represent generalised conditions, and usually incorporate probable high end or bounding estimate exposure concentrations and existing guideline values. Tier 1 is often deterministic and will usually consider very conservative, reasonable worst-case or worst-case scenarios based on readily available data. Sensitivity testing can be incorporated into this tier.
 - The Tier 1 chemical risk assessments in the *National assessment of chemicals associated with coal seam gas extraction in Australia* make generic conservative assumptions and use standard values and simple modelling to represent a generic Australia-wide situation for environmental risk assessments. For the human health risk assessments, high-end realistic assumptions were used for exposure estimations. Robust hazard information was evaluated for this tier.
- **Tier 2 (detailed):** Tier 2 chemical risk assessments include refined or more detailed modelling, more refined or detailed assumptions to represent actual working sites and the use of a deterministic approach or simple probabilistic approaches (often involving expert judgement) in both the exposure and hazard assessment components of the risk assessment. The inputs include high-end and bounding estimates. Sensitivity testing can be incorporated into this tier.
 - For the environmental risk assessments, the *National assessment of chemicals associated with coal seam gas extraction in Australia* used more complex modelling, regionally specific information about receptors, some site-specific data for the transfer pathways, conservative estimates and assumptions in modelling to represent bioregional situations, and regionally specific upper bound estimates of chemical usage.

Tier 3 (refined) chemical risk assessments, if undertaken, typically include more refined data in the hazard and exposure assessments, along with more local and site-specific data. Probabilistic methods may be introduced. Uncertainty should be estimated using methodologies that are appropriate for a combination deterministic/probabilistic approach by US EPA (2014b). Sensitivity testing can be incorporated into this tier. The exposure assessment as part of *National assessment of chemicals associated with coal seam gas extraction in Australia* used more complex modelling, more site-specific data for the transfer pathways and environmental receptors, and central tendency estimates and assumptions in the models to represent working site situations.

If undertaken, probabilistic risk assessments use more complex models and equations to represent working sites, and incorporate a probabilistic approach in both the exposure and

hazard assessment components of the risk assessment⁹. The inputs include site-specific data, realistic assumptions, and distributions of data. Probabilistic approaches are used and uncertainty is described where possible. Sensitivity analysis should be incorporated into this tier. The *National assessment of chemicals associated with coal seam gas extraction in Australia* did not use probabilistic approaches as the data required were not available at the time of assessments.

⁹ For example, in the environmental risk assessment context, a probabilistic approach for the determination of PECs and PNECs, or deterministic PNEC with more refined ecotoxicity testing if data are not available for the probabilistic approach.

3 Problem formulation and planning the risk assessment

3.1 Planning the risk assessment

Planning and problem formulation require defining the bounds of the risk assessment to ensure the process delivers outputs and outcomes that can inform decision-making. Common steps involved in planning the risk assessment include (adapted from US EPA 2014a, 2017a and 2017b):

- management goals and options – determine the management goals and outcomes that the risk assessors are balancing, such that ‘the margin of exposure to workers or the public is greater than 100 and therefore considered of low concern to human health’ or ‘the risk quotient for each chemical is less than one and is therefore of low concern for the environment’. Definition of management options at this stage refers to the types of management interventions considered acceptable. For example, agreement to the removal or substitution of higher risk chemicals, implementing mechanical separation, use of Personal Protective Equipment (PPE), increasing monitoring effort, etc.
- regulatory requirements – determine applicability and relevance of regulatory requirements to the risk assessment
- scope and complexity – the scope and complexity of the risk assessment could range from screening studies using conservative assumptions, to complex scenarios using site-specific data. This should include the approaches to be taken, an explanation of whether the risk assessment will be qualitative or quantitative (or a mix of both), what tiers of assessment will be utilised, and whether the assessment will be deterministic or probabilistic (or a combination of both).

Determining the regulatory requirements relevant to the risk assessment is an important component in planning the risk assessment. As with other industries, coal seam gas extraction is subject to regulation. States and territories are the primary regulators of coal seam gas extraction activities, although the Commonwealth also has a role¹⁰. Regulatory

¹⁰ Australian Government regulation relevant to coal seam gas exploration, development and operations in terms of use and impacts of chemicals are regulated by the Australian Government primarily through the following legislation:

- *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) provides a legal framework to protect and manage nationally and internationally important flora, fauna, ecological communities and heritage places — defined in the EPBC Act as matters of national environmental significance. Since June 2013, water resources (in relation to coal seam gas and large coal mining development) have been listed as a matter of national environmental significance (known as the ‘water trigger’). A water resource relates to ground water and surface water, and includes organisms and ecosystems that contribute to the physical state and environmental value of the water resource
- The *Water Act 2007* (Water Act) is the central piece of legislation dealing with the management of water resources in the Murray-Darling Basin. Coal seam gas developments that have the potential to impact on Murray-Darling Basin water resources will be required to comply with the Basin Plan and any water resource plan made under the Basin plan.
- *Industrial Chemicals (Notification and Assessment) Act 1989* (ICNA Act) provides a framework for the assessment of health and environmental effects of industrial chemicals, and sets out regulatory obligations on importers, manufacturers and exporters of industrial chemicals. Chemicals used in coal seam gas operations are regarded as industrial chemicals and are subject to the legislative requirements (including assessment activities) prescribed by this Act

frameworks include legislation and policy relating to matters such as environmental protection, water, waste management, land use planning, extractive activities (petroleum), work health and safety, access, landholder consultations, and include specific codes of practice developed for the industry. Individual companies may also use defined management practices and standard operating procedures. Regulation often pertains to specific aspects of coal seam gas operations. Key coal seam gas operations where such regulation is relevant include: drilling, cementing, hydraulic fracturing, containment of flowback and produced water, water treatment, disposal, management of wastewater, salts, brines, and metals, monitoring and reporting.

It is also important to undertake a review of existing and proposed domestic and international regulation of each chemical¹¹. In particular, environmental regulations in the following jurisdictions and international conventions should be considered:

- Australia (Commonwealth, state, and territories)
- Canada
- European Union
- New Zealand
- USA
- Stockholm Convention
- Montreal Protocol
- Rotterdam Convention
- Chemical Weapons Convention.

Engaging with stakeholders and risk communication are important aspects of the planning and problem formulation phase (see Section 7). Some of the questions likely to be relevant to external stakeholders include (adapted from enHealth 2012a):

- has the problem been clearly defined?
- how will the risk assessment assist with resolving the problem?
- have the interests and concerns of affected parties been considered in formulating the problem?
- has the scope of the risk assessment been adequately defined and is it clear what elements will or will not be considered?
- have multiple chemical hazards (from using more than one chemical or from mixtures of chemicals) been identified, and can they be considered in a cumulative or mixture approach?
- are the data available and of suitable quality?

▪ *National Environment Protection Measures (NEPM)*, created under the *National Environment Protection Council Act 1994*, provide national objectives for a variety of environmental matters. Most pertinent to a coal seam gas risk assessment is the 'assessment of site contamination' (NEPM 2013) and 'national pollutant inventory' (NEPM 2008)

▪ *Workplace Health and Safety Act (2011)*, enacted to provide a nationally consistent approach to work health and safety, which has direct relevance to a human health risk assessment.

¹¹ For example, see Appendix E: Risk Assessment Dossier (Section 1.2.4).

3.2 Problem formulation

Problem formulation lays the foundation for the risk assessment. It is used to define the objectives and major considerations of the risk assessment. It allows the risk assessor to determine what is and isn't relevant and defines the boundaries of the risk assessment. A well-structured problem formulation focuses the assessment on the most important risks. Problem formulation (enHealth 2012a) requires that the risk assessor assemble and integrate the available information and data for consideration in the assessment.

The problem formulation stage (US EPA 2014a) involves:

- defining the management goals, the aim of the risk assessment and the approaches to be taken
- outlining the regulatory environment that applies in the situation being assessed (involves consideration of Commonwealth, state / territory, and local government requirements, and may also include consideration of international requirements)
- defining the scope, complexity, and objectives of the risk assessment and clearly identifying the problem
- defining the receptors and assessment endpoints that address risk management goals
- generating conceptual site models that represent predicted key relationships between stressors, exposure and assessment endpoints
- an analysis plan which summarises what will be done during problem formulation and the hypotheses regarding the risk to be tested.

The problem formulation stage requires:

- collating all relevant existing information to develop an initial picture of the activities being assessed and how they could pose a risk to people or the environment – including the development of the conceptual site model
- determining the relevant regulations that may control the activities or specify requirements for the risk assessment
- identifying the methodology and complexity for analysing the risk (exposure and hazard), keeping in mind this may evolve as the assessment progresses
- considering how multiple hazards, mixtures, and cumulative impacts will be assessed
- questions that require answers as part of the risk assessment
- consultation with stakeholders to ensure all relevant matters are covered by the risk assessment.

3.3 Risk Analysis Plan

The problem formulation stage of a chemical risk assessment includes development of a risk analysis plan that outlines the management goals, scope, aim and complexity of the chemical risk assessment. The risk analysis plan is an internal working document for risk assessors and managers and is not part of the risk assessment for a chemical. For the coal seam gas industry, the focus of problem formulation is on the chemicals associated with coal seam gas extraction. This includes chemicals associated with drilling activities, cementing and well completion, perforation propellants, acid clean out and pre-wetting chemicals, hydraulic fracturing, and fluid management activities, including produced and waste fluids. It also includes naturally occurring geogenic chemicals mobilised by drilling or hydraulic

fracturing and found in drilling fluids and drilling muds, flowback and produced water, brines, and treated water. The transportation of chemicals to well sites, storages, or water treatment facilities is also captured in this process. The risk analysis plan is used to outline the management goals, scope, aim and complexity, and methods of the chemical risk assessment for risk managers, risk assessors, and stakeholders.

An analysis plan is prepared and used to outline what data must be collected to allow an exposure and effects assessment to inform the risk characterisation. The questions that are likely to need to be answered in such a risk assessment include:

- which chemicals are likely to be used?
- how can the chemical reach the environment?
- where is the chemical likely to be found: water, soil, air, food?
- are organisms at risk – aquatic or terrestrial or both?
- are people at risk – workers or public?
- how will they be exposed (through drinking, eating, breathing, dermal contact)?
- what is the estimated environmental concentration of the chemical in the event of an accidental release?
- how long will the exposure last?

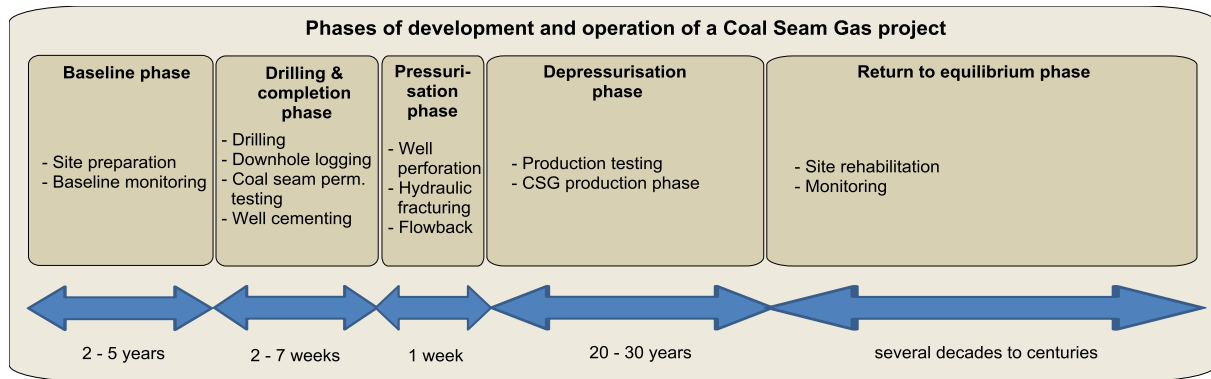
The analysis plan should also address how the information required to answer these questions will be collected.

Risk assessments generally estimate the risk to a given target organism, system, or (sub)population. For a human health risk assessment, the receptor is often used to designate people who may be exposed to an environmental hazard (e.g. direct occupational exposure or indirect exposure of the public through different environmental exposure pathways) (enHealth 2012a). It can also refer to sensitive populations (e.g. pregnant women, children), or human systems or organs within the human organism adversely impacted by the toxicity of a particular substance. For an environmental risk assessment, a receptor may include any organism (other than human), the habitat that supports the organism, or the whole ecosystem (US EPA 2014a). The receptors specific to a risk assessment need to be defined during problem formulation, as they will influence decisions about the scope and the assessment approach.

3.4 Conceptual site models

Graphic and other conceptual site models (sometimes referred to as “conceptualisations”) provide powerful means to communicate complex industrial processes, transport-fate, and receptor relationships (DoE 2015; DEWHA 2008). A conceptual site model covers the way chemicals might get into the environment, what happens to the chemicals (where they go and where they might end up), what exposure pathways are relevant for the situation, and which receptors might be affected – in a graphical format or in a flowchart type format. Examples of graphic conceptualisations of coal seam gas chemical risks are provided in Figures 3.1, 5.1, 5.2, and 5.3. Other examples are provided in DoEE (2017b, 2017c, and 2017d), Mallants et al (2017a and 2017b), DoE 2015, NEPM (2013), and enHealth (2012a).

For example, the lifetime of an individual coal seam gas well, or an entire coal seam gas field, can be divided conceptually into different phases (Figure 3.1). Each phase has a number of typical activities with a relatively well-defined duration and commensurate set of risks. Importantly, these risks are not equally distributed across time and space.



Note. Duration of each phase is indicative (length of arrows is not to scale).

Figure 3.1 Phases of development and operation of a coal seam gas project with typical activities (Mallants et al. 2017a)

The phases of development and operation of a coal seam gas well field are described in Mallants et al. (2017a) as follows:

1. **Baseline or pre-development phase:** starts when the site is being established and includes activities such as site identification, site access and preparation, baseline monitoring prior to production well construction. This may take between two to five years.
2. **Drilling and completion phase:** includes activities such as well construction starting with a bare site, building a pad and pond, setting up the rig, drilling, installing casing and piping, and cementing. This is followed by pump installation, completion of the surface gathering system, and connecting the well to the gathering system. The duration of the phase is normally from two to seven weeks per coal seam gas well.
3. **Pressurisation or hydraulic fracturing fluid injection phase:** starts with the first injection of hydraulic fracturing fluid into the coal formation and terminates when the last fluid is injected. There may be a number of injection events in the life-time of the site. The duration of the injection phase is from hours to days.
4. **Depressurisation phase:** starts soon after hydraulic fracturing phase ends, and covers both flowback and production, including the extraction of gas and water from the coal seam until gas and water extraction ends. The total duration of the depressurisation phase may be up to 20 or 30 years.
5. **Return to equilibrium or post-operational phase:** starts at the end of the depressurisation phase and finishes when groundwater pressures have been restored to their pre-operational levels. It includes activities such as decommissioning, plugging, rehabilitation, and monitoring. This is done progressively as wells are depleted, plugged, and abandoned. The cessation of water extraction via a coal seam gas well does not necessarily result in an overall restoration of the original groundwater pressures. Duration of the post-operational phase can be easily in excess of 100 years (Mallants et al. 2017a; Arrow Energy 2012), and might in some circumstances take a thousand years or longer to reach a new equilibrium (Mallants et al. 2017a; CH2MHill 2013).

Examples of graphic conceptual site models for coal seam gas risk assessments are provided in Mallants et al. (2017a and 2017b) and DoEE (2017b, 2017c, and 2017d). A copy

of a graphic conceptual site model for the Pressurisation Phase (that is, the injection phase of a coal seam gas extraction operation) is set out below:

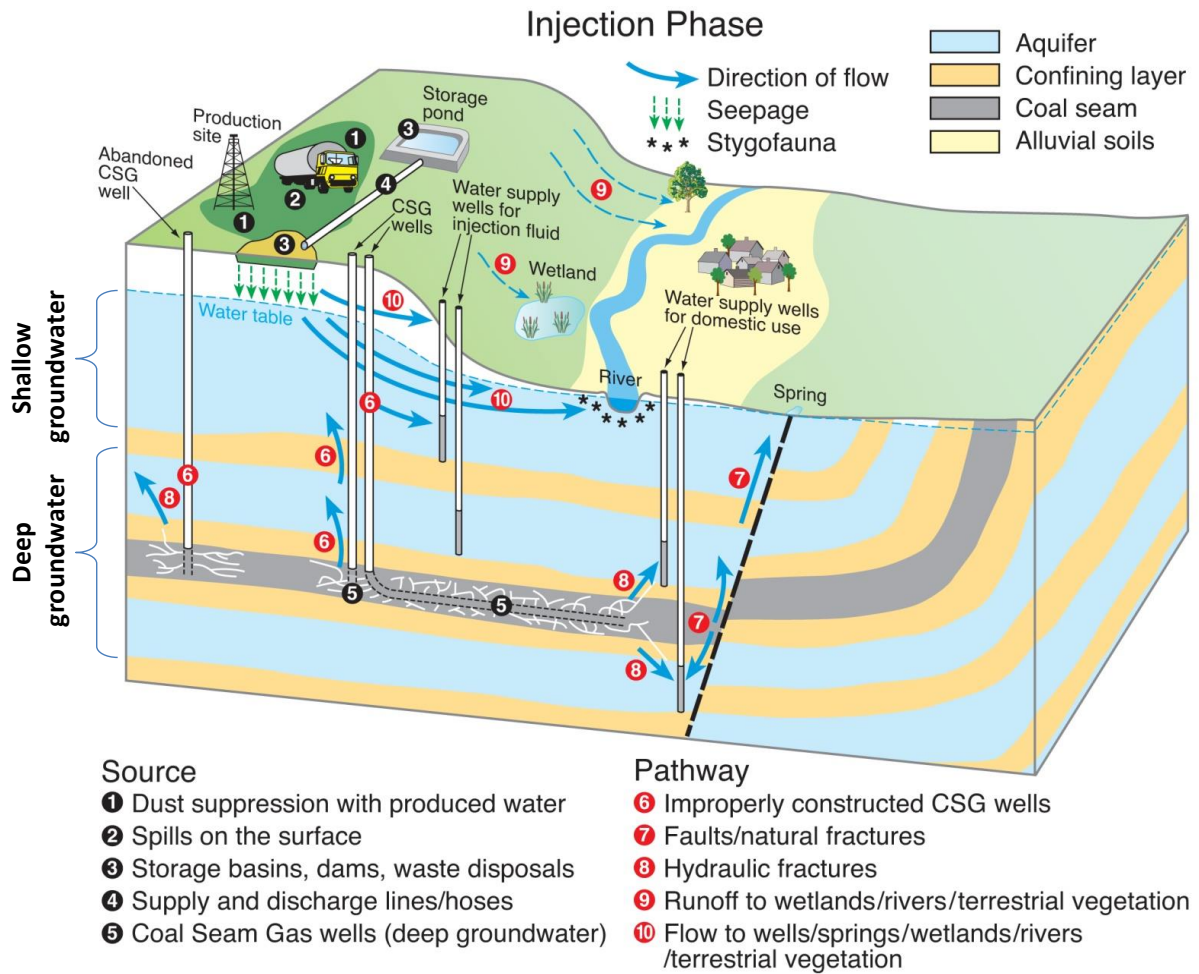


Figure 3.2 Graphic conceptual model of the pressurisation phase of coal seam gas extraction. The conceptualisation depicts potential chemical release points (sources), likely transport-fate pathways, and relevant receptors (Mallants et al. 2017a)

The US EPA's Ecological Risk Assessment (US EPA 2014a, 2017a and 2017b) provides extensive advice on problem formulation, as does the EPHC's Environmental Risk Assessment Guidance Manuals (EPHC 2009a and 2009b) and enHealth's Environmental Health Risk Assessment: Guidelines (enHealth 2012a).

3.5 Checklist

Table 3.1 Checklist for the planning and problem formulation component of the risk assessment

Planning and problem formulation		✓
1	Define the management goals, the aim of the risk assessment, the approaches to be taken, and applicability of regulatory requirements	
2	Define the scope, complexity, and objectives of the risk assessment to clearly identify the problem	
4	Identify the methodology and complexity (tier level) for analysing the risk (exposure and hazard), keeping in mind this may evolve as the assessment progresses	

3	Generate conceptual models representing predicted key relationships between stressors, exposure and assessment endpoints	
5	Consider how multiple hazards and cumulative impacts can be assessed.	
6	What data will be required? Are the data available and accessible? What are the data quality criteria? What are the data gaps and uncertainties?	
7	Have the interests and concerns of affected parties been considered in formulating the problem?	

4 Data requirements

This chapter provides guidance on the data required for a chemical risk assessment. The data and information required to accurately and transparently identify chemicals associated with coal seam gas extraction are listed in Section 4.1. The type of chemical information required for assessing the environmental transport and fate of the chemicals being assessed is listed in Section 4.2. Sections 4.3 and 4.4 discuss the data required for environmental and human exposure and health and environmental hazard assessments. For examples of chemical identification and associated data in the coal seam gas extraction context, refer to SCER (2013), IESC (2015), and NICNAS (2013 and 2017a).

Considering the questions identified during problem formulation, data requirements cover the following aspects:

- chemical identification
- data required for understanding, determining, and modelling exposure pathways
- data required for hazard assessments
- data required for risk assessments
- data for evaluation of quality and analytical processes and models (including uncertainty analysis).

The extent of data required depends on the problem formulation. Important information required for exposure assessment includes identifying and determining routes of exposure and estimating exposure concentrations. For the hazard assessments, important information required includes hazard information for identifying the chemicals of low concern and potential concern, and evaluating relevant toxicity data and relationships from toxicology studies both for human health and environmental receptors. Data requirements can be influenced by whether the risk assessment involves:

- new or existing anthropogenic chemicals, natural substances, and / or materials
- individual chemicals and proprietary products or compounds (that is, mixtures of chemicals)
- anthropogenic drilling and hydraulic fracturing chemicals, naturally occurring geogenic chemicals, chemical and radioactive tracers
- any chemical impurities or trace contaminants.

Previous coal seam gas chemical risk assessments, risk dossiers, and issues such as commercially sensitive business information may also influence data availability.

4.1 Sources of data and information

Information on the identity, physico-chemical properties and environmental fate and effects of 113 chemicals associated with coal seam gas extraction in Australia in the period 2010-2012 is contained in DoEE (2017b) and NICNAS (2017a). Where those reports include an assessment of a chemical or there is an assessment (published on the NICNAS website¹²) under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework, it may be possible to draw on these to simplify the assessment of the risks of using that chemical for a

¹² <https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments>

proposed coal seam gas extraction process; for example, assessors could refer to the IMAP reports as a source of hazard information. Most chemicals associated with coal seam gas extraction are used for other industrial purposes. The IMAP assessment framework was established to identify and rapidly assess existing industrial chemicals on the Australian Inventory of Chemical Substances (AICS) that had not previously been assessed. Priority is given to chemicals on AICS that are considered most likely to be hazardous to human health or the environment.

Section 4.1.1 provides details of databases and other useful resources for information on the properties of many industrial chemicals.

Information may also be available in risk assessments conducted by international regulatory agencies such as the US EPA, European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), and Environment Canada. Primary sources of information such as laboratory studies conducted in accordance with OECD or US EPA methods are generally more reliable than secondary sources (EPHC 2009a). However, when considering the chemicals associated with coal seam gas extraction, it is often necessary to rely on secondary sources because primary information may not be available. Therefore, information from secondary sources should be cross-checked with other references, where possible.

Peer-reviewed scientific literature is an important source of information, especially for less common chemicals or more specialised data. Chemical information in the scientific literature will usually be framed in a particular context. This context must be carefully considered to ensure that the information is relevant to coal seam gas operations. For example, the environmental exposure pathways for a biocide that is used in coal seam gas drilling and / or hydraulic fracturing fluids and in the formulations of industrial coatings will be different because of their intended uses and the locations at which they are to be used. Thus, information in the literature on the environmental risks associated with using the biocide in an industrial coating may have limited relevance for coal seam gas operations.

Hazard Information may be available in risk assessments conducted by international regulatory agencies such as the US EPA, the European Food Safety Authority (EFSA) and Environment Canada. Other sources of information include Beilstein's Handbook of Organic Chemistry, Gmelin's Handbook of Inorganic Chemistry, the Merck Index, and the CRC Handbook of Chemistry and Physics. Technical and academic publications are also valuable resources.

The available information on physico-chemical and fate and effects properties may be incomplete, even for common chemicals (see Sections 4.2 and 4.3). For example, the Henry's constant, the octanol-water and soil-water partitioning coefficients and the degradation half-life are often unavailable. In such cases, they must be estimated by comparison with analogues or by using QSAR models (see Sections 4.5.1 and 4.5.2). Additionally, toxicity data are often limited to one or two species (typically algae and / or fish), or there may be no toxicity data available. Toxicity can sometimes be estimated by analysis of data on analogue chemicals. Section 4.5 of this manual, EPHC (2009a), and Environment Canada (2003) provide detailed advice on the use of analogue and QSAR data. Certain substances¹³ are however difficult or impossible to model using QSAR analysis. When critical data are unavailable, and QSAR modelling or analysis of analogues are not appropriate, a greater reliance on other lines of evidence is necessary (see Sections 4.7.4 and 8.2).

¹³ Certain substances are difficult or impossible to model using QSAR analysis including, for example, polymers, UVCBs, surfactants, chemicals with very low water solubility, high log K_{ow} chemicals, ionisable chemicals; inorganic and organometallic chemicals.

Information on the intended use of a chemical, the quantities and concentrations to be used, estimates of possible release quantities, runoff volumes, and distances to potentially exposed environmental entities will be specific to the proposed coal seam gas operation. This information will directly inform the chemical risk assessment and can usually be found in environmental impact statements provided by coal seam gas companies in their submissions to state and Commonwealth governments.

4.1.1 **Databases and other sources of data**

Existing databases can provide chemical identification, physico-chemical information, and toxicity / ecotoxicity data. Chemical identity, relevant measured physico-chemical properties and measured ecotoxicological data can be obtained using the Chemical Abstracts Service Registry Number (CAS RN) from the OECD Quantitative Structure Activity Relationships (QSAR) Toolbox (OECD 2015b). Other useful ecotoxicological resources include the US EPA Ecotoxicology Database (ECOTOX) (US EPA 2015a), the US Risk Assessment Information System¹⁴, and the Australasian Ecotoxicology Database (for example, Langdon et al. (2009)). These toolboxes and databases contain comprehensive databases of chemical identities and experimental results from the literature for thousands of chemicals.

For human health hazard assessments, detailed guidance on selecting sources of toxicological data and health criteria, as well as evaluating quality of studies is provided in Section 5.12 in enHealth (2012a).

The following databases and tools are useful starting points for information on the identities and properties of industrial chemicals:

- The NICNAS website (which contains information about chemicals listed in the Australian Inventory of Chemical Substances¹⁵, and chemicals that NICNAS has assessed)
- OECD QSAR Toolbox¹⁶: <http://www.qsartoolbox.org/>;
- OECD eChemPortal: eChemPortal – Substance Search tool <http://www.echemportal.org/echemportal/page.action?pageID=9>;
- US NIH PubChem search tool: The PubChem Project: <https://pubchem.ncbi.nlm.nih.gov/>;
- US EPA EPI Suite¹⁷: <https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>
- US Risk Assessment Information System <https://rais.ornl.gov/>.

Other information services and databases include the subscription services SciFinder and Reaxys.

4.2 **Chemical identification**

Accurate identification of the chemicals associated with a given coal seam gas extraction operation is essential for hazard and exposure assessment and risk management and communication. The list of identified chemicals should include all chemicals associated with drilling activities, cementing and well completion, perforation propellants, acid clean out and

¹⁴ The US Risk Assessment Information System is accessible via: <https://rais.ornl.gov>.

¹⁵ Australian Inventory of Chemical Substances maintained by NICNAS under the ICNA Act: <https://www.nicnas.gov.au/forms/Australian-Inventory-of-Industrial-Substances> [accessed 23/10/2017]

¹⁶ OECD QSAR Toolbox <http://www.qsartoolbox.org/>

¹⁷ US EPA EPI Suite: <https://www.epa.gov/tsca-screening-tools/epi-suite-estimation-program-interface>.

pre-wetting chemicals, hydraulic fracturing, and fluid management activities, including produced water and waste fluids. It should also include naturally occurring geogenic chemicals mobilised by drilling or hydraulic fracturing and found in drilling fluids and drilling muds, flowback and produced water, brines, and treated water (e.g. dosing agents to enable re-use, to assist reverse osmosis processes, anti-corrosives, biocides, etc). Chemicals associated with coal seam gas extraction can include industrial chemicals, polymers, natural substances and materials. The identification and description of a coal seam gas chemical should also include any known chemical impurities or trace contaminants.

The accurate identification and description of the chemicals associated with coal seam gas extraction can directly influence the quality and transparency of the chemical risk assessment. The data required are outlined in SCER (2013) and IESC (2015), and includes information such as:

- names of the companies producing drilling and fracturing fluids and associated products
- proprietary names (trade names) of compounds (drilling and fracturing fluid additives) being used
- chemical names and Chemical Abstracts Service registration numbers (CAS RNs) of each additive used in each of the fluids
- general purpose and function of each of the chemicals used
- the total mass or volume of the fluid to be used / injected
- concentrations (mg / L or g / kg) of chemicals used in different fluids at different stages of operations
- safety data sheets for the chemicals or chemical products used.

Discrete chemicals should be defined by a Chemical Abstracts Service (CAS) Registry Number (CAS RN) and the CAS preferred chemical name, plus any proprietary and common names. Their formula and structure should be adequately described, and should be cross-checked with information in the Australian Inventory of Chemical Substances (AICS)¹⁸. Each chemical's purpose or function within the coal seam gas operation should be explained. The identity of each individual substance is an important part of the risk assessment process. For example, the CAS RN can be used to confirm a chemical's listing in the AICS, and can be used as input to modelling tools such as the Organisation for Economic Co-operation and Development's (OECD) Quantitative Structure Activity Relationships (QSAR) Toolbox (OECD 2015c) which contains a large database of relevant chemical properties, toxicological and ecotoxicological data.

4.2.1 Chemicals in formulation and blends

This guidance manual focuses on chemicals used for drilling and hydraulic fracturing. Drilling and completing coal seam gas wells consists of a series of separate activities, including drilling, cementing, and testing, after which the well can either enter production or be prepared for perforation and well stimulation (often referred to as hydraulic fracturing). Hydraulic fracturing involves injecting gas, fluid, or gels under high pressure into the coal

¹⁸ The Australian Inventory of Chemical Substances (AICS) is a database of chemicals available for industrial use in Australia, including for coal seam gas extraction. The AICS can be accessed via: <https://www.nicnas.gov.au/chemicals-inventory-AICS>. There are two main sections of the AICS: public and confidential. The AICS provides chemical identify information and any associated regulatory obligations, including conditions of use. A chemical listed on AICS may be used, imported or manufactured in Australia. If the chemical is not listed in the AICS, or the proposed use falls outside the scope of its stated purpose in AICS, NICNAS must be notified (unless an exemption applies) and an assessment conducted.

seam layers to fracture the gas-containing coal layers. The fluids used in hydraulic fracturing are typically formulated using water, proppant (that is, material such as sand or quartz used to prop open the fractures) and a mixture of chemicals. The exact mixture may differ depending on the location, the geology at the site, the type of well, and the nature of the coal seam being fractured. Individual chemicals, blends of chemicals, and chemical mixtures could be considered during the assessment.

4.2.2 *Flowback and produced water*

One way the chemicals used in drilling and hydraulic fracturing can reach the environment is in flowback and produced water. Flowback water is the water extracted from the coal seam after the drilling and / or hydraulic fracturing occurs. It is described as flowback water until the volume of fluids injected into the ground has been extracted. Produced water is the water extracted from the coal seam once a significant proportion of the injected chemicals have been recovered – that is, produced water should primarily consist of formation water from the coal seam with minimal anthropogenic chemicals. Put another way, the water quality of produced water should not be significantly different from the natural formation water.

The scope of the assessment should include consideration of the chemicals present in flowback, produced and other water associated with gas extraction including brines. Well-head monitoring and mechanistic studies may be required to identify these.

Injected chemicals and chemical mixtures, flowback and produced water, and water stored prior to treatment may contain geogenic chemicals, monitoring isotopes, tracers and other anthropogenic chemicals as well as the original components of the drilling and hydraulic fracturing fluids. The brines produced during Reverse Osmosis (RO) treatment processes may also contain these chemicals. The concentrations of geogenic contaminants mobilised from the coal seam will depend on the composition of the hydraulic fracturing agents and the nature of the coal seam being fractured.

An example of a list of water quality parameters, including potential geogenic analytes, is provided in Appendix A (based on monitoring parameters presented in, for example, Hydrobiology 2013 and Parsons Brinkerhoff 2015). Data requirements need to be tailored to the risk assessment task and problem formulation (for example, the risk assessment may require data such as: speciation of certain metals, different Naturally Occurring Radioactive Materials (NORMs), or different laboratory detection limits etc.).

4.3 Data required for exposure assessment

4.3.1 *Quantities and concentrations*

The quantities and concentrations of chemicals associated with coal seam gas extraction and / or mixtures being used are integral to Point of Release modelling and determination of Predicted Environmental Concentrations (PECs) for different environmental compartments. Data on quantities and concentrations will depend on the use and release patterns of the chemical(s) being assessed and the tier at which risk is assessed.

The following may be considered, depending on the scope of the assessment:

- quantities (volumes and / or masses) and concentrations (mg/L or mg/kg) of drilling and hydraulic fracturing chemicals and mixtures transported, stored, and injected or returned to inventory
- quantities (volumes and / or masses) and concentrations (mg/L or mg/kg) of chemicals released to the atmosphere during the mixing / blending activities

- quantities (volumes and / or masses) and concentrations (mg/L or mg/kg) of anthropogenic and geogenic chemicals in flowback and produced waters and brines
- quantities (volumes and / or masses) and concentrations (mg/L or mg/kg) of salts and metals produced per year per well (as a result of higher salinity of formation water compared with surface waters)
- characteristics of waste fluids transfer and storage
- operational and production conditions (i.e. level of containment and other mitigation measures) and external factors such as flood risk
- details of existing risk control measures.

Data may include, but are not limited to:

- information on transport characteristics (e.g. travelling route, truck size, number, frequency and volumes of chemical transported)
- storage characteristics at each potential point of release (e.g. site of storage, location of the storage facility, number and volumes of chemical stored, storage time)
- usage characteristics at each point of release
- distance of the operational site from the local population and environmental entities¹⁹
- details of waste disposal and wastewater storage (e.g. the minimum and maximum capacities [volume] of the storage dams that store produced and flowback waters, seepage rates, manufacturing and design specifications, etc)
- the sources feeding the dams (e.g. flowback water only, produced water only, or a combination of both, and percentages of each) and the concentrations of anthropogenic and geogenic chemicals in the flowback and produced water held in the storage ponds
- the number of wells per hectare and the minimum and maximum number of wells feeding a storage dam under specific period (e.g. weeks, months)
- the amount (volume / day) of flowback water and produced water collected per well
- the percentage of solids in the flowback water and produced waters
- the volumes of wastewater (flowback water, produced water and the wastewater from the dams) used in each area for dust suppression and irrigation
- details of wastewater treatment methods
- management of brine permeates produced by water treatment facilities.

An example of the data requirements can be found in the *National assessment of chemicals associated with coal seam gas extraction in Australia*, which includes point of release models for each of the above.

4.3.2 Exposure routes and compartments

This section outlines data required to quantify the amount of a chemical that may be released into the environment and identify and characterise key environmental compartments

¹⁹ Particular attention should be paid to sensitive environmental entities that are less than 2 000 m from the coal seam gas operation (NICNAS 2017d). However, entities further than this may also require consideration.

(sometimes referred to as environmental media). This information assists in modelling exposure pathways. These can include:

- aquatic – surface water and groundwater
- terrestrial – soil
- air – on-site and ambient.

The list of data in the following paragraphs is not exhaustive and a risk assessor may have only part or all of the desired information. The required information will be guided by the scope of the risk assessment as well as the type of risk assessment being undertaken (i.e. qualitative or quantitative), which will also drive the need for further data generation if it is deemed that there is a paucity of information for the level of assessment needed.

The following information relating to environmental compartments should be considered for an *environmental* exposure assessment:

- identification, location (spatial coordinates) and description (physico-chemical, chemical and biological parameters) of aquatic (e.g. streams), terrestrial (e.g. soil) and ambient air compartments at coal seam gas operational sites and the surrounding environment
- surface and groundwater hydrology (including springs, streams, wetlands, and groundwater-dependent systems; their hydrological flow regimes; and the movement of groundwater and its connections with losing and gaining surface water systems)
- Rainfall, flow, and flood data, including flood frequencies and rainfall intensity (important for considering potential spills and pond overflows)
- catchment size and slope of the terrain (to calculate potential run-off at point of exposure)
- protected aquatic and terrestrial species and ecosystems near the site, including Matters of National Environmental Significance (MNES)²⁰.

Exposure pathways for human health are also closely related to these environmental compartments. For example, point of release scenarios may relate to occupational exposure, while environmental compartments affected through different chemical transfer pathways may result in exposure to the public.

The following information should be considered when gathering data for the *human health* exposure assessment:

- distance from nearest coal seam gas well / site / operation / discharge or spill location to water sources used for human consumption (including groundwater if applicable). If data are not available, conservative assumptions should be made
- population information, including distances to dwellings and population centres
- how chemicals are stored at a site and how fluids are mixed together (delivered already mixed or mixed on site, etc.)
- where and how the chemical is used (including description of processes, activities, and products) and number of workers at site

²⁰ The information required to identify and characterise environmental receptors can be sourced from government tools such as the Protected Matters Search Tool [accessed 23/10/2017]: <http://environment.gov.au/epbc/protected-matters-search-tool>.

- characteristics of the chemicals (see chemical properties in Section 4.2): physical state, vapour pressure (for liquids), dustiness (e.g. powder, pellets) (for solids), etc.
- concentrations of chemicals in mixtures
- operational conditions (i.e. level of containment)
- efficiency of local ventilation (for indoor activities only)
- duration of work activity in which contact with chemicals may occur
- details of existing risk management measures (e.g. personal protective equipment (PPE) used, use of enclosed mixing hoppers, closed and automated batching machinery, etc.).

4.3.3 *Data required for assessing the transport and fate for each chemical*

Understanding the fate of a chemical in the environment, and how it is transported through the environment, is a critical part of the chemical risk assessment process. There are physico-chemical parameters that assist in predicting the transport and fate of a chemical in the environment.

The transport and fate of a chemical can include:

- rapid degradation (by the sun, through temperature and pressure, environmental conditions, microbiological metabolism) – which means the chemical doesn't get transported far or accumulate in sediments, etc
- some degradation / water soluble – the chemical breaks down in a reasonably short time frame but moves with water so it can travel some distance
- Some degradation / attachment to organic carbon – the chemical breaks down in a reasonably short time frame but can also adhere to the organic carbon in soil, sediment, or suspended sediment, so the chemical travels a shorter distance but can accumulate in higher concentrations at some locations
- Persistent and attaches to organic carbon – the chemical doesn't really break down into its component parts under environmental conditions but it attaches to organic carbon in soil, sediment or suspended sediment, so it accumulates but doesn't travel far
- Persistent and water soluble – the chemical doesn't break into its component parts and is water soluble so travels some distance.

Data are required to inform the extent of loss of chemicals from solution and the potential for chemicals to move from one environmental compartment to another. The chemical fate pathways which may result in loss of chemicals (e.g. through degradation), or subsequent exposure in a secondary receiving environment, need to be understood to more reliably predict the environmental exposure of chemicals associated with coal seam gas (DoEE 2017b, 2017c, and 2017d; Mallants et al. 2017a and 2017b).

Table 4.1 and Table 4.2 outline some common data requirements and the types of data that may be used to help predict how the chemicals may move in surface and subsurface environments, and where they might end up. The actual data required for a chemical risk assessment will depend on a variety of factors, including the level of assessment. If a tiered approach is used, the initial tier will use simple models with conservative estimates. For

higher tiers, chemical and site-specific information is used to predict the extent of degradation and mobility from one receiving environment to another.

The *National assessment of chemicals associated with coal seam gas extraction in Australia* identified three vital parameters for preliminary exposure assessment: the time taken for half of the chemical to degrade (DT_{50}), partitioning coefficients (K_d , K_{oc} , and K_{ow}), and Henry's Law Constant (K_H). These data are a major determinant of the mobility of chemicals from soil to water, from water to sediment, or between water and air. For example, within the aquatic compartment chemicals with high $\log K_{oc}$ or $\log K_{ow}$ value partitioning coefficients will tend to partition to sediment whereas, chemicals with low coefficients will partition to water²¹.

Table 4.1 Common data requirements

Data requirements
Chemical Identifier (Chemical Abstracts Services Registry Number [CAS RN])
Chemical names (CAS name and synonyms; IUPAC names; common names if available)
Molecular and structural formulae (molecular weight or number average molecular weight for polymers)
SMILES string
Physico-chemical properties
Dustiness (solids)
Melting and boiling points
Relative density
Vapour pressure and volatility
Vapour pressure of active chemical (Pascal (SI))
Henry's Law Constant (K_H)
Physical state (i.e. solid, liquid or gas)
Solubility in water
Solubility in organic solvents (at 15 to 25°C)
Partition coefficient (pK_a)
n-octanol / water partition coefficient (K_{ow})
effect of pH (4-10) on the n-octanol / water partition coefficient
soil partition coefficient (K_d)
Abiotic degradation rate
Stability in water, hydrolysis rate, photochemical degradation, quantum yield and identity of breakdown products, dissociation constant
Estimated photochemical oxidation
Hydrolysis rate of relevant metabolites
Direct phototransformation of relevant metabolites
Electrical Conductivity (EC or $\mu S/cm^{-1}$ at 25°C)

²¹ $\log K_{oc}$ values describe a chemical's organic carbon normalised partitioning coefficient, while $\log K_{ow}$ values describe the chemical's n-octanol-water partitioning coefficient.

Table 4.2 Other commonly used types of data

Fate and behaviour in the environment
Route of degradation in soil – laboratory studies Aerobic degradation Anaerobic degradation Soil photolysis
Rate of degradation in soil (Laboratory and/ or field based) Time taken for 50% of the active chemical to degrade (DT50) Aerobic degradation – active chemical (at 20°C and 10°C) Aerobic degradation – relevant metabolites (at 20°C) Anaerobic degradation – active chemical (at 20°C and 10°C) Anaerobic degradation – relevant metabolites (at 20°C)
Field Studies Soil dissipation testing in representative soils Soil residue testing Soil accumulation testing on relevant soil
Mobility studies Adsorption/desorption of the active chemical Adsorption/desorption of the relevant metabolites Column leaching of the active chemical Column leaching of the relevant metabolites Aged residue column leaching Leaching (TLC) Lysimeter studies Field leaching studies Volatility
Ready biodegradability of the active chemical
Degradation in aquatic systems Aerobic degradation in aquatic systems, metabolite identification Anaerobic degradation in aquatic systems, metabolite identification Water/sediment systems
Degradation in the saturated zone of the active chemical and metabolites
Rate and route of degradation in air
Monitoring data concerning Fate and behaviour (active and metabolites)
Other / special studies
Bioconcentration potential Aquatic bioavailability Biomagnification potential

Once there is an understanding of how the chemical behaves in the environment, the next step is to estimate the concentration in each relevant medium where people or the environment may be exposed.

The environmental exposure and fate of a chemical depends on its movement, transport, and likely destination within the environment. The potential for human and environmental exposure is estimated by consideration of factors that include the quantity and concentration

of the chemical being transported and stored, where it will be used, the properties of the chemical, the frequency and duration of any releases to the environment, the exposure pathways, and the environmental fate of the chemical (DoEE 2017b, 2017c, and 2017d; Mallants et al. 2017a and 2017b). To predict the exposure of chemicals associated with coal seam gas to human beings and / or the environment, the chemical fate pathways which may result in loss of chemicals (for example adsorption, alteration, and degradation) or subsequent exposure in a secondary receiving environment need to be understood.

In a tiered approach, simple models often use high-end or bounding estimates (the highest possible exposure) and assumptions. For modelling higher tiers, chemical and site-specific information can be used to more accurately predict the extent of degradation and mobility from one receiving environment to another (see Sections 2.2.3 and 4.3).

4.3.4 **Monitoring Data**

While predicting the behaviour of a chemical and environmental concentrations using physico-chemical parameters and relevant models can provide valuable insights, monitoring and measurement of actual concentrations are often necessary to confirm the predictions or to estimate environmental concentrations when models are not valid for a particular chemical. Notwithstanding the need to prevent exposure to hazardous chemicals and a precautionary approach to chemical emissions, measurements may also be needed to establish the conditions of the environment into which the chemicals might be discharged or spilled.

Monitoring is a systematic and planned series of observations that, when appropriately analysed and reported, provide information about the state of the environment (e.g. a terrestrial compartment). Monitoring can be for a wide variety of purposes. Monitoring data – including physico-chemical, chemical, geological and hydrogeological, epidemiological and biological data in humans and the aquatic and terrestrial compartments – are critical to exposure and hazard assessment, and are generally preferred to modelled scenarios if chemicals are already in use. Quality control and assurance of these data are critical. For further guidance, enHealth (2012a, Chapter 14) and / or the *Australian guidelines for water quality monitoring and reporting* (ANZECC and ARMCANZ 2000b) should be referred to. These publications discuss methods and routines for monitoring programs.

Some of the critical aspects to consider when using monitoring data in a risk assessment include:

- the objectives and design of the monitoring program, including spatial variability, sampling sites or populations (e.g. appropriate reference and control sites, the availability of biological reference ranges for parameters to be investigated), timing of sampling, frequency of sampling, ethical and confidentiality considerations, precision and accuracy (number of samples) and parameters to be measured. The collection of demographic data such as gender and age for populations may be particularly relevant to human biological monitoring programs.
- quality control and assurance of the data used:
 - in the field – use of appropriate sampling methodologies, devices, and the appropriate tissue and / or fluid samples, protocols to minimise contamination, inclusion of blanks and duplicates, appropriate sample preservation and storage and chain of custody documentation (for example, covering the entire chain of custody from sample collection “at site” through to lab analysis)
 - in the laboratory – selection of appropriate analytical methods and analytes (e.g. chemical or its metabolite), appropriate laboratory protocols / blanks / duplicates,

sufficient resolution in laboratory detection limits for chemical measurements, ensuring sample storage times are not exceeded, and appropriate chain of custody and laboratory reporting

- how the results will be managed, particularly for human health studies. It is important before embarking on a monitoring program that the results of the testing can be interpreted in a meaningful way. Factors other than environmental contamination (e.g. water intake, strenuous physical activity, heat, diet, cigarette smoking, etc.) can affect biological monitoring results and should be taken into consideration. Such investigations require a very clear understanding of purpose, the endpoint to which data will be compared is well understood, and that the monitoring is health-based and is not intrusive. Ethics approvals may also be required.

4.4 Data required for hazard assessment

4.4.1 Human health

Existing hazard classifications of chemicals for occupational health and safety should be noted (NOHSC 2004; Safe Work Australia 2015). Examples of databases and information sources that could be used to identify hazard information are provided in enHealth (2012a) and NICNAS (2017c and 2017d).

Detailed guidance on selecting sources of toxicological data and health criteria, as well as on evaluating the quality of the studies, is provided in Section 5.12 of the *enHealth Guidelines for Assessing Human Health Risks from Environmental Hazards* (enHealth 2012a). These approaches are also directly applicable to the assessment of chemicals associated with coal seam gas extraction. Risk assessors are encouraged to refer to the existing guidance documents for direction on hazard identification and dose response assessment. The level of detail required depends on the applicable tier of risk assessment and stakeholder requirements / concerns.

A comprehensive data package required for human health hazard assessment will generally consist of the following elements:

- toxicokinetics: this refers to the process of uptake of a compound by the body, the biotransformation it undergoes, the distribution of the substance and its metabolites in tissues, and its elimination from the body. Also known as ADME (Absorption, Distribution, Metabolism, and Excretion)
- acute toxicity: this refers to short-term toxicity. Acute toxicity studies investigate the effects of single exposures to a substance. Results from these studies include the median lethal concentration (LC₅₀) from an inhalation study or the median lethal dose (LD₅₀) from an oral or dermal study
- irritation / corrosivity: skin and eye irritation (i.e. the production of reversible damage to skin or eyes) are typical toxicity endpoints investigated in acute toxicity tests. When a substance produces irreversible damage to the skin or eyes following application to a test animal, this is referred to as corrosion (i.e. corrosivity)
- sensitisation: this refers to when a substance induces an allergic response or hypersensitivity of the skin or airways following dermal or inhalation exposure (skin or respiratory sensitisation)

- repeat dose toxicity: this refers to animal toxicity experiments in which doses are administered repeatedly over a longer time frame than for an acute test. Examples include short-term repeat dose toxicity tests with exposure duration of up to 90 days in rodents, or chronic toxicity tests which typically last for the greater part of the lifespan of the test animal, usually 18 months in mice and 2 years in rats
- genotoxicity: this refers to studies designed to determine whether a test substance can perturb genetic material to cause gene or chromosomal mutations
- carcinogenicity: this refers to studies to determine whether a substance or a mixture can induce cancer or increase its incidence. Typically, in rodents, long-term (i.e. chronic) toxicity studies are conducted simultaneously with carcinogenicity investigations. Chronic toxicity tests typically last for the greater part of the lifespan of the test animal, usually 18 months in mice and 2 years in rats
- reproductive toxicity: this refers to studies designed to provide information about the effects of a test substance on reproductive performance (e.g. effects on sexual function and fertility) in both male and female animals. When the adverse effects are observed in offspring as a result of exposure during pregnancy, this is referred to as developmental toxicity. Effects in offspring due to exposure through lactation are also considered
- other adverse health effects closely linked with the above (e.g. neurotoxicity, immunotoxicity and endocrine disruption).

Such a comprehensive data set may not be readily available for use in coal seam gas chemical risk assessment performed by non-government assessors. In such cases, information available may be limited to the data held by the manufacturer, importer, or service provider; data in the relevant safety data sheet; and other information available in international databases and the scientific literature. Toxicity data should be from robust national and international sources such as WHO, ATSDR, OECD, ECHA, US EPA, NICNAS, APVMA, SWA, etc. If robust toxicological and ecotoxicological data are not available, it may be necessary to engage an expert toxicologist to assess the value of data from a broader range of sources.

There will be situations, however, where there are no relevant toxicity data for a chemical. When data are not available for a chemical, data for a structurally similar suitable analogue may be used or effects may be predicted using QSAR tools (see Section 4.4.2). Justification should be provided for the choice of analogue used. Any gaps in the data should be documented. Examples of toxicity data applied in coal seam gas risk assessment can be found in NICNAS (2017c and 2017d).

4.4.2 Environment

4.4.2.1 Ecotoxicity data

Ecotoxicity data are used to determine the toxic hazards posed by a chemical to terrestrial and aquatic organisms. The assessment process involves collecting all available acute and chronic data and considering how this data can inform the assessment. The Department of the Environment and Energy recommends that ecotoxicity endpoints be presented in tables (DoEE 2016a).

Ecotoxicity data are obtained from a suite of toxicity tests using indicator species and should be considered for the aquatic and terrestrial compartments (Batley et al. 2017). Ecotoxicity data should be selected for the environmental compartments that the chemical is expected to partition to – for most chemicals associated with coal seam gas extraction, this will include

the aquatic compartment. For aquatic ecosystems potentially affected by coal seam gas chemicals, test aquatic organisms should cover three trophic levels. Typical test species include used are typically species such as alga, duckweed, hydra, daphnia, midge, freshwater shrimp, and freshwater fish (see Table 4.3). For potentially affected terrestrial ecosystems, typical test organisms include earthworms and lettuce.

The minimum data set for environmental risk assessments is given in Table 4.3 below.

Table 4.3 Minimum data set for environmental risk assessment – three trophic levels.

Test	Test guideline
Acute fish toxicity test	OECD TG 203 or similar
Acute immobilisation test and a chronic reproduction test on <i>Daphnia</i>	OECD TG 202 or similar
Chronic algal growth inhibition test	OECD TG 201 or similar

Ecotoxicity endpoints which can be used include:

- Lowest Observed Effect Concentration (LOEC) and No Observed Effect Concentration (NOEC)
- Lethal concentration (LC) LC_x, Effect Concentration (EC) EC_x²²
- Maximum Allowable Toxicant Concentration (MATC) – reported as the geometric mean between NOEC and LOEC (See equation 2, Section 7.3.1.3.)

The available ecotoxicity data should be assessed for adequacy and completeness (as outlined in Section 4.7). Standard ecotoxicity methods are based on guidelines from the OECD²³, US EPA, and Environment and Climate Change Canada (e.g. OECD 1995b; US EPA 2002a; US EPA 2002b, Environment and Climate Change Canada 2017). Ecotoxicity endpoints obtained from tests conducted on locally relevant species are preferred to northern hemisphere analogues (refer to ANZECC and ARMCANZ (2000a) guidelines). If endpoints are taken from non-standard tests, a discussion of their origins and reliability should be included. Table 4-3 lists examples of additional aquatic studies that may be considered in risk assessments of chemicals associated with coal seam gas extraction in Australia. Sediment bioassays and terrestrial ecotoxicology tests should also be included in the assessment where relevant, including data for species such as amphibians, reptiles, and / or birds (e.g. OECD 2015a; OECD 2008; OECD 2006b; OECD 2009). The reader is referred to Simpson and Batley (2016) for guidance on sediment assessments. Further information on other taxonomic groups such as birds, mammals, arthropods, soil micro-organisms, earthworms and aquatic organisms are also described in EPHC (2009b).

²² EC_x and LC_x refer to concentrations that are lethal to a certain percentage 'x' of the individuals (LC_x) or the concentrations that cause 'x' per cent of individuals to experience a given effect or the concentration which on average causes a 'x' per cent effect (EC_x) (Warne et al. 2014). For example, LC₁₀ is the toxicant concentration that is expected to be lethal to 10% of a group of organisms under specified conditions.

²³ OECD Series of ecotoxicity testing [accessed via: <http://www.oecd.org/chemicalsafety/testing/seriesontestingandassessmentecotoxicitytesting.htm> on 24 Nov 17].

Table 4.4 Examples of additional aquatic studies that may also be considered in risk assessments of chemicals associated with coal seam gas extraction in Australia.

	Organism (Endpoint and test duration)	Reference
Acute endpoints	Freshwater duckweed: <i>Lemna sp.</i> plant growth inhibition, 7 d (OECD TG 221)	OECD (2006)
	Freshwater shrimp: <i>Caridina nilotica</i> mortality / juvenile survival, 96 h	US EPA (2002a)
	Freshwater midge: <i>Chironomus sp.</i> , immobilisation, 48 h (OECD TG 235)	OECD (2011)
Chronic endpoints	Freshwater daphnid: <i>Daphnia magna</i> reproduction test (OECD TG 211)	OECD (2011)
	Freshwater fish (early-life stage toxicity) (OECD TG 210)	OECD (2013)

Where endpoint data are unavailable for a specific chemical, estimates may be able to be obtained using the chemical structure and measured data from chemically similar compounds (i.e. an analogue chemical) (OECD 2007 and 2015c). Alternatively, QSAR modelling can be used to estimate endpoints (See section 4.4.2). However, if no suitable model or analogue is available, targeted ecotoxicological tests are required.

The minimum data set for quantitative coal seam gas chemical risk assessments comprises acute toxicity tests for fish and invertebrates and a chronic test for algae, however chronic data for fish and invertebrates are preferable if it is available. Acute endpoints should be scaled by the appropriate acute-chronic conversion factor to give an estimate of chronic toxicity. (Batley et al. 2017; Warne et al. 2016; ANZECC and ARMCANZ 2000a). Ecotoxicity testing for aquatic (water and sediment) and terrestrial species should be incorporated (e.g. US EPA 2000a; OECD 2006a; OECD 2009; OECD 2015a). Assays should consider assessment methods for endocrine disruption (e.g. OECD 2008; OECD 2010; OECD 2012a; OECD 2012c).

An example of ecotoxicity data applied in a coal seam gas risk assessment context can be found in DoEE (2017b, 2017c, and 2017d). Further background information and details can also be found in the *Environmental Risk Assessment Guidance Manual for industrial chemicals* (EPHC 2009a).

It is preferred that coal seam gas chemical have measured data for ecotoxicity endpoints from studies conducted in accredited laboratories using nationally or internationally recognised ecotoxicology testing guidelines and protocols. While relevant field study, mesocosm, and / or microcosm data are not considered critical ecotoxicology endpoint data, they can be used to corroborate results from lab studies (Batley et al. 2017; EU 2011).

Guidelines for qualitative categorisation of acute and chronic aquatic ecotoxicity data are set out in Tables 4.5 and 4.6 (corresponding to criteria in DoE (2016), GHS (UN ECE 2015), and EPHC (2009a and 2009b)).

Table 4.5 Qualitative categorisation of acute aquatic toxicity data (T)

Short-term (acute) toxicity (T)		
Very toxic	Algae or other aquatic plants: 72 or 96 h E _r C ₅₀ Crustacea: 48 h EC ₅₀ Fish: 96 h LC ₅₀	≤ 1 mg/L

Toxic	Algae or other aquatic plants: 72 or 96 h E _r C ₅₀ Crustacea: 48 h EC ₅₀ Fish: 96 h LC ₅₀	> 1 but ≤ 10 mg/L
Harmful	Algae or other aquatic plants: 72 or 96 h E _r C ₅₀ Crustacea: 48 h EC ₅₀ Fish: 96 h LC ₅₀	> 10 but ≤ 100 mg/L

Table 4.6 Qualitative categorisation of chronic aquatic toxicity data (T)

Long-term (chronic) toxicity (T)			
	Adequate chronic toxicity data available		Adequate chronic toxicity data not available
	Non-rapidly degradable chemicals	Rapidly degradable chemicals	
Very toxic with long lasting effects	NEC or EC ₁₀ ≤ 0.1	NEC or EC ₁₀ ≤ 0.01	LC ₅₀ or EC ₅₀ ≤ 1.00 and No rapidly biodegradability data and BCF ≥ 500 or, if absent, Log K _{ow} ≥ 4.2
Toxic with long lasting effects	0.1 < NEC or EC ₁₀ ≤ 1.0	0.01 < NEC or EC ₁₀ ≤ 0.1	LC ₅₀ or EC ₅₀ ≤ 1.00 and No rapidly biodegradability data and BCF ≥ 500 or, if absent, Log K _{ow} ≥ 4.2
Harmful with long lasting effects	-	0.01 < NEC or EC ₁₀ ≤ 0.1	LC ₅₀ or EC ₅₀ ≤ 1.00 and No rapidly biodegradability data and BCF ≥ 500 or, if absent, Log K _{ow} ≥ 4.2
May cause harmful long lasting effects	NEC or EC ₁₀ ≤ 1.0 mg/L and no acute toxicity and lack of rapid biodegradability data and BCF ≥ 500 or, if absent, Log K _{ow} ≥ 4.2		

4.4.2.2 Persistence (P)

Persistence refers to whether, and how fast, a chemical degrades in the environment over time. Chemicals degrade in the environment in a variety of ways, and biotic (microbial) and abiotic transformation pathways should be considered. Abiotic pathways include degradation by hydrolysis, photolytic degradation and by reaction with atmospheric hydroxyl radicals.

Chemicals that are persistent in the environment may cause chronic health problems, particularly in humans and animals that are high in the food chain.

The Stockholm Convention provides scientifically based criteria for identifying persistent organic pollutants (POP)²⁴. The criteria for persistence in Annex D of the Stockholm Convention are expressed as single-media criteria, as follows:

²⁴ For further information on the Stockholm Convention see:
<http://www.environment.gov.au/protection/chemicals-management/pops> and
<http://chm.pops.int/default.aspx>.

- evidence that the half-life of the chemical in water is greater than two months, or that its half-life in soil is greater than six months, or that its half-life in sediment is greater than six months; or
- evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of the Convention.

Considerations under the second criteria may include, for example, where the chemical has a half-life greater than six months in anaerobic conditions but less than six months under aerobic conditions.

The persistence criteria presented in Table 4.7 have been adopted in Australia and are consistent with the Stockholm Convention criteria (EPHC 2009a).

Table 4.7 Single-media persistence criteria for chemicals

Persistent (P)	
For PBT purposes a chemical is considered persistent in a particular media if its half-life in the media exceeds the following:	
Media	Half-Life [d]
Water	60
Soil	182
Sediment	182
Air	2

Standard tests for half-life in various media are given in Table 4.8 below.

Table 4.8 Standard tests for half-life in various media.

Medium	Test	Reference
Water/sediment	Test No. 308: Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD TG 308)	OECD (2002a)
Soil	Test No. 307: Aerobic and Anaerobic Transformation in Soil (OECD TG 307)	OECD (2002b)
Air	Tests and estimation methods in OECD (1993)	OECD (1993)

Tests performed to guidelines listed in Table 4.8 are preferred where available, however biodegradation studies may also be used. Ready biodegradability tests conducted under OECD 301A-F guidelines measure whether the chemical degrades sufficiently in a 10-day window over a 28-day period to be classed as ready biodegradable. If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days.

Tests conducted under less stringent guidelines, such as the inherent biodegradability test OECD 302A-C, show whether the chemical has the inherent potential for biodegradation. In these tests, a result indicating greater than 70% mineralisation indicates potential for ultimate biodegradation, greater than 20% mineralisation indicates inherent, primary degradation, and less than 20% degradation indicates that the substance is not biodegradable and may be persistent. These tests must be interpreted carefully; many inherent biodegradability tests,

demonstrate only primary biodegradability and not total mineralisation. A positive result indicates that the test substance will not persist indefinitely in the environment, but complete biodegradation cannot be assumed. A negative result for inherent biodegradation should be taken as evidence that the substance is persistent.

Australian threshold criteria for persistence are based on half-life data (Table 4.7). However, qualitative results from biodegradation studies may be used to perform persistence categorisation, as summarised in Table 4.9.

Table 4.9 Persistence categorisation

Study result	P categorization
Ready biodegradable	Not Persistent
Ready, but failing the 10-day window	Not Persistent
Fails ready biodegradation test	Inconclusive
Inherently biodegradable	Inconclusive
Fails inherent biodegradation test	Persistent.

4.4.2.3 Bioaccumulation, bioconcentration, and biomagnification (B)

Bioaccumulation is the general term describing a process by which chemicals are taken up by a plant or animal either directly through exposure to a contaminated medium (soil, sediment, water) or by eating food containing the chemical. Bioaccumulation refers to all routes of exposure. Related terms are bioconcentration, which is the net result of uptake, transformation and elimination of a substance in an organism due to waterborne exposure; and biomagnification, in which chemical concentrations in plants or animals increase through the food web (e.g., predators have greater concentrations of a particular chemical than their prey) (US EPA 2015a). Examples of chemicals that bioaccumulate and / or biomagnify include some:

- some metals such as lead, selenium and mercury
- dioxin and dioxin-like compounds such as polychlorinated biphenyls (PCBs)
- some polycyclic aromatic hydrocarbons
- most organochlorine pesticides (aldrin, chlordane, dieldrin, toxaphene, DDT)
- some brominated flame retardants (tetrabromobisphenol A (TBBPA))
- some per- and poly-fluorinated alkyl substances (PFASs, such as PFOS and PFOA).

Bioaccumulation is discussed in terms of the bioconcentration factor (BCF) or the bioaccumulation factor (BAF) depending on the type of data available, and the predominant route of uptake. The BCF is defined as the ratio of the concentration of the chemical in an organism relative to the concentration in the surrounding medium, and only takes into account uptake from the medium in which the organism lives. For aquatic organisms, uptake from water is considered to be the predominant route of uptake unless the chemical is very hydrophobic, in which case, uptake from food becomes important. BAF measurements take dietary uptake into consideration in addition to uptake from the medium. BCF measurements are generally appropriate for chemicals with a log K_{ow} of less than 6. For highly lipophilic chemicals with a log K_{ow} of greater than 6, a bioaccumulation factor (BAF) measurement

is more appropriate than a BCF. Qualitative categorisation of bioconcentration factor is shown in table 4.10.

Several standard test guidelines are available for determining the BCF or BAF of a chemical, but the OECD 305 test guideline for bioaccumulation in fish is normally used. In the absence of measured BCF or BAF data, the log K_{ow} may be used as a surrogate. The Department of the Environment and Energy (DEWHA in EPHC 2009a and 2009b) has adopted the following criteria for bioaccumulation:

A substance is considered bioaccumulative if it has a BCF or BAF of greater than 2000 or, in the absence of BCF or BAF measurements, if the log K_{ow} is greater than 4.2.

Table 4.10 Qualitative categorisation of bioconcentration factor (B)

Bioconcentration factor (B)	
Bioaccumulative	BCF > 2 000
	BAF > 2 000
	In the absence of any BCF or BAF measurements, a log K_{ow} ≥ 4.2

A discussion of secondary exposure through the aquatic food chain may also be appropriate. The biomagnification factor (BMF) describes the relative concentration of the chemical in a predatory animal compared with the concentration in its prey. A BMF of greater than 1 indicates that chemical has the potential to biomagnify in the food chain. Such a chemical is also classified as bioaccumulative. The BMF may be estimated from either the measured BCF or the measured log K_{ow} using criteria set out in EPHC (2009a and 2009b). Default BMF values for organic substances are shown in table 4.11.

Table 4.11 Default BMF values for organic substances

Log K_{ow} of chemical	BCF (fish)	BMF
< 4.5	< 2 000	1
4.5 - < 5	2 000 – 5 000	2
5 – 8	> 5 000	10
> 8 - 9	2 000 – 5 000	3
> 9	< 2 000	1

4.5 If no human health or environmental data are available

The available information on the physico-chemical, fate and effects properties of chemicals is often incomplete, even for common chemicals. For example, measured values for the Henry's Law constant, the octanol/water partitioning coefficient and the degradation half-life are often unavailable. Any gaps in the data should be documented. If measured toxicity / ecotoxicity data are not available for a chemical or product used in coal seam gas operations, then the following options should be considered:

- toxicity data from analogous chemicals can be referred to where chemical ingredients and composition are well characterised. Care should be taken to ensure the use of appropriate analogue chemicals (also referred to as “surrogates”). A note must be made of which analogous chemical is being compared. The use of analogous chemical data must also be justified

- validated QSAR models to predict the toxicity of organic chemicals
- for mixed solutions in environmental risk assessment, toxicity data should be referenced for each separate chemical; with whole mixture toxicity through direct toxicity testing (DTA) being used to assess any potential additive, antagonistic, or synergistic toxicity effects
 - if Direct Toxicity Assessment is required, testing methods include Hydrobiology (2013), ANZECC and ARMCANZ (2000a), and OECD (1995a). Selection of test species should reflect local conditions where possible
 - due to cost, time, and ethical considerations, the conventional approach to human health risk assessment often relies on evaluating toxicity data where chemicals have been administered to animals as single entities. Data for mixtures is often unlikely to be available. enHealth (2012a, Chapter 12) outlines theoretical approaches for assessing the impact a mixture of chemicals may have on the overall risk assessment.

Most chemicals associated with coal seam gas extraction are also used for many other purposes. The use of data from an analogous chemical (referred to as analogue data)²⁵ and modelling tools to infer toxicity of a chemical are briefly addressed below. These approaches may be useful where there is a paucity of relevant toxicity data.

4.5.1 Analogues

Analogue data, i.e. data on a chemically similar substance or multiple substances, may be substituted, or 'read-across' in some cases in lieu of specific missing data. However, analogue data are appropriate for organic chemicals only. Deciding whether chemicals are similar enough to be regarded as analogues and for which similar or a regular pattern of hazard effects can be inferred is complex and requires expert judgement. This involves consideration of chemical structures and confirming, where possible, the potential for chemicals to have similar modes or mechanisms of action for their human health or environmental effects. The end use of the analogue data will determine their applicability (OECD 2007; EPHC 2009a; EPHC 2009b). In some situations, data from another chemical or chemical group can be used, such as:

- isomers which have similar structure activity profiles
- closely related homologues
- relevant precursors and breakdown products, along with information on metabolism and degradation.

The data for the related compound (or compounds) should be included in the assessment report for the chemical, clearly stating the identity (chemical name and CAS RN) of the related compound (test substance) and why it was selected. When data for an analogue chemical are used to address one or more toxicological end-points, the data for the analogue's other end-points must be compared and discussed in relation to the main chemical. This will provide information on the similarities and differences in the properties of the main chemical and its analogue (OECD 2007; EPHC 2009b; ECHA 2012a).

Internationally accepted guidance is available on data gap filling for hazard endpoints by grouping of chemicals and read-across (ECHA 2017; OECD 2014). In addition, the OECD

²⁵ Analogue is a chemical compound that is structurally similar to another but differs slightly in composition (as in the replacement of one atom by an atom of a different element or in the presence of a particular functional group)

QSAR Toolbox is available as a workflow tool and hazard endpoint database that allows a consistent approach to the development and reporting of chemical categories and read-across of chemical data based on OECD guidance (OECD 2015a).

4.5.2 QSARs

For organic chemicals, where experimental or analogue data are not available, values may be predicted using suitable QSAR modelling. This can be performed at a screening level, although it is preferable to use measured data for effects assessment and for estimation of PNECs or exposure concentrations.

Some substances are difficult or impossible to model using QSAR analysis, including:

- polymers
- chemicals of unknown or variable composition, including complex reaction products and biological materials (UVCBs)
- surfactants
- chemicals with very low water solubility
- high log K_{ow} chemicals
- ionisable chemicals
- inorganic and organometallic chemicals.

When experimental data are not available for a substance and QSARs cannot be applied, and there is no acceptable analogue, a greater reliance on other lines of evidence will be required (see Section 4.7.4).

QSAR is a prediction method and there is a certain probability that the prediction is poor, even for well evaluated models. Consequently, predictions from QSAR models should not be the only line of evidence for preparing a risk assessment of a chemical. The result of a QSAR should be evaluated for consistency in the light of available experimental data and validated estimates from other end-points. When evaluated together with test results, QSAR estimates can provide a more complete understanding of the physico-chemical and toxicological characteristics of the substance.

Some specific factors that influence the potential toxicity of a substance include:

- the presence of chemical structures and functional groups associated with ecotoxicity (e.g. quaternary ammonium compounds, amines, peroxides, epoxides, anilines, halogenated aromatics, phenolics, heterocyclic compounds, metal salts)
- the net charge of the compound (cationic vs. anionic)
- the stability of the substance in water (e.g. some substances, such as peroxides, can undergo rapid hydrolysis in water)
- the log K_{ow} of the substance (a log K_{ow} between 4 and 5 may suggest a high potential for aquatic effects – more important for neutral organic compounds)
- water solubility cut-offs.

Many QSAR models have been developed and some are publicly available. Depending on the purpose, different models may be used. For any use of QSAR models, the background information and assumptions of the models should be documented. The user should verify

that the prediction obtained from the model falls within the domain (this often depends on the training set of chemicals used to validate the model).

Commercial QSAR models may have limitations in terms of transparency and communicability to stakeholders. For more detailed discussion on the use of QSARs, see the Environmental Risk Assessment Guidance Manuals (EPHC 2009a and 2009b) and the OECD QSAR Toolbox (OECD 2015b). More general guidance on QSAR models is also provided in, for example, Worth, Netzeva, and Patlewicz (2007). An example of QSAR modelling can be found in DoEE (2017b, 2017c, and 2017d) using ECOSAR v1.1 (US EPA 2012a), which is the primary component of the QSAR Toolbox's model but also available as a stand-alone product.

4.6 Mixture toxicity data

In cases where testing of complex mixtures or blends of chemicals is required (such as drilling fluids, hydraulic fracturing fluids, flowback and produced waters, RO permeates and brines) techniques such as Whole-of-Effluent Toxicity testing (WET: US EPA 2000b), or Direct Toxicity Assessment (DTA: ANZECC and ARMCANZ 2000a; van Dam and Chapman 2001) provide useful methods for determining the overall toxicity of the mixture. If the Direct Toxicity Assessment results show elevated levels of toxicity it is important to determine what components of the chemical mixture are contributing most to the overall toxicity levels of the mixture, which will allow them to be identified and eliminated from the mix. In this case Toxicity Identification Assessment (TIA) techniques (Norberg-King et al. 1991, 1992; Mount and Norberg-King 1993; ANZECC and ARMCANZ 2000a; van Dam and Chapman 2001) can be adapted and incorporated into the mixture toxicity evaluation²⁶.

4.7 Data evaluation

4.7.1 Introduction

Guidance on evaluating the suitability of data for use in an exposure or hazard assessment is provided below. This includes sourcing data, checking the data quality, and identifying and filling data gaps. Data quality influences how confident risk assessors can be in the results of a study and the conclusions they may draw from it.

Data may be gathered from the scientific literature or relevant new studies using laboratory methods (toxicity and / or ecotoxicity data, chemical analysis etc.). Peer-reviewed scientific literature is an important source of information, especially for less common chemicals and for more specialised information that is not included in databases. Technical and academic publications are also a valuable resource. Information is sometimes available in risk assessments conducted by other regulatory agencies such as through the OECD, the US EPA, the European Food Safety Authority, European Chemicals Agency and Health and Environment Canada.

Test data that have been generated following established guidelines (e.g. OECD or US EPA), and performed following principles of good laboratory practice (GLP) are preferred. GLP defines a set of standards or principles for the planning, performance, monitoring, recording, reporting and archiving of a laboratory study. As described by EPHC (2009a), GLP includes procedures necessary for the appropriate conduct of a physical, chemical or toxicological test. When these guidelines and practices are followed, confidence in the quality of the study data is increased. Non-guideline studies may also be considered in a weight of

²⁶ For further information on Direct Toxicity Assessment and Toxicity Identification Assessment, see ANZECC and ARMCANZ (2000a), Volume II, Section 8.3.6 (at <http://www.agriculture.gov.au/SiteCollectionDocuments/water/nwqms-guidelines-4-vol2.pdf>).

evidence approach. Therefore, assessing the quality of the data (reliability, relevance and adequacy) based on good laboratory practice is critical and is further described below.

4.7.2 Data quality

Data quality should be assessed for all data types such as physico-chemical, environmental ecotoxicity, animal toxicity data and epidemiological studies. Data reliability, relevance and adequacy are integral to a data quality assessment and these terms have been defined by Klimisch et al. (1997) (paraphrased from and further details described in EPHC 2009a and 2009b):

- reliability: evaluating the inherent quality of a test report or publication with reference to standardised methodologies, the experimental procedure and description of results for evidence of the clarity and plausibility of the findings
- relevance: the extent to which data and tests are appropriate for a particular hazard identification or risk characterisation
- adequacy: the usefulness of data for hazard / risk assessment purposes. When there is more than one study for each end-point, the greatest weight may be given to the study that is the most reliable and relevant.

The reliability of the data is a key initial consideration because without knowledge of how the study has been conducted all other considerations may be irrelevant. Approaches for determining data reliability are described in Chapter 3 of the OECD Manual for Investigation of High Production Volume (HPV) Chemicals (OECD 2005). Further detail on the application and use of a reliability scoring method is described in the Environmental risk assessment guidance manual for industrial chemicals (EPHC 2009a), and in EPHC (2009b). An alternative method, for water quality related data, is described in ANZECC and ARMCANZ 2000a and US EPA's Aquatic Toxicology Information and Retrieval (AQUIRE) database (US EPA 1984, 1992, 1994, and 1995). These methods assign a level of reliability (reliability score) to studies and / or data based on whether they meet certain criteria. More focus can then be placed on using the findings from the study with the highest reliability.

An alternative approach by Klimisch et al. (1997) was developed as a scoring system for reliability, particularly for ecotoxicology and health studies (however, it may be extended to physico-chemical and environmental fate and pathway studies). After assigning the relevant Klimisch code to each study, those with the lowest scores would be the most reliable. The use of Klimisch codes provides a useful tool for organising the studies for further review. For example, they enable the risk assessor to focus on the most highly reliable study first in order to allow time to later consider relevance and adequacy (EPHC 2009a and 2009b; Zweers and Vermiere 2007). The approach developed by the US EPA for the OECD (OECD 2005) provides more information than the Klimisch system by describing and evaluating key reliability criteria addressing the overall scientific reliability and validity of the information reported in the study. Both systems are compatible and may be used alone or together to evaluate data quality.

The review of data reliability should include assessment and documentation of:

- full citations and reference for data used from studies
- chain-of-custody for samples (from sampling site to laboratory) and tests conducted
- appropriate negative and positive controls and replication
- measured as opposed to nominal concentrations

- appropriate statistics (where applicable)
- species, strain, number, gender and age of organisms
- dose / concentration levels
- duration and length of exposure.

A clear understanding of factors affecting the speciation, persistence, bioavailability and toxicity of a chemical or mixture of chemicals will also significantly improve the reliability of data. Any data used in a model should have its source and validity identified. Where there are multiple data sources for a parameter, they should be weighted or combined, or both, in appropriate mathematical ways (see, for example, DoEE 2017b and 2017d).

The next step is to determine whether the data are relevant, and whether they are adequate for exposure, hazard and risk assessment. Sources of data that have passed initial screening for reliability should be given preference. Determination of relevance and adequacy is undertaken on a case-by-case basis and is based on sound scientific judgement. To determine relevance, assessors should consider whether the study contains data directly applicable to the environment or to human health, and to the exposure pathways and receptors conceptualised in the risk assessment. Determination of adequacy can depend on considerations such as the precision of the end points, whether different studies differ in their results for the same test, the adequacy of the study design, statistical power of the test, and how relevant the data are.

A variety of types of scientific evidence may be available when assessing the risks associated with the use of a chemical associated with coal seam gas extraction. Data from high quality toxicological studies may not be available. In such cases, all the data should be evaluated and weighted appropriately in a weight of evidence approach, including the relative values / weights of data and / or studies (see Section 4.7.4).

4.7.2.1 Laboratory testing

The quality assessment process described above should be applied to laboratory testing for new chemicals or for chemicals for which there are insufficient data. For example, in the case of toxicity data, the relevant endpoint (and appropriate dilutions, if applicable), appropriate replication, use of relevant organisms and exposure duration should be considered in the design of the experiment. For chemical analysis, the use of appropriate replication, controls, field and laboratory controls, and the resolution of the analyte (e.g. appropriately low laboratory detection limit) need to be considered. For further details and guidance, refer to ANZECC and ARMCANZ (2000b), enHealth (2012a), Hobbs et al. (2005) and relevant OECD or US EPA protocols.

4.7.3 Uncertainty management

Uncertainty management of a risk involves systematically dealing with, and documenting, uncertainties throughout the risk assessment and identifying priorities that may require further attention / management (OECD 1991). Risk assessments should be accompanied by uncertainty and sensitivity analyses, which play important roles in model development, calibration and decision-making (Yang 2011).

The assumptions, quantified uncertainties and sensitivity analysis undertaken should be documented for all steps in the risk assessment (data acquisition, exposure and hazard assessment and risk characterisation). This helps in understanding the reliability of and confidence in the risk assessment and identifying whether further data and information are required and if the problem formulation needs to be reiterated and refined.

Further information on uncertainty analysis, sensitivity analysis, and variation is provided in Section 8.1. The World Health Organisation's (WHO) Program for Chemical Safety has a harmonisation program which has produced several publications on handling uncertainty (IPCS 2008 and 2014)²⁷. Examples of uncertainty management in a coal seam gas context are described in the Environmental Risk Assessment (DoEE 2017c, and 2017d) and Human Health Risk Assessment (NICNAS 2017d).

4.7.4 Weight of evidence

Weight-of-evidence analysis helps determine whether the compiled data sets are adequate. In some cases, multiple sources of possibly conflicting evidence will be available, and expert judgement is to be applied in choosing the best sources. A weight-of-evidence approach assesses the relative values / weights of different pieces of gathered information (ECHA 2010). Its use in human health and environmental risk assessments has increasingly been recognised as advantageous, as it allows the use of less conclusive (but important) data / studies when combined with other information and enables an overall risk (or weight of evidence score) to be ascertained from several lines of evidence or environmental attributes (ECHA 2010; TCEQ 2014; Becker et al. 2015). The approach can include methods that are entirely or partly qualitative (professional judgement), semi-quantitative (ranking systems) or quantitative (e.g. probability or multivariate approach). Methods that produce repeatable results regardless of the approach are preferred (EU 2003; ECHA 2010, 2012a). The design of the ranking system should consider data reliability, adequacy, relevance and quantity in evaluating overall risk or weight of evidence as discussed above. Several guidance documents include useful discussions of the application of weight of evidence, including Batley et al. (2017), ECHA (2010, 2012a; 2012b), NHMRC (2006), Simpson and Batley (2016) and the NICNAS webpage²⁸.

Checklist

Table 4.12 Checklist for gathering of data to inform risk assessment

Data requirements		✓
1	Identify the chemical, mixtures or chemical identities in mixtures / flowback / produced water / wastewater (Section 4.1)	
2	Obtain chemical information, along with information of fate and behaviour of the chemical(s) in the environment (Section 4.2)	
3	Gather data for the exposure assessment (i.e. chemical quantities and concentrations, exposure routes and compartments) (Section 4.3)	
4	Gather data for the hazard assessment (Section 4.4)	
5	Evaluate data quality (Section 4.6) and determine if further data are required	
6	Determine, analyse and report on the uncertainty within the acquired data (Section 4.7.3)	
7	Analyse weight of evidence to determine the adequacy of the available data as a whole (Section 4.7.4)	

²⁷ See, for example, IPCS (2008) which can be accessed via: http://who.int/ipcs/publications/methods/harmonization/exposure_assessment.pdf?ua=1; and IPCS (2014) which can be accessed via: http://who.int/ipcs/methods/harmonization/uncertainty_in_hazard_characterization.pdf?ua=1.

²⁸ NICNAS information on weight of evidence. <https://www.nicnas.gov.au/notify-your-chemical/assessment-methodologies/weight-of-evidence> [accessed 24/10/2017]

5 Guidance for exposure assessment

5.1 Overview for human and environmental exposure

Site-specific details, including qualitative and quantitative data, are often important for exposure assessment (see Problem Formulation in Section 3.1). Chemical sources, release scenarios, points of release, likely fate and transfer pathways of the chemical and receptors (human and environmental) should be identified and conceptualisations should be developed to link these together. Examples of conceptualisation and models used for coal seam gas scenarios are described in (DoEE 2017b, 2017c, and 2017d; Mallants et al. 2017a and 2017b).

The assessment of the fate and pathways of a chemical should follow a tiered approach so that the level of effort involved in the assessment is commensurate with the potential risk (see Section 2.2.3). This approach allows the assessment to be refined using increasingly sophisticated models representing the chemical quantity, points of release, transfer pathways and environmental receptors. Further assessment is generally required if the risk is unacceptable in the lower tier assessment.

Conceptual site models (NEPM 2013) outlining the links between coal seam gas operations and potential exposures to people or the environment can be used to define the exposure scenarios evaluated in the exposure assessment. Exposure scenarios set out the conditions and assumptions about sources of emissions, exposure pathways, amounts or concentrations of agents, and exposed organisms, systems, or (sub)populations. Exposure scenarios can help in the evaluation and quantification of exposure in a given region (OECD-IPCS 2003); and as such should, in combination with the conceptual site model, set out the facts, assumptions, and inferences that the discrete situations where potential exposure might occur (van Engelen et al. 2007). Further detail about relevant methods is available in the *Environmental Health Risk Assessment: Guidelines for Assessing Human Health Risks from Environmental Hazards* (enHealth 2012a). Additional information on international approaches to exposure assessment can be found within the OECD “Assessment of Chemicals” literature (OECD 1999) and in the US EPA Toolbox (US EPA 2015b).

The exposure of a receptor to a chemical depends on many factors including the following:

- likely volume to be used
- likely concentration of release to the environment
- dilution / dispersion mechanisms
- rate of transport
- chemical transformations / reactions (including degradation) and binding occurring within the environment prior to exposure
- biogeochemical and / or physiological mitigation or enhancement mechanisms
- variability or heterogeneity of the chemical.

In many cases, exposure pathways for human health and the environment can be similar, particularly with respect to release of chemicals to the atmosphere or surface waters and / or groundwater. However, occupational handling of chemicals during storage, transport, use and disposal is an additional consideration for human exposure. In all cases, exposure and therefore the risk of environmental or human health effects is a function of the mitigation measures implemented during the chemical lifecycle.

Consideration of mitigation measures may be an iterative process whereby additional mitigation measures are incorporated into progressively more detailed tiers of the exposure part of the risk assessment until an acceptable level of residual risk is achieved. Examples of mitigation measures may include using engineering controls, segregation of industrial processes, bunded pallets, adsorbent packaging, double-walled containers, limiting stored / transported volumes, separation of incompatible substances during transport and / or storage, use of pre-diluted substances, chemical elimination and substitution, use of personal protective equipment and use of the lowest risk transport routes.

5.2 Identification of chemical sources and point of release

Potential sources of releases of chemical associated with coal seam gas extraction should be identified. Chemicals may be released intentionally or unintentionally, either directly or indirectly into air, surface water, groundwater, or soil. Consideration should be given to how the product (and chemicals therein) will be used, the quantity to be used and how they might be released to the environment. Potential chemical sources and the human and environmental exposure pathways for chemicals associated with coal seam gas extraction (DoEE 2017b, 2017c, and 2017d; Mallants et al. 2017a and 2017b) may include:

- direct contact during mixing, cleaning, and maintenance of equipment
- spills and leaks (storage pond leaks, overflows, and seepage; volatilisation; aerial dispersion; soil contamination)
- transportation (e.g. trucks, pipelines etc.)
- direct or intentional release applications (i.e., above ground and “down hole” chemical usage and transfer via groundwater to surface-water receptors)
 - drilling, cementing, chemical and radioactive monitoring
 - perforation, acid clean out, pre-wetting, hydraulic fracturing
 - disposal via land spray while drilling or bury and cover techniques
 - irrigation, dust suppression, construction, water supply
- flowback and produced water
- volatilisation of chemicals from evaporation / retention ponds
- discharge (e.g. overtopping, bund failure etc.)
- dust emissions (e.g. from cementing products or other substances containing fine particles)
- incomplete combustion of gases and volatile organics in flares
- well blowout from equipment failure during operation.

A list identifying potential chemical sources and risk events should be generated to identify all potential environmental risks and impacts associated with coal seam gas chemicals. This list should cover all potential exposure pathways. Potentially incomplete exposure pathways should not be used to “screen out” identified hazards too early in the risk assessment process – a rigorous conceptualisation, coupled with robust hypothesis testing, is required to ensure that potential risks are not under-estimated or ignored. Conclusions about whether exposure pathways are incomplete, or likely to be insignificant, should be appropriately supported by, for example, baseline and subsequent monitoring data, health studies, validated modelling results, and / or expert judgement (NEPM 2013). An example of potential risk sources and release events is provided in Table 5.1, from the Environmental Risk Assessment of Chemicals Used in WA Petroleum Activities Guideline (WA DMP 2013).

Table 5.1 Examples of risk events, chemical sources, and their environmental impact (AECOM 2017; WA DMP 2013).

Possible sources of risk	Source / Risk Event	Potential health and environmental impacts
Surface chemical spills and leaks	Chemical onsite storage leaks / spills Spills during transfer of chemicals Transport related spills Evaporation / retention pond seepage / leaks / overflows Surface well blowout	<ul style="list-style-type: none"> • Air emissions i.e. volatile chemicals • Groundwater contamination • Surface water contamination • Soil contamination • Potential health impacts on local residents • Potential impacts on vegetation, crops and pastures • Potential impacts on local fauna and livestock
Drilling through aquifers and well completion	Fluid loss and drilling chemicals migrate into overlying aquifer(s) over time	<ul style="list-style-type: none"> • Groundwater contamination • Potential health impacts on stock and domestic groundwater users • Potential impacts on irrigated crops • Potential impacts on industrial and town water supplies
Perforation, acid cleanout / pre-wetting, injection, and hydraulic fracturing	Loss of well integrity	<ul style="list-style-type: none"> • Groundwater contamination • Surface water contamination • Soil contamination • Potential health impacts on stock and domestic groundwater users • Potential impacts on irrigated crops • Potential impacts on industrial and town water supplies
Air emission	Flaring Spills during transfer of chemicals Transport related spills Surface well blowout Retention pond air emissions Construction, drilling, transport	<ul style="list-style-type: none"> • Air emissions i.e. volatile chemicals • Dust and particulates • Potential health impacts to local residents
Other	Unrestrained fauna access to evaporation / retention ponds	<ul style="list-style-type: none"> • Loss of local fauna, livestock through direct chemical exposure • Potential chemical tainting of crops, pasture, livestock, drinking water, etc.
	Trespass and un-authorised access to evaporation / retention ponds	<ul style="list-style-type: none"> • Potential health impacts but not if only a short duration of exposure
	Inappropriate reuse / disposal of flow back, produced water, brines, salts, filters, membranes, unused chemicals, packaging and	<ul style="list-style-type: none"> • Soil contamination • Surface water contamination • Shallow groundwater

	containers	contamination <ul style="list-style-type: none"> Potential health impacts on local residents and workers
	Disposal of drill cutting and spent drilling muds (land spray while drilling, bury and cover)	<ul style="list-style-type: none"> Soil contamination Shallow groundwater contamination Surface water contamination

5.3 Estimation of release quantities (Q)

Release point models are used to estimate the potential releases to the environment from the chemical life cycle stages in a coal seam gas operational site. DoEE (2017b, 2017c, and 2017d) identified transport, storage, industrial use and disposal as distinct stages in the life cycle of a chemical associated with CSG operations. These are not exhaustive and additional stages may be identified during risk assessment. Releases may be accidental (such as transport accidents, leaks and spills) or intentional (such as irrigation, or dust suppression), where potential chemical sources should be identified as listed above.

The composition of fluids or solids (single chemicals, formulated products or blends) and the potential release volumes and concentrations should be accurately identified and quantified.

The environmental exposure conceptualisation reports of the *National assessment of chemicals associated with coal seam gas extraction in Australia* (DoEE 2017b; Mallants et al. 2017a and 2017b) describe examples of potential release points for chemicals associated with coal seam gas extraction at specific life-cycle stages. Figure 5.1 illustrates the life-cycle stages and potential release points for chemicals associated with coal seam gas extraction.

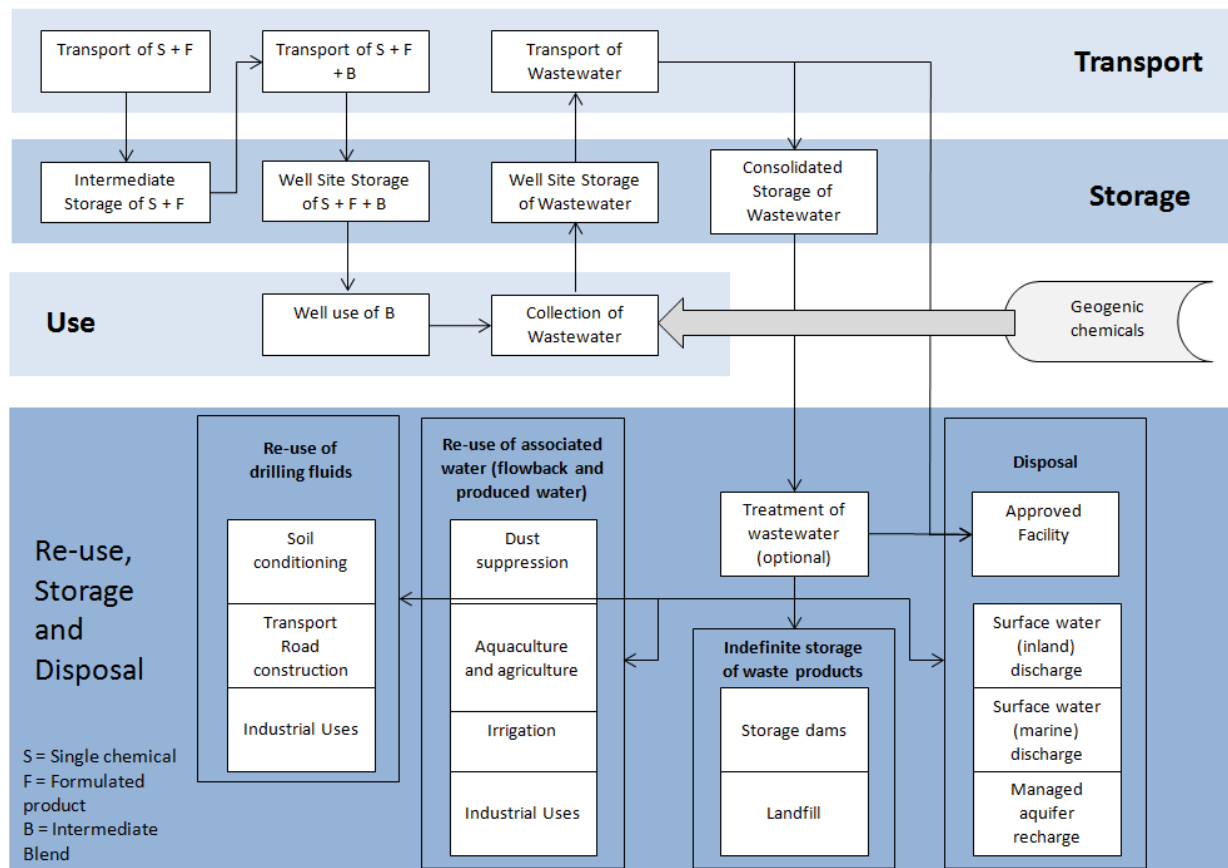


Figure 5.1 Life-cycle stages of chemicals associated with coal seam gas extraction (DoEE 2017b)

The environmental exposure conceptualisation reports (DoEE 2017b; Mallants et al. 2017a and 2017b) provide examples of the calculation of release quantities for each release point and the factors which may influence release quantity. The variables included in the equations are tailored to the life-cycle stage of the chemical (e.g. transport, storage or use), and represent the amount of chemical stored or transported, the probability of transport accidents, or the amount of chemical returned from a well. These are not intended to be prescriptive. Relevant release point equations specific to each risk assessment should be developed and thoroughly documented. For each chemical source and point of release, the likely fate and transport of the chemical should be considered, and are described in the next section.

Examples of assumptions and calculations that may apply to the assessment are provided in the conceptualisation reports of the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (DoEE 2017b and 2017d [Appendix A]; Mallants et al. 2017a and 2017b). Assumptions and calculations will be dependent on data availability and the assessment tier applied. Inputs for a Tier 1 assessment will be more generalised than subsequent assessments. In the higher, more detailed tiers of the risk assessment the likelihood or frequency of a release under various scenarios may be considered.

5.4 Identification of exposure pathways

Exposure assessment needs to consider exposure pathways and the environmental fate and partitioning of chemicals released to the environment. The environmental fate pathways indicate what happens to a chemical released into the environment, and allows the likely exposure levels for receptors (human and ecological) to be determined.

Determining the fate of the chemical should take into account its physical and chemical properties, transformation processes, mobility and how it reacts with the environmental media in which it is released. For example:

- chemicals in air emissions will be mobilised from their source and dispersed at a rate depending on their ability to disperse and weather conditions
- chemicals released to surface water flows may be mobilised away from the source at a rate depending on solubility and water flows
- depending on persistence, solubility and soil binding properties, chemicals released to soil may remain at a site for many years or be transported to surface water or percolate into groundwater.

Therefore, the fate and transport pathways for a chemical will affect potential exposure routes for sensitive receptors. The environmental exposure conceptualisation reports (DoEE 2017b; Mallants et al. 2017a and 2017b) provide examples of chemical fate pathways and receiving environments which are relevant to the transfer of coal seam gas contaminants between different environmental compartments. The pathways, illustrated in Figure 5.2 and described below, include run-off, airborne deposition, partitioning and sedimentation, volatilisation, degradation, attenuation, and infiltration. To assist delineation of relevant pathways, each is described in more detail below:

- **run-off:** Surface run-off may occur during a rainfall event resulting in the transport of chemicals in the soil compartment to a secondary site in the soil compartment or into an aquatic compartment

- **dust deposition:** Occurs when chemicals in the soil compartment become airborne in dust and are transported as particulates through the air before settling in a secondary site. This transport mechanism is driven by wind and may result in exposure to the aquatic and terrestrial compartments
- **adsorption to soil particles and sediments:** Chemicals may have an affinity for particulates in soil or be suspended in water and sediment at the bottom of waterbodies. The chemical's physico-chemical properties and suspended particle concentration in the water will determine whether the predominant pathway involves direct partitioning to sediment, or settling to sediment over time, and whether the chemical can become re-suspended in the water column at a later point in time
- **volatilisation:** May occur when chemicals / contaminants partition to air from the surface of soils or waterbodies in which they are present (such as storage dams holding wastewater and drilling fluids, rivers and wetlands, or the soil) or directly during the various hydraulic fracturing activities. The likelihood and extent of a chemical volatilising from soil and water is determined by individual chemical properties and environmental factors and is important for determining potential exposures of the local community (NICNAS 2017c and 2017d; Mallants et al. 2017a and 2017b)
- **degradation:** Results in the removal of a chemicals / contaminant from a compartment through transformation. Transformation can occur in storage ponds or elsewhere in aquatic and soil compartments via various mechanisms including biodegradation, geo-attenuation in aquifers, photolysis and hydrolysis. Transformation products may be formed for which the fate also needs to be assessed. Some transformation products can be more mobile and more toxic than the original substances (in most cases, they will be less toxic)
- **infiltration to groundwater:** Occurs when chemicals / contaminants in soil leach through the soil profile towards groundwater. This may also arise from storage dam leaks or overtopping during extreme rainfall events
- **shallow groundwater transport:** Chemicals / contaminants that reach the groundwater can be transported through shallow aquifers and expressed in surface water receptors.
- **deeper groundwater transport (see Mallants et al 2017c):**
 - chemicals / contaminants may be transported through deeper groundwater from the coal seam targeted by hydraulic fracturing into an overlying / underlying aquifer
 - a rupture in the casing of the CSG well to result in hydraulic fracturing fluid being injected into an aquifer
 - chemicals travelling through deeper groundwater along a targeted coal seam until they encounter either a water bore or a fault leading to an aquifer.

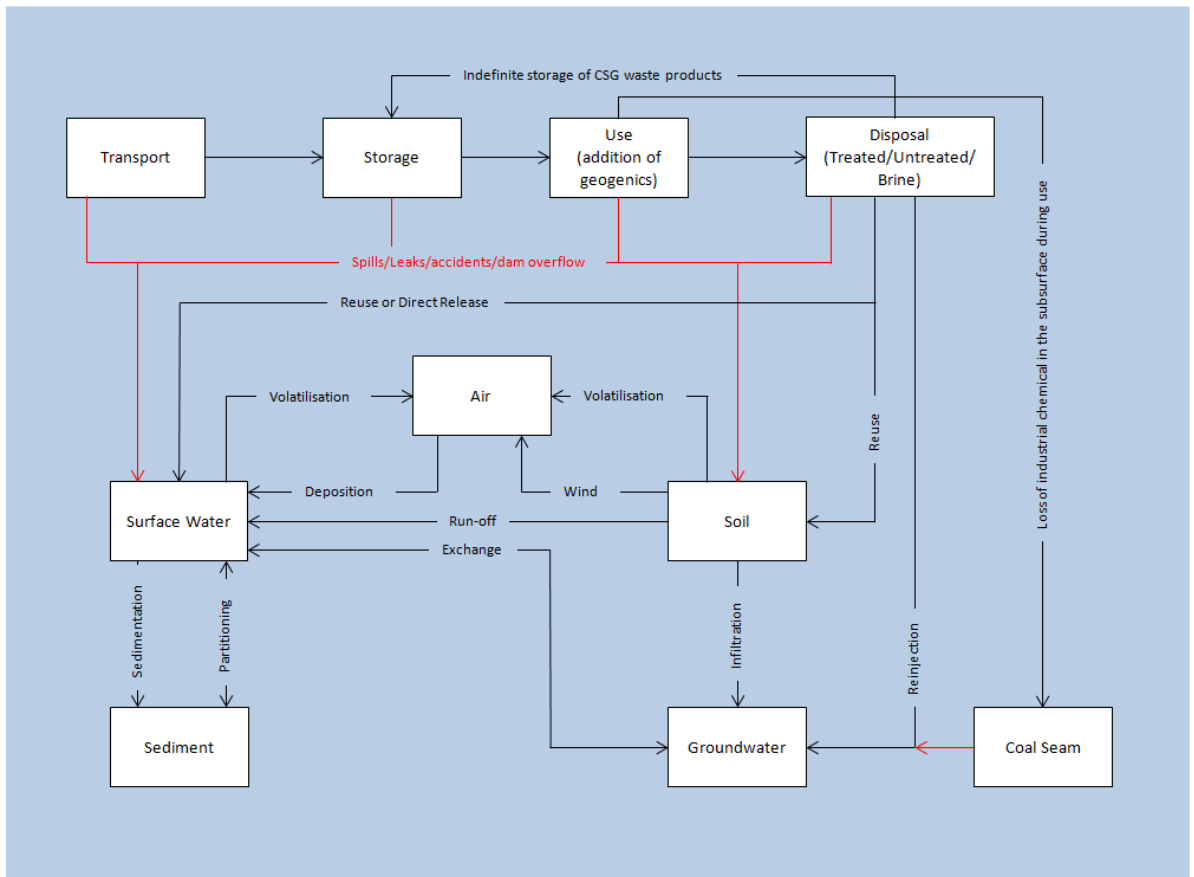


Figure 5.2 Simplified transport and fate pathways for chemicals associated with coal seam gas extraction (red lines show unintended releases) (after DoEE 2017b)

The environmental exposure conceptualisation reports provide examples of chemical fate pathways and receiving environments relevant to the transfer of coal seam gas contaminants between different surface and near surface environmental compartments. Deeper groundwater transport pathways are described and analysed in more detail in Mallants et al. (2017c). Figure 5.3 illustrates a number of potential deeper groundwater transport and fate pathways for chemicals associated with coal seam gas extraction. Drilling-related transport pathways should also be considered and conceptualised, particularly during drilling operations (where overlying aquifers may be directly exposed to drilling fluids) and during disposal of spent drilling fluids and associated cuttings (for example, in landspray while drilling and bury and cover disposal).

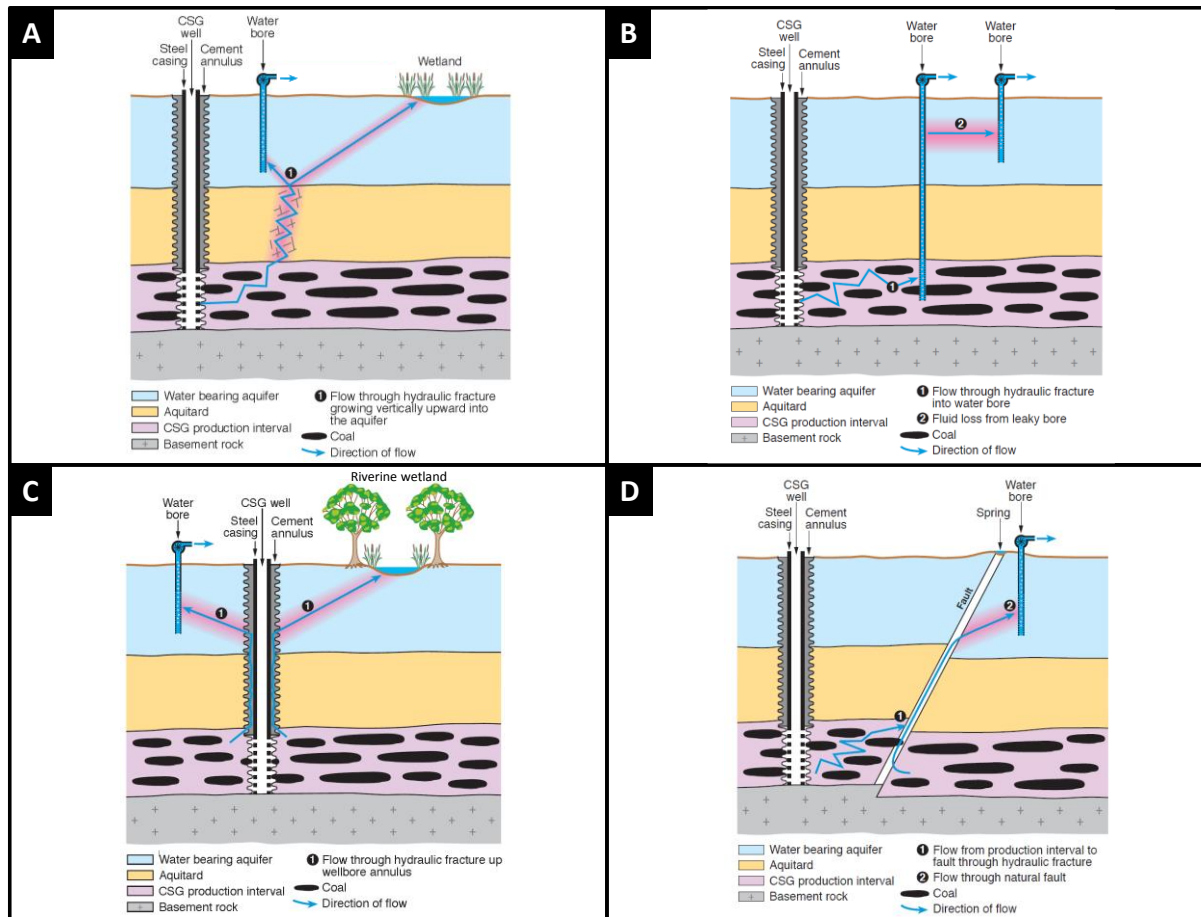


Figure 5.3 Simplified deeper groundwater transport and fate pathways for chemicals associated with coal seam gas extraction (Mallants et al. 2017c). Pathway A: fracture growth and / or chemical transport into an overlying aquifer. Pathway B: fracture growth and / or chemical transport into a proximal well or bore through pre-fracturing permeability and new induced fractures. Pathway C: Well rupture during injection and / or chemical transport via the cement or annulus. Pathway D: fracture growth and / or chemical transport into a natural, pre-existing fault or fracture. Not to scale.

Relevant field studies on the environmental fate of the chemical should also be used if available. Where numerical data are available, mathematical expressions are used to estimate the predicted environmental concentrations (PECs) after the chemicals are released and at the point of contact with human and environmental receptors.

The degradation and attenuation of a chemical along an environmental transport pathway will depend on its particular characteristics and the conditions in the environment. Further information is available in Apte et al. (2017a and 2017b) and in Mallants et al (2017c).

Detailed analysis of the environment fate of some substances is not required. Examples include insoluble, chemically inert and non-toxic substances, and natural substances such as wood dusts. In such cases, especially where the behaviour of the substance in the environment is well understood, a summary is sufficient. An example of an assessment of wood products (including nut hulls) may be found in Appendix D of the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (DoEE 2017d).

To qualitatively assess environmental exposure, the partitioning of the chemical into different environmental compartments (air, water and soil) should be analysed. This behaviour is a direct consequence of physico-chemical properties. For instance, chemicals with a high log K_{oc} will partition to soil rather than remain in the water compartment whereas, highly water

soluble chemicals with a low K_{ow} will preferentially remain in the water compartment. Chemicals that have a high Henry's law constant will partition to air.

5.5 Predicted environmental concentrations (PECs)

Measured environmental concentrations (MECs) of chemicals are the preferred primary data source to inform risk assessment and should be a priority for monitoring programs. Risk assessment aims to provide an estimate of risk which reflects the actual risk as closely as possible, within the limitations of the available information. Where measured environmental concentrations are unavailable or cannot be collected, predicted environmental concentrations (PECs) are calculated. Therefore, derived PEC values should be presented together with the numerical input values used for their derivation, the source of these values and the reasoning behind their selection. Risk assessors will need to be aware and report the level of conservatism that has been incorporated into the calculations and the degree to which that mitigates the uncertainties inherent in the inputs (see Section 4.7.3 on uncertainty management and Section 7 on risk communication). For each tier of assessment, the assumptions typically become less conservative as more data and more detailed analysis provides increasing confidence that the calculations represent real world systems.

PECs should be calculated for different human and environmental receptors of concern. A key consideration in the derivation of the PEC is the potential for direct or indirect release of a chemical into the receiving environment. Indirect release requires the modelling of a transfer pathway with assumptions made about the dispersion, dilution, chemical transformation and other mitigating factors over the length (time and / or spatial) of the pathway. They could include an ambient air PEC, aquatic PEC and a terrestrial PEC. The environmental fate of the chemical or mixture of chemicals, as well as the different life cycle stages of potentially affected humans, plants and animals could also be considered (see, for example, Figure 5.1, Figure 5.2, and Figure 5.3).

Hydrodynamic groundwater and / or surface water models, coupled with chemical speciation models, are tools to provide estimates of PECs along transfer pathways. For each PEC calculation, the variables and equations leading up to the production of the final PEC should reflect a logical progression from release quantity (Q) at a specific point of release to the ultimate derivation of aquatic and terrestrial PECs. Where aquatic exposure is indirect, runoff equations can be used to derive terrestrial PECs and ultimately aquatic PECs. There are often numerous pathways for exposure, and numerous assumptions that could be made about controlling processes within each pathway.

Assessors may need to consider the likely modes of "failure" of containment, the volume of the chemical likely to be involved in the release, the concentration of the chemical, and the probability of those failure modes (for a fully probabilistic approach) in calculating the release quantity (Q). If a Tier 1 calculation indicates that the Q value for this scenario is too high to produce an acceptable risk profile (i.e. PEC is too high), a higher tier assessment should consider the effect of mitigation measures.

For examples of exposure assessments which form part of the *National assessment of chemicals associated with coal seam gas extraction in Australia* see DoEE (2017a) and Mallants et al. (2017a and 2017b). As part of the national assessment, Mallants et al. (2017a and 2017b) developed a dynamic web-based tool that can be used calculate dilution factors for chemicals transported through shallow groundwater. These dilution factors are suitable for shallow groundwater systems in coal seam gas regions in Australia and for a Tier 1 assessment. The dilution factors can be combined with information about the initial concentration of chemicals at the point of release to calculate PECs at receptors.

In subsequent research Mallants et al. (2017c) developed a set of tools that can be used to calculate the PECs of chemicals that move along deeper underground pathways. These

include a set of dilution factors for sites where the geology is similar to two test regions, and a modelling approach to estimate dilution factors in other cases.

Further reading on calculation of PECs can be found at the OECD (OECD 2015c), US EPA (US EPA 2015b), and Trent University (EQC model) (Trent University 2013) websites. No single model for the calculations of PECs is recommended as models should be appropriate for the chemical properties, release scenarios, and tier of assessment under consideration.

5.5.1 Calculating PECs for human receptors

The term *receptor*, in the context of human health risk assessments, is often used to designate people, or specific groups of people, who may be exposed to an environmental contaminant, and to whom the risk assessment would be directed. It can be used in the scientific literature also to refer to the systems or organs within the human body adversely impacted by the toxicity.

The emphasis in this manual is on providing guidance for risk assessments specifically for chemicals associated with coal seam gas extraction. Identification of receptor locations and pathways by which people, or groups of people, might be exposed is an integral part of any human health risk assessment (enHealth 2012a). Sections 5.2 to 5.4 of this guidance manual outline how chemicals associated with coal seam gas extraction can be released to air, soil, surface water, sediment and groundwater at or near coal seam gas extraction wells or operations. Humans can be exposed to chemicals associated with coal seam gas extraction directly in the workplace (occupational exposure), or indirectly through environmental contamination of surface water, groundwater and / or ambient air (public exposure).

Occupational exposure may occur during transport, storage and handling of chemicals used for coal seam gas extraction, including during activities such as mixing, blending, cleaning and maintenance. In practice, the extent of occupational exposure depends on various factors, including safe work practices and automated handling procedures. There are a range of standard industry practices that minimise exposure to chemicals used in a workplace. Such practices often include protective clothing (such as work boots, long pants and long sleeved shirts), personal protective equipment (such as gloves and respirators) and materials handling equipment²⁹. NICNAS (2017c and 2017d) indicated the primary exposure routes to chemicals used in gas extraction are likely to be dermal contact and / or inhalation of vapours, aerosols, and / or dust. Oral exposures are usually assumed to be adequately restricted by routine industrial hygiene measures.

Public exposure may occur as a result of contamination of ambient air or water (surface and shallow ground water) used for drinking, general domestic activities (such as bathing, cooking, and washing), or recreational purposes. Consequently, public exposure routes may involve oral, dermal, and / or inhalational exposure. The extent of exposure is governed by the amounts and concentrations of chemicals released into the environmental media, and the extent of transfer and attenuation prior to reaching the public (NICNAS 2017c and 2017d).

Figure 5.3 is an example of a conceptual diagram for possible human exposure pathways to chemicals associated with coal seam gas extraction. The risk assessor should define the exposure routes applicable to the situation being assessed and determine if additional exposure pathways (to those shown in Figure 5.3) may be possible. Conclusions regarding whether exposure pathways are incomplete or likely to be insignificant should be appropriately supported by baseline and subsequent monitoring data, health studies,

²⁹ The effect of such standard practices may be included in iterations of the exposure assessment. For example, having been assessed a non-liquid chemical as a hazard in the absence of protective equipment, dermal exposure to a chemical might only occur through the hands (due to protective clothing, eye protection, dust filters, etc). The risk assessment process can then be used to determine if additional measures such as gloves are required to prevent exposure.

validated modelling results, and / or expert judgement and outlined in the conceptual site model.

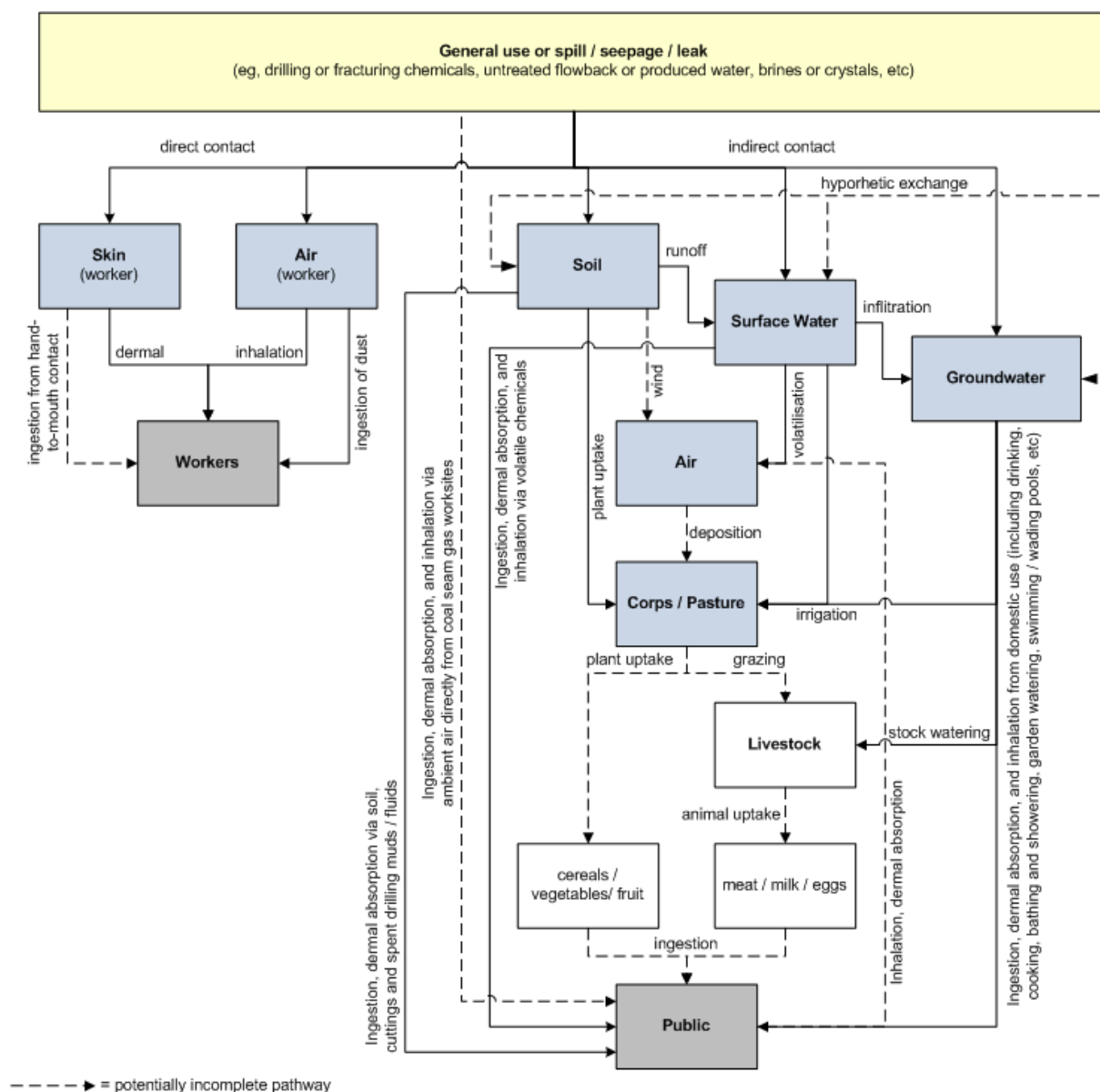


Figure 5.4 Potential human exposure routes to chemicals associated with coal seam gas extraction (after Mallants et al. 2017a).

Selected exposure scenarios should, where possible, assess both realistic worst-case and typical exposures. Realistic worst-case is regarded as the level of exposure which is exceeded only in a small percentage of cases (e.g. 90th or 95th percentile of the exposure distribution) (enHealth 2012a). Where available, actual exposure measurements, provided they are reliable and robust in terms of sample integrity, number of samples, analytical appropriateness, etc. are usually preferred to calculated or modelled estimates of exposure.

Different scenarios to consider for both exposure of workers and the public are briefly described below. The reader is referred to the relevant guidance documentation for each model (for example, US EPA (2012a), ECETOC (2014) and Kahl et al. (2014)) and other relevant references for further information (e.g. ECHA (2012a; 2012b) and OECD (2012d)). Specific examples of models used by NICNAS as part of the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* for both worker and public

scenarios in the coal seam gas context are detailed in Mallants et al. (2017b) and NICNAS (2017c and 2017d).

For workers, in the absence of monitoring data, exposure may be estimated using mathematical models. Numerous occupational exposure models are available, and the risk assessor should determine the most appropriate to use for the particular situation being evaluated. Such models are often applicable to a diverse range of chemicals, with exposure typically estimated using expert knowledge of the industrial process, substance physico-chemical properties, use pattern, and control methods. The types of data required as inputs into various models are provided in Section 4. Examples of some models in a coal seam gas context for inhalation and dermal exposure are detailed in NICNAS (2017d).

Table 5.2 provides examples of existing models for estimating dermal and inhalational workplace exposure to chemicals. These modelling tools produce inhalation or dermal exposure estimates from a simple description of the chemical type and basic conditions of chemical use. For workplace exposure, the available models discussed in Table 5.2 are conservative by design and tend to overestimate exposure (ECHA 2012a). Comparing the results with measured data, using more than one model in parallel, or providing analyses of model sensitivity may help quantify or reduce the uncertainty of the exposure estimates (ECHA 2012a).

Public exposure to chemicals requires an understanding of the sources of contamination, the routes of contaminant flows, the receiving environments affected and how humans interact with, and absorb, contaminants from these receiving environments. As with environmental exposure assessment, direct measurement / monitoring data are preferred where available, but in the absence of measured coal seam gas chemical concentrations in environmental media (air, surface water, soil, and groundwater), concentrations may be modelled or otherwise calculated using the guidance provided for calculating PECs in environmental compartments. In the absence of monitoring data, chemical concentrations in air may be predicted with validated dispersion models.³⁰

In the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia*, NICNAS (2017d) specifically used the DoEE (2017b) surface transport modelling for transport incidents and CSIRO sub-surface soil and shallow-groundwater modelling methodologies (DoEE 2017b; Mallants et al. 2017a and 2017b)³¹ to evaluate different pathways that together contribute to potential human exposures via the environment. In subsequent research Mallants et al. (2017c) developed a set of tools that can be used to calculate the PECs of chemicals that move along deeper underground pathways. These include a set of dilution factors for sites where the geology is similar to two test regions, and a modelling approach to estimate dilution factors in other cases.

Table 5.2 Examples of workplace exposure models

Model	Comments
The Estimation and Assessment of Substance Exposure (EASE) model, developed by the UK Health and Safety Executive (HSE).	The EASE model was developed to be applicable to a wide range of substances and circumstances of use. The data underpinning the model come from the UK National Exposure Database (NEDB). The model

³⁰ The topic of air dispersion modelling is not addressed in this manual, as comprehensive advice and technical requirements needed by Australian jurisdictions are available from individual States (e.g. QLD DEHP 1994; EPA NSW 2001, 2005, and 2017; EPA Vic 2013).

³¹ Useful interactive software for calculating dilution factors for sub-surface chemical contaminant transport in soil and shallow groundwater is detailed in Mallants et al. (2017a and 2017b); and is accessible via the CSIRO web site.

Model	Comments
	predicts a range of expected exposures for the given set of circumstances, rather than a specific concentration. The development and further evolution of the model has been described by Cherrie et al. (2003) and Tickner et al. (2005). A critical assessment of the utility and performance of the EASE model is provided by Creely et al. (2005). This model has been incorporated into the ECETOC TRA tool, which is freely downloadable from http://www.ecetoc.org/tra .
The Einfaches Maßnahmenkonzept Gefahrstoffe (i.e. 'Easy-to-use workplace control scheme for hazardous substances') (EMKG) EXPO-TOOL, developed by the German Federal Institute for Occupational Safety and Health (BAuA).	The EMKG-EXPO-tool is based on the banding approach originally developed by the UK Health and Safety Executive, and only functions for inhalation exposure. The tool predicts a lower and upper value for an exposure range (in mg/m ³ for solids and ppm for vapours). ECHA (2012a) recommends the upper value be used for risk characterisation in order to arrive at a conservative estimate. The tool can be downloaded free of charge from http://www.reach-helpdesk.de/en/Exposure/Exposure.html .
The European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) Targeted Risk Assessment (TRA) tool.	The TRA tool can be downloaded free of charge from http://www.ecetoc.org/tra .
MEASE for metals and inorganic substances, which combines the approaches from the ECETOC TRA tool, the EASE expert system and the health risk assessment guidance for metals (HERAG project).	The MEASE tool can be downloaded freely from http://www.ebrc.de/mease.html .
The 'Stoffenmanager' (Dutch for 'substance manager') tool, developed by TNO, Arbo Unie and BECO(EY). The tool is accepted by the Dutch Labour Inspectorate as a method to evaluate exposure to chemical substances at the workplace.	A basic version of the Stoffenmanager tool is freely available from https://stoffenmanager.nl/ . A premium version requires a paid subscription.
The RISKOFDERM dermal model, the result of a project funded under the 5th Framework Programme of the European Community, developed by Eurofins.	The toolkit is freely downloadable from http://www.eurofins.com/product-testing-services/services/research-development/projects-on-skin-exposure-and-protection/riskofderm-skin-exposure-and-risk-assessment/download-of-riskofderm-toolkit.aspx .
The Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER), developed by the United States Environmental Protection Agency.	ChemSTEER is a tool which can be used to conduct a screening level workplace exposure and release assessment. It is freely available from http://www.epa.gov/oppt/exposure/pubs/chemsteer.htm .

Human internal doses resulting from consumption and / or contact with contaminated environmental media can be estimated using standard risk assessment exposure equations combined with, in the absence of measured data, default exposure factors (i.e. body weight, body height, soil ingestion etc.) (enHealth 2012b). A generic formula for calculating the

internal dose from various media is described in US EPA-RAGS-A guidance on risk assessment (US EPA 1989), and cited in enHealth (2012a).

The generic formula is:

$$I = \frac{C \times CR \times EFD}{BW} \times \frac{1 \times CF}{AT} \quad \text{[Equation 2]}$$

Where:

- I = dose (i.e. intake) of chemical (usually expressed as mg/kg bw/day).
- C = average chemical concentration in media over the exposure period (e.g. mg/L, mg/kg, or mg/m³).
- CR = contact rate; the amount of contaminated media contacted per unit of time or event (e.g. L/day, m³/day).
- EFD = exposure frequency and duration (how long and how often exposure occurs). EFD may be based on the product of two parameters: EF (exposure frequency, e.g. days/year) and ED (exposure duration, e.g. years).
- BW = life stage body weight, usually averaged over the exposure period (kg).
- AT = averaging time, period over which the exposure is averaged (e.g. hours, days, months, years). This will depend on the nature of the adverse effect (e.g. acute or chronic) being assessed and the exposure scenario predicted. For non-threshold adverse effects (e.g. genotoxic carcinogenesis) where exposure may be assumed to be over a lifetime the AT value most commonly used is 70 years. For threshold effects AT values of 36 years (30 as an adult and 6 as a child) for public exposure and 30 years for worker exposure are recommended (enHealth 2012a and 2012b; ASC NEPM 2013 B4 and B7).
- CF = conversion factor, if units in above parameters do not match.

Where specific routes of exposure are considered, Equation 2 may be modified to incorporate route-specific information. Specific examples of calculations used by NICNAS as part of the *National Coal Seam Gas Chemicals assessment* with modified versions of the above equation for inhalation, dermal and oral exposure for workers and the public are available in NICNAS (2017c and 2017d).

Human internal doses from the different relevant exposure pathways may be assessed individually and / or can be summed to generate an overall internal dose (i.e. intake) for comparison with toxicological information from the hazard assessment. The calculations of internal doses from external exposures must always take into consideration absorption or bioavailability factors for the specific route of exposure. It is common practice to assume 100% adsorption or 100% bioavailability unless robust information is available indicating otherwise. Methodologies to estimate bioavailability in soil are becoming more accessible.

The risk assessor is referred to enHealth (2012a, Section 4.6) and the National Environment Protection Measure (NEPM 2013) for the relevant detailed exposure equations and enHealth (2012b) for a compilation of suggested default Australian exposure factors. Exposures may be differentiated into short-term or long-term exposures for comparison with relevant health effects data (see Chapter 6). In addition, when considering public exposures to chemicals associated with coal seam gas extraction, because of different consumption patterns, anthropomorphic characteristics and chemical hazard susceptibilities, estimates should be calculated for different life stages (e.g. a 1 to 2 year old child and an adult). Exposure estimates should include a description of the impact of uncertainties relevant to the exposure

and / or risk estimate. For specific examples of public exposure estimates for chemicals associated with coal seam gas extraction, the reader is referred to NICNAS (2017d).

5.5.2 Calculating PECs for environmental receptors

For an environmental exposure assessment, receptors are entities, such as organisms, (sub)populations, or ecosystems. Receptors may be exposed to chemicals through several pathways. The receiving environment comprises a range of environmental compartments (soil, surface water, groundwater, sediments, air) into which a chemical has been, will be, or could be released (DoEE 2017b). Potentially relevant environmental receptors include soil flora and fauna (such as soil microorganisms and earthworms), livestock, agricultural crops (including, for example, irrigated crops, vines, fruit and vegetables), wildlife (such as native plants and animals), and ecological communities. Care should be taken to ensure that potential environmental risks are not under-estimated. This can be achieved by ensuring that relevant sensitive receptors are included in the chemical risk assessment and that sufficient endpoints and trophic levels are incorporated into the analysis. For example, current statistical approaches aim to protect 95% of aquatic species. For chemical risk assessments at higher tiers, risk assessors will need to identify appropriate sensitive environmental receptors at regional, local or site scales, as distinct from the use of generic exposure scenarios and receptors used in Tier 1 assessments (see Section 2.2.3).

Chemicals are generally at their largest volumes and highest concentration during transport and storage. Concentrations are generally lower for intentional repeated releases, such as use of chemicals in drilling / hydraulic fracturing, and irrigation or dust suppression with untreated or partially treated flowback or produced water. Risks to receiving environment compartments are likely to be higher nearer to the source of gas extraction operations, such as coal seam gas well sites, where chemicals are more concentrated and are unlikely to disperse or be diluted immediately following release. Therefore, the risk may be best mitigated at the source to minimise wider distribution of the chemicals. Receiving environments require thorough characterisation of the physico-chemical parameters to be used for modelling, and identification of important and relevant key receptors to understand potential risks (DoEE 2017b; Mallants et al. 2017a and 2017b).

Higher tiered assessments should include the following main steps to define the environmental receptors:

- map coal seam gas sites
- define and map key receptors such as Matters of National Environmental Significance (MNES) or state legislated protected species or ecosystems in the target area
- map and parameterise regional and local geological features and groundwater flows, including faults, aquifers and aquitards
- define and map specific aquatic and groundwater dependent receptors in target area
- describe and map the target area to determine potential run-off areas.

Suitable criteria should be used to identify key receptors that might be affected by chemical contamination (such as those used in DoEE 2017b). Useful criteria include the following:

- aquatic ecosystems containing protected species or ecological communities that may be in the bioregion (for example, an aquatic ecosystem can include algae; aquatic invertebrates such as protected snails, dragonflies, amphipods etc.; water plants; fish; frogs; reptiles such as turtles; and aquatic birds)
- Terrestrial ecosystems containing protected listed species that may be in the bioregion such as:

- protected plants and animals
- threatened ecological communities, (including Great Artesian Basin springs and the plants and animals that inhabit them)
- groundwater-dependent ecosystems (e.g. terrestrial flora and fauna; gaining and losing surface water systems; aquifer and cave ecosystems; springs, wetlands, estuarine and near-shore marine ecosystems)
- ecosystems declared as protected state / national / world heritage in the bioregion
- ecosystems declared as protected Wetlands of International Importance (“Ramsar sites”) and nationally important wetlands (sites listed in the *Directory of Important Wetlands in Australia* (Environment Australia 2001) and migratory bird habitat) in the bioregion³²
- perennial and ephemeral rivers and streams that are near to the tenements and areas with coal seam gas wells
- rivers that are directly connected to protected national / international heritage, wetlands of international importance, threatened ecological communities, groundwater-dependent ecosystem.

An environmental exposure assessment includes an estimation of chemical release, consideration of environmental fate and partitioning behaviour, and the derivation of predicted environmental concentrations (PECs). For chemicals associated with coal seam gas extraction, exposure assessments describe the potential exposure scenarios, how release of chemicals from coal seam gas extraction activities may result in contamination of soil, surface water, air, sediment, and / or groundwater compartments. Four key stages of the chemical lifecycle should be considered in detail during the exposure assessment to determine their potential for the release of drilling and hydraulic fracturing chemicals into the environment: transportation, storage, industrial use, and disposal. During the exposure assessment the important features of each of these stages should be analysed, and the chemical fate pathways and the receiving environments evaluated. Potential release points can, for example, include:

- transport and handling related spills or leaks
- overflow, leakage, and seepage from storage impoundments
- well casing failures
- industrial accidents
- poor recovery of fluids injected during the hydraulic fracturing process
- intentional surface applications of treated or untreated produced water for beneficial use

Once chemicals enter the receiving environment, their fate pathways are conceptualised to inform predictions of the transfer or transformation of contaminants between different

³² Australia currently has [65 Ramsar wetlands](#) that cover more than 8.3 million hectares. Ramsar wetlands are those that are representative, rare or unique wetlands, or are important for conserving biological diversity. These are included on the List of Wetlands of International Importance held under the [Ramsar Convention](#). Australia also has more than [900 nationally important wetlands](#). These are wetlands that are a good example in a particular area, an important habitat for native species, or that have outstanding heritage or cultural significance. Nationally important wetlands are listed on the directory of important wetlands. See <http://www.environment.gov.au/water/wetlands/about> for further information.

environmental compartments. Potential points of release at working sites are included in the conceptualisation, based on where in the lifecycle an accidental spill of chemical or intentional release to the environment may occur. Examples include:

- transport of chemicals
- storage of chemicals at intermediate warehouse sites
- storage of chemicals at individual well sites
- use of chemicals at individual well sites
- management of coal seam gas waste fluids (i.e. flowback and produced waters)
- storage of coal seam gas waste fluids
- irrigation
- dust suppression.

The environmental exposure scenarios and points of release may, depending on data availability, extend to the contamination of animal or plant-based food produce and / or regional air sheds. As part of this analysis a series of mathematical expressions are often developed and, coupled with the required input data, are used to quantify estimates of chemical concentrations in the receiving environment following release. Users of this manual are directed to DoEE (2017b, 2017c, and 2017d) for detailed examples of environmental exposure assessment calculations.

In the simplest terms, the predicted environmental concentration, or PEC, is calculated using Equation 3:

$$PEC = \frac{Q}{V} \quad \text{[Equation 3]}$$

Where:

Q = the quantity of a chemical released into the environment

V = the volume of the receiving environment medium.

This is however a simplification of the actual concentration, as it assumes instantaneous mixing and is only representative of the PEC at an instant in time without allowing for changes in the environment. The amount of chemical may change over time due to a range of factors including additions from further releases to the environment. It may also decrease due to degradation (biotic and abiotic), or as a result of chemical transport to other environmental compartments (including, for example, to air by volatilisation or to sediments by partitioning. It may also be transported from the initial receiving environment to a secondary receiving environment. Generally, the system is assumed to be static (i.e. no changes in quantity or volume), but dynamic systems algorithms can be used, if required, to simulate more realistic scenarios, such as those in higher tier assessments.

The main transport and fate pathways for chemicals are considered to be runoff, volatilisation, deposition, sedimentation, infiltration and transport in shallow groundwater, and degradation. Overall, the approach to developing conceptual exposure scenarios should be:

- based on a mass balance approach
- tiered – refinement of initially conservative (upper bound) scenarios to more realistic ones occurs only if unacceptable risks are demonstrated in the lower tiered assessment

- precautionary – considers the realistic high end estimate appropriate to each tier, to ensure that hazards and risks are not under-estimated or overlooked
- incorporate, or act as a surrogate, for multiple releases.

The PECs generated during the exposure and hazard assessment analysis are then compared in the risk analysis stage of the risk assessment with the Predicted No Effect Concentrations (PNECs) for each chemical to calculate a risk quotient:

$$RQ = \frac{\text{exposure}}{\text{toxicity}} = \frac{PEC}{PNEC} \quad [\text{Equation 4}]$$

Where:

RQ = the Risk Quotient

PEC = the Predicted Environmental Concentration [mg/L], and

PNEC = the Predicted No Effect Concentration [mg/L].

Based on the RQ derived for each chemical, the risk is then classified in accordance with the principles outlined by EPHC (2009a and 2009b) and ANZECC and ARMCANZ (2000a), as outlined in Section 7.3.

5.6 Checklists

5.6.1 Checklist for human health exposure assessment

Table 5.3 Checklist for human health exposure assessment

Human health exposure assessment		✓
1	Identify the chemical sources and define points of release of chemical(s) (Section 5.2)	
2	Estimate release quantities of the chemical(s) (Section 5.3)	
3	Identify and define exposure pathways for the chemical(s) (Section 5.4)	
4	Identify and define the receptors and exposure routes (occupational exposure and public exposure) applicable to the situation being assessed	
5	Describe, measure and / or calculate exposure concentrations (PECs) for occupational exposure and public exposure	
6	Calculate the internal dose	
7	Describe approach, models used and uncertainties in the data used (Section 4.7.3 and 8.2).	

5.6.2 Checklist for environmental exposure assessment

Table 5.4 Checklist for environmental exposure assessment

Environmental exposure assessment		✓
1	Identify the chemical sources and define points of release of chemical(s) or mixtures (Section 5.2)	
2	Estimate release quantities of the chemical(s) (Section 5.3)	

Environmental exposure assessment		✓
3	Identify and define transfer pathways for the chemical(s) (Section 5.4)	
4	Describe, measure and / or calculate the potential or predicted environmental concentration (PECs) of the chemical(s) for the identified environmental compartment(s) using the scenarios developed during point of release, transfer pathway and receptor assessments (Section 5.5.2). Quantities of release, concentrations and probability of occurrence should be integrated here (Section 5.3)	
5	Identify and define the environmental receptors that may be at risk of exposure applicable to the situation being assessed (Section 5.7)	
6	Describe approach, models used and uncertainties in the data used (Section 4.7.3 and 8.2).	

6 Guidance for human health risk assessment

6.1 Introduction

This chapter provides guidance on assessing hazards to human health and characterising the risk. The risk characterisation phase includes the following steps:

- identify chemicals associated with coal seam gas extraction and the exposure routes. Measure / estimate environmental concentrations and corresponding exposure doses (described in the exposure guidance in Section 5)
- screen chemicals for low concern using a validated screening approach (see Chapter 4 and Section 6.2)
- identify and collate available chemical information and toxicity data. Identify the critical health effects and characterise the dose-response relationship from toxicological studies (Section 6.3 and 6.4)
- characterise public and occupational health risks (Section 6.4) by combining estimated human dose from the exposure with the toxicological information from the hazard assessment (Section 6.3)
- determine appropriate uncertainty / safety factors for interpretation of results (Section 6.4).

With every assessment, an uncertainty / sensitivity analysis should be undertaken for which the reader is referred to Section 4.6 in this manual and Chapter 5.15 of enHealth (2012a) for further guidance.

6.2 Screening of chemicals for low human health concern

An estimate of health risk, by definition, is a function of the intrinsic hazard of a chemical, and the extent of exposure. If either hazard or exposure is negligible, the health risk is also negligible. For this reason, in human health risk assessment, it is appropriate to optimise resources by first screening chemicals associated with coal seam gas extraction to identify chemicals already known to be of low hazard and, therefore, of low concern for human health.

Chemicals of low concern for human health should be of low concern for both workers and the public, and have a low likelihood of causing adverse effects in these different populations if an exposure occurs. This screening process for chemicals associated with coal seam gas extraction in the human health assessment framework is depicted in Figure 6.1 below.

Chemicals not assessed as 'low concern' in the screening process will require further assessment, for which the potential for exposure (see Section 5) and hazard (Section 6.3) should be assessed and a human health risk characterisation be undertaken (see Section 6.4). Screening allows resources to be concentrated on chemicals that have the most potential to pose a risk. The screening process described in this section is for the human health risk assessment only. Care should be taken to ensure that chemicals which may be of potential concern are not unintentionally screened out.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework developed by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) provides an example of a screening process. The IMAP framework was established to identify and rapidly assess chemicals on the Australian Inventory of Chemical Substances (AICS) that had not been subjected to previous assessment. The approach has been validated by national experts, and an adapted approach used in the National Assessment is considered by NICNAS to be appropriate for identifying drilling and hydraulic fracturing chemicals of low concern for human health. Details of the screening process that identifies chemicals of low concern specifically for human health hazards are provided in NICNAS (2016a and 2017b).

In the first instance, the chemical(s) to be considered may be compared with the chemicals already assessed under the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* using the adapted IMAP screening process (NICNAS 2016a and 2017b). Chemicals already screened using this approach and identified by NICNAS to be of “low concern because of low hazard”³³, do not require further assessment. If the chemical(s) being assessed are not considered to be of “low concern because of low hazard” and / or were not assessed by NICNAS, the following screening methodology can be adopted prior to undertaking a full risk assessment.

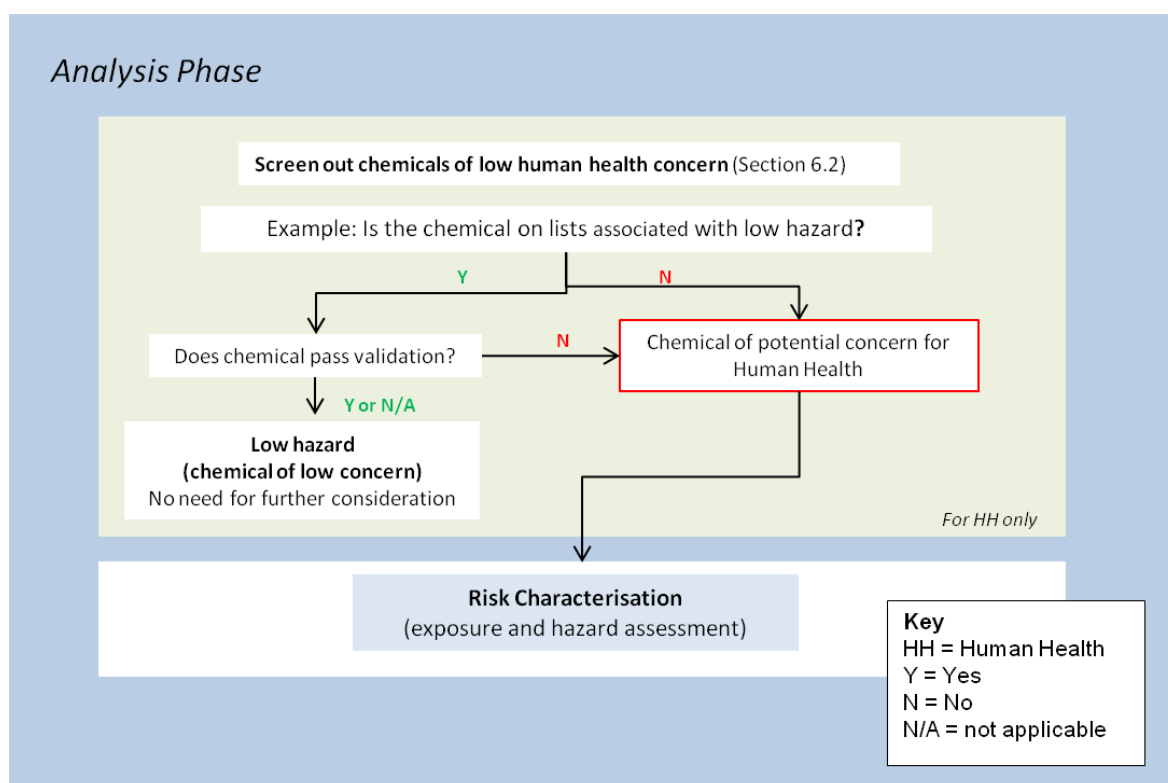


Figure 6.1 Overview of screening process to identify chemicals of potential concern for human health

The screening process used in the IMAP framework (NICNAS 2016a) encompasses the following steps:

- identify chemicals of potential low concern for human health based on existing national or international lists of substances applicable to chemicals associated with coal seam gas extraction

³³ CSG chemicals of low hazard identified in NICNAS (2017a) [accessed 24/10/2017]:
<http://www.environment.gov.au/water/coal-and-coal-seam-gas/publications/chemicals-of-low-concern-for-human-health-based-on-an-initial-assessment-of-hazards>

- apply validation rules developed by NICNAS in the IMAP framework to confirm low concern
- identify additional chemicals of low concern – such as certain binary inorganics, organic acid salts, hydrates, naturally occurring substances, polymers.

6.2.1 Step 1: Identifying chemicals of potential low hazard based on existing lists

If the coal seam gas chemical to be assessed is on a national or international pre-determined list of chemicals identified to be of low concern for human health hazards, then it is likely the use of that chemical in coal seam gas extraction in Australia will also be of low concern to human health. This assumption may be confirmed by the use of lists of low hazard chemicals which have been developed for chemicals associated with coal seam gas extraction as part of the IMAP framework.

When a chemical associated with coal seam gas extraction is not found to be listed in the 'low-hazard' lists, it does not imply that the chemical will in fact present a risk to human health. Rather, it may mean that they may not have been previously evaluated by Australian and / or International agencies that developed the lists for the quantities and or uses of them by the coal seam gas industry.

As part of the review of existing schemes used in Australia and overseas, NICNAS (2017b) recommend the use of the specific tools and lists presented below. If a chemical is listed on either of the following 2 lists as being of low concern, then unless it is found on a list of chemicals of potential concern, no additional validation is required:

- US EPA High Production Volume (Indicator 1)³⁴
- REACH Annex IV³⁵.

If a chemical is listed on any of the following three lists as being of low hazard / low concern, additional validation (Section 6.2.2) is required to ensure the conclusion is relevant for coal seam gas operations:

- Inert Ingredients eligible for the US Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)³⁶
- US Food and Drug Administration (FDA) Generally Regarded as Safe (GRAS) (Type 1)³⁷

³⁴ The US EPA High Production Volume (HPV) chemicals are those which are manufactured in or imported into the US in amounts \geq 1million pounds/year. Indicator 1 denotes those chemicals not considered a candidate for testing, based on a preliminary US EPA review indicating testing would not further our understanding of the chemical's properties. Chemicals on the list can be searched by CAS number or chemical name on the following webpage [accessed 24/10/2017]: <https://www.epa.gov/chemical-research/prioritization-high-production-volume-chemicals-under-chemical-assessment-and>

³⁵ Annex IV of the European REACH regulation (i.e. Registration; Evaluation; Authorisation; and restriction of Chemicals) contains a list of substances exempt from registration on the basis that they are considered to cause minimum risk due to their intrinsic properties (EC 2008).

³⁶ The US FIFRA requires all pesticides, with very limited exceptions, to be registered with the US EPA prior to sale in the US. Certain pesticides are exempt on the basis that they pose minimal risk to humans and the environment, provided they satisfy certain conditions. The list of inert ingredients is available at the following webpage [accessed 24/10/2017]: <http://www2.epa.gov/minimum-risk-pesticides/inert-ingredients-approved-use-minimum-risk-pesticide-products>.

³⁷ This list contains food substances that are not subject to pre-market review and approval by the US Food and Drug Administration (FDA) because they are generally regarded by qualified experts as safe (GRAS) under the intended conditions of use. Their safety has been established through scientific procedures or through a long history of use in food. The Type 1 category contains substances deemed not to be a hazard to the public when used at levels that are now current or might reasonably be expected in the future. The database of substances GRAS can be searched at the following webpage: www.accessdata.fda.gov/scripts/fdcc?set=SCOGS. [accessed 24/10/2017]

- REACH Annex V³⁸

Prior to determining a chemical as being of low concern, careful consideration should be given to the potential for unintended cross-contamination during the production process of the chemical in question, as unintended trace contaminants may be associated with unexpected toxicity.

6.2.2 Step 2: Apply validation rules from IMAP framework to chemicals of potential low hazard

NICNAS (2017b) has developed a number of additional validation rules that must also be satisfied in order for the conclusion that a chemical poses only a low concern / low hazard in coal seam gas extraction. This extends to which “low hazard chemical” lists can be used for initial screening of a chemical and which require additional validation of “low hazard” classification of the chemical.

If a chemical is found on any of the lists requiring additional validation, and any of the criteria below are met, further assessment of the chemical should be undertaken:

- chemicals identified as a concern or for which regulatory action has been taken overseas³⁹
- chemicals identified in human umbilical cord blood⁴⁰
- chemicals meeting the hazard criteria underpinning the IMAP framework:
 - listed as hazardous chemical in Safe Work Australia’s Hazardous Substance Information System (HSIS)⁴¹
 - classified as hazardous in the EU Regulation on Classification, Labelling and Packaging (CLP)⁴²
 - classified as a Group 1, 2A or 2B carcinogen by International Agency for Research on Cancer (IARC)⁴³
 - listed in latest National Toxicology Program (NTP) Report on Carcinogens (RoC)⁴⁴
 - listed in US EPA Integrated Risk Information System (IRIS) as carcinogenic to

³⁸ Annex V of the European REACH regulation (i.e. Registration; Evaluation; Authorisation; and restriction of Chemicals) contains a list of substances exempt from registration because registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH. The list contains both specific and more generic entries (EC 2008). The latter are descriptors of chemical characteristics or manners in which they are formed; determination of whether chemicals fit into some of these categories may require expert judgement.

³⁹ Chemicals identified as a concern are defined as those meeting any of the subsequent hazard criteria in this list.

⁴⁰ This could be determined by means of a literature search of several scientific and general databases using descriptive search terms combined with the chemical name and / or identifier.

⁴¹ Accessible and searchable via the Safe Work Australia website [accessed 24/10/2017]:
<http://hsis.safeworkaustralia.gov.au/>

⁴² Accessible and searchable via the European Chemicals Agency website [accessed 24/10/2017]:
<https://www.echa.europa.eu/>

⁴³ List of classified substances available via the IARC website [accessed 24/10/2017]:
<http://monographs.iarc.fr/ENG/Classification/>

⁴⁴ Latest version available via the NTP website [accessed 24/10/2017]:
<http://ntp.niehs.nih.gov/pubhealth/roc/index.html>

humans, or likely / probable / possibly carcinogenic to humans⁴⁵

- classified by the American Conference of Governmental Industrial Hygienists (ACGIH)⁴⁶ in carcinogen categories TLV-A1, -A2, or -A3
- listed in Category 1 or Category 2 on EU list chemicals with endocrine disruption classifications⁴⁷
- listed by the Agency for Toxic Substances and Disease Registry (ATSDR) to be neurotoxic⁴⁸
- chemicals included in the Poisons Standard (the Schedule for Uniform Scheduling of Medicines and Poisons (SUSMP) (for example TGA 2015)), except where the listing is in Appendix B
- chemicals removed from Annex IV of REACH (EC 2008) as part of the review process⁴⁹
- chemicals listed as substances of very high concern (SVHCs) according to Annex XV of REACH⁵⁰
- strong or moderate acids and bases⁵¹, quaternary ammonium salts⁵², and anhydrous deliquescent materials⁵³
 - the following additional chemicals can however be identified for inclusion as low concern chemicals: binary inorganic and organic acid salts consisting of Na⁺, K⁺, Mg⁺, Ca⁺², Cl⁻, CO₃⁻², PO₄⁻³, NO₃⁻¹, OH⁻¹, O⁻² and SO₄⁻², and simple salts of acetate, citrates, lactates, tartrates, malates and di- and tri- phosphates
- As hydrates of a substance or hydrated ions are formed by association of a substance with water, the hydrates of chemicals considered as being of low concern for human

⁴⁵ The IRIS database is searchable via the US EPA website [accessed 24/10/2017]: <http://www.epa.gov/IRIS/>

⁴⁶ This list is not freely available online. ACGIH publishes a guide to occupational exposure values, which contains the carcinogen classifications (e.g. ACGIH 2017) and can be accessed by members via: <http://www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations/overview>. [accessed 24/10/2017]

⁴⁷ The compiled list of potential endocrine disruptors can be downloaded as a Microsoft Access database via the European Commission's website [accessed 24/10/2017]: http://ec.europa.eu/environment/chemicals/endocrine/strategy/substances_en.htm#priority_list

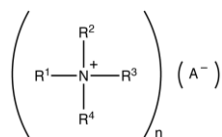
⁴⁸ ATSDR lists a number of substances as having effects on the nervous system. The listing can be accessed via the ATSDR website [accessed 24/10/2017]: <http://www.atsdr.cdc.gov/substances/toxorganlisting.asp?sysid=18>

⁴⁹ The risk assessor should ensure the latest version of Annex IV is reviewed.

⁵⁰ European REACH regulation SVHCs in the candidate list, including Articles 7, 31 and 33 of the REACH regulation.

⁵¹ The strength of an acid or base is determined by the extent of its ionisation in aqueous solution. Strong acids (such as HCl) and strong bases (such as NaOH) are 100% ionised, whereas weak acids/bases are <5% ionised.

⁵² A quaternary ammonium salt is an ionic compound that has the following general structural formula, where the R groups could be hydrogen atoms, alkyl groups, aryl groups, or any combination thereof. (A⁻) could be any anion present in salt. These substances are typically used in cosmetics and laundry products.



⁵³ Deliquescent materials are substances (mostly salts) that have a strong affinity for moisture and will absorb relatively large amounts of water if exposed to it. Deliquescent salts include CaCl₂, MgCl₂, ZnCl₂, K₂CO₃, and NaOH. Because of their very high affinity for water, these substances are often used as desiccants.

health are themselves also considered as low concern for human health, as are hydrates where the anhydrous form is ruled out due to desiccation effects

- certain naturally occurring chemicals and some materials, for which there are no known toxicological effects (e.g. nut hulls) may also be considered to be of low concern to human health. However, it should not be assumed that dusts from these substances do not present a hazard to human health (NICNAS 2017b)
- polymers which meet NICNAS's New Chemicals Program Polymer of Low Concern (PLC) criteria may similarly be considered by NICNAS to be of low concern to human health. Details for the criteria and application to chemicals associated with coal seam gas extraction are provided in NICNAS (2015).

6.2.3 Step 3: Determine chemicals of low concern and chemicals of potential concern

Once step 1 and 2 of the screening process are completed, chemicals determined to be of low concern require no further assessment. The remaining chemicals are of potential concern and require further assessment. Exposure to them can be assessed, modelled and / or measured according to the approaches discussed in Section 5. A hazard assessment can be carried out as outlined in Section 6.3, and the human health risk characterised as described in Section 6.4.

When chemicals are screened to be of low concern, the assessor should clearly document and communicate the chemical(s) assessed, the lists and literature used, the screening process applied and uncertainties should also be discussed to support the conclusion of low concern (see Sections 4.6).

6.3 Hazard assessment for human health

The identification of hazards involves examining the capacity of an agent to cause adverse health effects in humans and / or animals, and a dose-response assessment examines the quantitative relationship between the exposure and the effects of concern (enHealth 2012a).

The risk assessor should collate information on the human health hazards of identified chemicals of potential concern. Existing hazard classifications for occupational health and safety, including exposure standards, should be noted. A risk assessment report should contain succinct toxicological profiles for each chemical of potential concern, typically with toxicological information for the relevant routes of exposure. A summary of the types of data required is listed in Section 4.4.1.

It is rare that comprehensive toxicological datasets will be available. As noted in Section 4, if robust national or international toxicology data are not available, it may be necessary to engage an expert toxicologist or ecotoxicologist to find and assess the value of data from a broader range of sources (NEPM 2013).

From the toxicological information, which may stem from authoritative agency reviews and / or peer-reviewed research publications⁵⁴, the critical health effect of concern should be identified. The exposure or dose to consider for a quantitative risk assessment, also referred to as the Point of Departure (PoD), should also be identified. The PoD includes doses such as No Observed Adverse Effect Level (NOAEL), Low Observed Adverse Effect Level (LOAEL) (in the absence of a NOAEL) or the benchmark dose (BMD). Uncertainty or safety factors relating to sources of uncertainty such as extrapolation between and within species or

⁵⁴ Examples of databases and sources which could be used to identify pertinent hazard information are provided in Section 4. Further information on hazard classifications can also be found in (United Nations 2015).

particular deficiencies in key toxicological studies such as no NOAEL being established are also identified.

Guidance on general hazard and risk characterisation approaches and the appropriate allocation of uncertainty or safety factors, is provided in enHealth (2012a). For the approach to human health risk assessment including application of uncertainty factors for the National Coal Seam Gas Chemicals Assessment, the reader is referred to NICNAS (2017d).

One of the main components in a human health hazard assessment is to determine if the chemical being assessed is likely to be carcinogenic or not (see Figure 6.2). In accordance with currently accepted practice, generally if a chemical is likely to be a genotoxic carcinogen⁵⁵, a non-threshold approach to risk assessment is considered appropriate (see Section 6.4.2). This involves identification or calculation of a cancer slope factor (CSF) or unit risk factor (URF), which is the probability (or risk) of the response (e.g. cancer) per unit of intake (usually expressed in mg / kg body weight/day) or exposure concentration, respectively, over a lifetime of exposure (enHealth 2012a). A step-wise decision-making approach for choosing dose-response data in risk assessment for carcinogenic chemicals is presented in enHealth (2012a - Figure 15). Detailed guidance for assessment of carcinogens is also provided in Chapter 11 of enHealth (2012a).

For chemicals with limited hazard information, it may be possible to fill data gaps from information for structural and / or mechanistic analogues and / or from the use of QSAR modelling⁵⁶ (See Section 4.4.2). Determination of the suitability of potential analogues should be done in a manner consistent with international guiding principles on the grouping of chemicals (Section 4.5.1 and ECHA 2017; OECD 2014).

6.4 Human health risk characterisation

Human health risk characterisation is defined as:

the qualitative and / or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment (FAO and WHO 2009).

It is in the risk characterisation step that the results of the risk assessment are presented. These results are provided in the form of risk estimates and risk descriptions that provide answers / information to the questions risk managers pose to risk assessors. These in turn provide the best available science-based evidence to be used by risk managers to assist in managing occupational or public safety (FAO and WHO 2009).

Risk characterisation can be conducted qualitatively through qualitative descriptive expressions of risk, or quantitatively through the derivation of numerical risk estimates as expressions of risk.

Qualitative risk characterisation will generally be of a descriptive or categorical nature. For some adverse human health effects (endpoints), it is either not possible, or data are not available, to conduct a quantitative characterisation of risk comparing numerical data from a

⁵⁵ enHealth (2012b, Section 11.4) provides suggested guidance for determining whether or not a rodent carcinogen is acting via a genotoxic mode of action. This guidance is also applicable to chemicals associated with coal seam gas extraction.

⁵⁶ Many QSAR models have been developed and some are publicly available. Depending on the purpose, different models may be used, but transparency is preferred. The user should verify if details underpinning the model functionality are available and whether the model is appropriate for the chemicals in question (this is often defined by the training set of chemicals used to validate the model). Commercial models may have limitations in terms of transparency and communicability to stakeholders. International guidance on the principles for validation of QSAR models is available (OECD 2007).

dose-response analysis to numerical data from an analysis of exposures. In such cases, where it is not appropriate or possible to characterise risks quantitatively, risks to human health can be assessed qualitatively. A qualitative risk characterisation differs from a quantitative risk characterisation in that risks are not represented by a numerical value, such as a margin of exposure (MOE) or a risk characterisation ratio (RCR). Rather, they are characterised by descriptions of the chemical hazards, exposure scenarios and operational conditions which are then integrated to draw conclusions as to the likelihood of adverse health effects. Qualitative risk assessments are dependent on supporting descriptions, argument and expert judgment. Examples of descriptive risk indicators are provided elsewhere (e.g. FAO and WHO 2009; NIOSH 2009; OGTR 2005; WA DoH 2010).

The human health risk characterisation focuses on the conduct of quantitative risk characterisation for chemical exposure. The precision of any such estimate will be limited by the data available to use in the assessment. There are advantages and disadvantages for using either method, but, in general, the type of risk assessment is dependent on both the level of information available and the tier of assessment required. Qualitative assessment is frequently used as a first step to quickly explore or implement protective measures where there is consensus that such measures would be immediately effective and useful (FAO and WHO 2009).

In practice, chemical risk assessments often require a combination of qualitative and quantitative risk characterisation, depending on the health effects associated with the chemical and the availability of data. For example, a quantitative risk characterisation may be appropriate for assessing serious systemic health effects (including carcinogenicity) from repeated exposures when quantitative hazard and exposure data are available. On the other hand, a qualitative risk characterisation may be sufficient for assessing acute non-systemic (local) reversible effects such as skin or eye irritation.

In a quantitative risk characterisation of occupational and public health risks associated with coal seam gas extraction, the estimated internal doses / intakes from the exposure assessment (Section 5) are compared with the toxicological values (threshold and non-threshold, if applicable) from the hazard assessment (Section 6.3) to generate numerical indices of the likelihood of health effects. The risk estimation method differs between threshold and non-threshold compounds. Figure 6.2, adapted from enHealth (2012a), outlines the stepwise approach whereby the decision to use a threshold or non-threshold approach can be taken. The two different approaches are discussed further in Sections 6.4.1 and 6.4.2, respectively.

During risk characterisation, the results from the exposure and the hazard assessment are used to interpret the risk posed to human receptors. The risk description should indicate the overall degree of confidence in the risk estimates, summarising uncertainties, citing evidence supporting the risk estimates (see Sections 4.6).

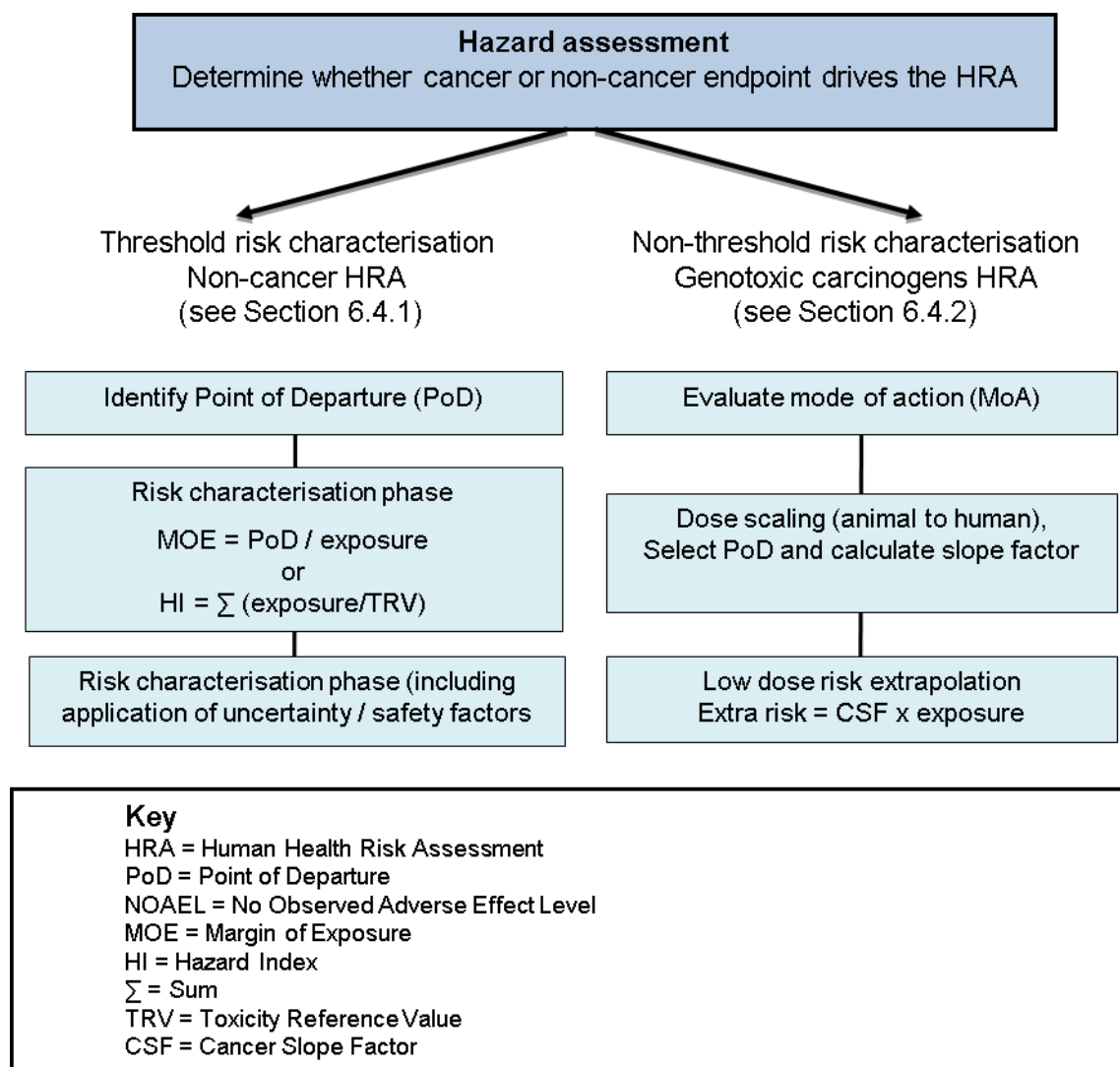


Figure 6.2 Decision tree for choosing a threshold or non-threshold model for risk assessment (after enHealth 2012a)

6.4.1 Threshold risk characterisation

There are two approaches described in this guidance manual: the ‘margin of exposure’ (MoE) and the ‘risk quotient’ (RQ) approaches. The approach used by NICNAS for industrial chemicals such as those in the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* is the MoE approach. The RQ approach is also a recognised Australian and international approach which depends on the availability, or calculation, of a Toxicity Reference Value (TRV) (enHealth 2012a). While the MoE approach is preferred for assessing chemicals associated with coal seam gas extraction, the method selected will depend on the problem and scenario being addressed and may need to be decided on a case by case basis in light of regulatory requirements.

The ‘margin of exposure’ (MoE) approach was used to assess the health risk to workers and the public from chemicals associated with coal seam gas extraction. Details of the application of this method are described in the NICNAS reports (NICNAS 2017c and 2017d). For each exposure scenario, an MoE is derived by comparing the point of departure (e.g. NOAEL) for long-term health effects from the critical toxicological study to the measured / estimated total human internal dose from all routes of exposure (Equation 5):

$$MoE = \frac{PoD}{human\ dose} \quad [Equation\ 5]$$

Where:

MoE = Margin of Exposure

PoD = Point of Departure (e.g. NOAEL) in mg/kg body weight (bw)/day

Human dose = measured or estimated human dose in mg/kg bw/day

As the MoE increases, the risk of potential adverse effects decreases because there is sufficient margin between the dose associated with health effects from the toxicological study and the exposure (internal dose) measured or calculated from the exposure assessment.

Following calculation of the MoE, uncertainty factors are used to determine whether it is large enough to indicate a low concern for human health (i.e. whether the total internal dose calculated in humans from exposures to contaminated environmental media is small enough compared to the dose at which no adverse health effects are expected in humans). For example, using a well-defined NOAEL from an animal toxicology study, an MoE indicating low concern for human health is usually taken to be 100 or greater, reflecting conservative default uncertainty factors of 10 to account for inter-species extrapolation (from animal studies to humans) and a similar factor of 10 to account for intra-species variability (differences between individual organisms) (ECETOC 2003; enHealth 2012a; NICNAS 2017d). Interpretation of the magnitude of the MoE is conducted on a case-by-case basis, taking into account all appropriate uncertainty factors (e.g. adequacy of the database, nature and severity of the health effect and inter- and intra-species variability).⁵⁷

NICNAS (2017c and 2017d) provides further descriptions on the choice of uncertainty factors applied to chemicals associated with coal seam gas extraction as part of the National Coal Seam Gas Chemicals Assessment. For example, an additional uncertainty factor of 3 was applied in cases where extrapolation from a lowest observed adverse effect level (LOAEL) to a NOAEL was required.

As an alternative to the MoE approach outlined above, the measured or estimated internal dose from the exposure assessment for chemicals with a threshold dose response can be divided by the appropriate threshold toxicity reference value (TRV) (if available) to produce a simple ratio, termed a 'risk quotient' (RQ).

$$RQ = \frac{Human\ Dose}{T-TRV} \quad [Equation\ 6]$$

$$Overall\ RI = \sum RQ\ for\ each\ exposure\ pathway \quad [Equation\ 7]$$

Where:

RI = Risk Index

RQ = Risk Quotient

Human Dose = measured or estimated human dose in mg/kg/day

⁵⁷ Importantly, uncertainty factors totalling more than 100 should not be used in coal seam gas chemical risk assessments analysing human health risks. Uncertainty factors greater than 100 in total suggest that the data is inappropriate and that the chemical risks cannot be assessed with sufficient accuracy.

T-TRV = Threshold Toxicity Reference Value (TRV) in mg/kg/day

The risk quotients for all exposure pathways for each chemical associated with coal seam gas extraction can also be summed to produce an overall risk index. For an individual chemical, the goal of the risk characterisation is to determine if the exposure exceeds an appropriate toxicity reference value (i.e. the overall RQ or RI > 1), in which case the exposure is regarded as of potential concern. For further guidance on the derivation of RI and RQ, the reader is referred to Sections 5.4 of enHealth (2012a).

If a chemical of concern associated with coal seam gas extraction has not been evaluated by a national or international agency and there is insufficient toxicological information to undertake a quantitative risk assessment, risks may be characterised using the Threshold of Toxicological Concern (TTC). The TTC has been used by the World Health Organisation (JECFA 2012), US Food and Drug Administration (FDA 1995), and European agencies (EFSA 2012; EC 1996) for risk assessment of chemicals present at low concentrations in various media and consumer goods. In Australia it has been used for setting criteria for chemicals in recycled water which could potentially be used as a source of potable water (EPHC 2006 and 2008).

6.4.2 Non-threshold risk characterisation

In Australia, a non-threshold risk characterisation method is typically only applied to known genotoxic carcinogens. A non-threshold dose-response relationship implies that the response incidence is zero at zero exposure, and that a finite level of risk may be determined (using extrapolation methodology) at any exposure level above zero (enHealth 2012a). The extrapolation methodology typically assumes linearity between the lowest experimentally derived dose and the zero dose (the origin). A discussion of the uncertainties with this assumption and the consequence this may have on risk assessment conclusions is available (in Section 3.10.2 of enHealth 2012a).

Genotoxic carcinogen risks are estimated as the additional probability of an individual developing cancer over a lifetime as a result of exposure to the carcinogen. The estimated life-time average daily intake, or exposure inhalation concentration, for each exposure pathway and the non-threshold toxic reference value (e.g. cancer slope factor or unit risk factor) are multiplied to produce pathway-specific estimates of increased lifetime cancer risks (ILCR) (enHealth 2012a).

$$ILRC = \text{Human Dose or Exposure Concentration} \times TRV \quad [\text{Equation 8}]$$

Where:

ILCR = Increased lifetime cancer risks

Human Dose = Measured or estimated human dose in mg/kg/day

Exposure concentration = Exposure concentration in mg/m³

TRV = Toxicity Reference Value in (mg/kg/day)⁻¹ or (mg/m³)⁻¹

'Target' risk levels in public health risk assessments typically range between 10⁻⁶ and 10⁻⁵ (i.e. an additional cancer risk of 1 in 1 000 000 to 1 in 100 000 people as a result of lifetime daily chemical exposure is typically considered acceptable). In occupational risk assessments the 'acceptable risk' may be higher (e.g. 1 in 1 000) (enHealth 2012a). NEPM (2013) considers an acceptable incremental lifetime risk of developing cancer arising from exposure to single or multiple carcinogens is 1 in 100 000. The decision of an 'acceptable risk' level is a socio-political matter requiring consultation with stakeholders.

6.4.3 Risk description

During risk description, the results of the risk estimation are used to interpret the risk posed to humans. The risk description should indicate the overall degree of confidence in the risk estimates, summarising uncertainties, citing evidence supporting the risk estimates, and interpreting the adversity of human health effects.

6.5 Checklist

Table 6.1 Checklist for human health risk characterisation – including hazard assessment and risk identification

Human Health risk characterisation		<input type="checkbox"/>
Screening		
1	Identify chemicals of low concern/potential concern and collate available information on the human health hazards using NICNAS validation rules described in Section 6.2	
Hazard assessment		
2	Collate and evaluate relevant toxicity data and dose response relationships from toxicology studies and nationally and internationally recognized sources. Identify the critical health effect, the dose for the point of departure (e.g. NOAEL), and develop toxicological profiles for the chemicals of potential concern.	
3	Determine whether carcinogenic chemicals are present, whether these are genotoxic, and follow described methodology using threshold or non-threshold assessment.	
Exposure assessment		
4	Estimate the internal dose from the monitoring data or the PEC from the modelled data	
Risk Characterisation		
5	Characterise public and occupational health risks by combining the estimated exposure doses from the exposure assessment with the toxicological values from the hazard assessment	
6	For threshold approach - calculate margin of exposure (MoE) or risk quotient RQ to characterise risk (Section 6.4.1) Delineate data uncertainties and determine appropriate uncertainty / safety factors for interpretation of MoE or derivation of TRV.	
7	For non-threshold approach – utilise non-threshold risk characterisation methods (Section 6.4.2)	

7 Guidance for environmental risk assessment

7.1 Introduction

This chapter provides guidance on assessing the environmental risk of chemicals associated with coal seam gas extraction. Both qualitative and quantitative environmental risk assessments of chemicals include four key elements:

- **Problem formulation:** Specifies what needs to be protected from harm and identifies potential harmful effects based on the properties of the chemical stressor, and potential exposure of receptors to stressors (see Section 3)
- **Fate and effects assessment:** Determines the environmental fate of the chemical stressor and the potential adverse effects (harm) to receptors caused by exposure to a chemical stressor
- **Exposure assessment:** Determines the potential exposure of receptors to the stressor (see Section 5)
- **Risk characterisation:** The risk is estimated by combining the exposure and hazard assessments to determine the seriousness and likelihood of harm.

7.1.1 Data guidelines for environmental risk assessments

Chapter 4 of this manual provides detailed advice on data sources, data selection, and quality evaluation of data to inform the assessment of coal seam gas chemicals. Irrespective of the approach (qualitative or quantitative), information should be obtained for each chemical on the parameters listed in Table 4.1, 4.2, and Sections 4.2 and 4.3. The following information is required:

- unique identity of the chemical including the Chemical Abstracts Service registry number (CAS RN) and name and, where possible, the molecular structure
- use and quantity of the chemical
- physico-chemical properties
- environmental fate characteristics
- environmental effects (ecotoxicity)
- bioaccumulation and biomagnification potential
- exposure pathways
- identity and characteristics of the environmental entities that may be exposed to the chemical
- the distance between potentially exposed environmental entities and the proposed coal seam gas operation⁵⁸.

⁵⁸ Particular attention should be paid to sensitive environmental entities that are less than 2 000 m from the coal seam gas extraction well (see NICNAS 2017d). However, entities that are 3 500m may also require consideration (Mallants et al. 2017c).

Once information has been gathered, expert judgement is applied in a screening assessment and, potentially, a more detailed qualitative risk assessment.

7.2 Qualitative approaches to risk assessment

According to the US EPA *Guidelines for Ecological Risk Assessment*:

“Although risk assessments may include quantitative risk estimates, quantitation of risks is not always possible. It is better to convey conclusions (and associated uncertainties) qualitatively than to ignore them because they are not easily understood or estimated.” (US EPA 1998)

The European Chemicals Agency also recommends qualitative risk assessment when quantitative assessment is impractical (ECHA 2012b).

Qualitative risk assessments use descriptions such as ‘moderately toxic’ rather than a numerical value to describe risk. Expert judgements will be used in both qualitative and quantitative risk assessments, and a reliable risk assessment must be based on transparent and sound scientific reasoning. Judgements are necessary when defining the scope of the problem, selecting (and rejecting) data, defining exposure pathways, applying weightings to data, selecting model parameters, characterising environmental effects and communicating risk (‘low risk’, ‘potentially high risk’ etc.).

The basic process for a qualitative risk assessment is the same as for a quantitative one, and comprises data-gathering and research, an exposure assessment, a hazard assessment and the synthesis of the exposure and hazard assessments into a risk assessment. It is not possible to provide prescriptive guidance on how to conduct a qualitative risk assessment, since the issues under consideration and the available data vary so widely from chemical to chemical, but careful study of a chemical’s properties and the manner in which it is used can often lead to robust conclusions. For example, chemicals may be identified as posing a low risk on grounds that include:

- ecotoxicity: if there is strong evidence that the chemical is not toxic to the organisms that may be exposed to the chemical as a result of its use in coal seam gas operations
- environmental fate: if the chemical is known to decompose rapidly into low risk components in the environment
- exposure: if there are no feasible pathways for organisms to be exposed to the chemical.

These are only indicative examples, and there are many other factors that may be relevant to determining risk. For example, if very large quantities of a chemical are released into a waterbody the short-term physico-chemical effects may pose a risk even if the chemical is not toxic and decomposes rapidly. For example, there may be loss of dissolved oxygen in a water body if a chemical has a high BOD, or there may be large changes to the pH of a water body due to an acid spill.

It is noted that it may not be possible to determine the level of risk posed by a chemical if there is insufficient data available, and that in this case, any critical data gaps should be identified as part of the assessment.

Examples of qualitative risk assessments conducted as a part of the *National assessment of chemicals associated with coal seam gas extraction in Australia* are attached in Appendix D.

7.2.1 Undertaking qualitative assessments

7.2.1.1 Gathering data and information

The foundation of a robust qualitative chemical risk assessment is a thorough review of the relevant scientific literature. The review should evaluate information on the physico-chemical properties (Sections 4), environmental fate (Section 5), and intrinsic hazard of the chemicals under consideration. Additionally, there may be information in the literature on known environmental risks associated with the use of the chemical. At a minimum, the review should cover the information set out in section 7.2.2 below for a screening assessment and sections 7.2.3 for a more detailed qualitative risk assessment. Relevant background information should include:

- the use of the chemical in the coal seam gas industry
- chemical properties, toxicity, and modes of action, especially those that are potentially harmful
- natural and anthropogenic sources of the chemical in the environment, including information on background concentrations
- relevant environmental receptors in regions potentially impacted by coal seam gas extraction

Background information can be used to identify the key factors for consideration in qualitative assessments: for example, degradation in the environment or potential to mobilise metal ions.

7.2.1.2 Chemical identity and physico-chemical properties

Qualitative assessments may involve both numerical (quantitative) data and qualitative information. Wherever possible, values for physico-chemical, fate, and effects properties – particularly toxicity – should be categorised and described using the guidance provided in Chapter 4. The same descriptions should be used for categorising the properties of chemicals where there is only qualitative information available. In such cases, expert judgements are needed to determine the appropriate category and the risk assessment should describe the basis for these judgements.

Information on chemical identity and important physico-chemical properties should be tabulated and includes the relevant data listed in Table 4.1 and Section 4.3. This information should include:

- CAS RN
- CAS and AICS names
- other names (including IUPAC and common names, if available)
- molecular formula and weight
- structural formula and SMILES string (if applicable).

Important physico-chemical properties should also be tabulated, including:

- aqueous solubility
- pKa
- log K_{ow}
- vapour pressure
- melting and boiling point.

Other physico-chemical properties such as Henry's constant should be included. Additionally, it may be useful to include a brief description of other notable properties. For instance, the chemical's acidity or alkalinity, its stability and oxidising potential, and its salinity. When physico-chemical properties are estimated by comparison with analogues or by using QSAR modelling this should be noted in the table of data (and the basis for the estimate should be explained in the table or below it).

7.2.1.3 Domestic and international regulatory information

A review of international and national environmental regulatory information should be undertaken, as described in Section 3.1 (also see Appendix E: Section 1.2.4).

7.2.1.4 Environmental transport and fate

The environmental fate and partitioning behaviour of a chemical determines where the chemical ends up in the environment if it is released (Section 5.4). The assessment should include a summary of information explaining how a chemical will behave in the environment including discussion of dissolution, speciation, partitioning into different environmental compartments (air, water and soil) (Section 5.4), persistence and bioaccumulation (Section 4.4.2.2) and any other relevant matters.

To qualitatively assess environmental exposure, the partitioning of the chemical into different environmental compartments (air, water and soil) should be analysed. This behaviour is a direct consequence of physico-chemical properties. For instance, chemicals with a high log K_{oc} will partition to soil rather than remain in the water compartment whereas, highly water soluble chemicals with a low K_{ow} will preferentially remain in the water compartment. Chemicals that have a high Henry's law constant will partition to air.

The propensity of a chemical to undergo long-range transport in the environment is affected by its ability to partition to water or the atmosphere or adsorb to particles in water or atmosphere (Sections 5.3 and 5.4). Additionally, the biodegradability and half-life of the chemical is important. Chemicals that partition to water or to the atmosphere, and degrade very slowly or have long half-lives in the respective compartment may undergo long-range transport. Conversely, chemicals that degrade very quickly or have a short half-life are unlikely to disperse over long distances.

7.2.2 Environmental effects (including PBT analysis)

Environmental effects analysis identifies the harm (if any) a chemical might do in the environment. Acute and chronic ecotoxicity data are used to determine the toxic hazards posed by a chemical to terrestrial and aquatic organisms. Environmental effects analysis also considers whether a chemical is persistent, bioaccumulative and toxic (PBT). PBT chemicals are of significant environmental concern as they can cause long-term harm if released to the environment. Such chemicals may also travel over long distances crossing national boundaries. Additionally, many PBT chemicals tend to biomagnify in the food chain. This

problem is particularly serious for air-breathing organisms (including humans) because the rate of depuration in these organisms is usually much slower than in aquatic organisms.

To determine whether a chemical is classified as PBT, the persistence and bioaccumulation categorisations are combined with the following toxicity criteria (Table 7.5). If the chemical is classified as persistent, bioaccumulative, and toxic – that is, it meets criteria for all three – then it is a PBT chemical. The use of such chemicals for industrial processes, including coal seam gas extraction, would then be subject to strict regulation.

Table 7.1 Toxicity criteria for the categorisation of potential PBT chemicals (DoE 2016a, GHS (UN ECE 2015), and EPHC 2009a and 2009b).

Toxic (T)		
For PBT purposes, in respect of aquatic toxicity, a chemical may be considered toxic under the following circumstances (corresponding to criteria for GHS chronic category 1)		
Non-rapidly degradable substances for which there are adequate chronic toxicity data available	Chronic EC ₁₀ (for fish)	≤0.1 mg/L and / or
	Chronic NEC or EC ₁₀ (for crustacea)	≤0.1 mg/L and / or
	Chronic NEC or EC ₁₀ (for algae or other aquatic plants)	≤0.1 mg/L
Rapidly degradable substances for which there are adequate chronic toxicity data available	Chronic EC ₁₀ (for fish)	≤0.01 mg/L and / or
	Chronic NEC or EC ₁₀ (for crustacea)	≤0.01 mg/L and / or
	Chronic NEC or EC ₁₀ (for algae or other aquatic plants)	≤0.01 mg/L and / or
Substances for which adequate chronic toxicity data are not available (providing criteria for P and B are met)	96 h LC ₅₀ (for fish)	≤1 mg/L and / or
	48 h EC ₅₀ (for crustacea)	≤1 mg/L and / or
	72 or 96 h EC ₅₀ (for algae or other aquatic plants)	≤1 mg/L
	And the substance is not rapidly biodegradable and / or the experimentally determined BCF is ≥500 (or, if absent, the log K _{ow} is ≥4.2)	
Toxicity to other (terrestrial) animals	Should be considered on a case by case basis, compared with the highly toxic classifications developed for target chemicals in EPHC (2009a and 2009b)	
Long term toxicity or evidence such as endocrine disruption effects	Should be considered on a case by case basis	

Assessors might also consider physico-chemical properties when considering environmental effects. For example, if very large quantities of a chemical are released into a waterbody the short-term physico-chemical effects may pose a risk even if the chemical is not toxic and decomposes rapidly (for example, loss of oxygen in a water body if a chemical has a high BOD, or changes to the pH of a water body from an acid spill).

7.2.3 Environmental exposure

A measure or estimate of the quantity (or concentration), frequency, and duration of chemical exposure is included in the exposure component of a risk assessment. The exposure assessment requires careful analysis of the proposed use to identify potential release points and quantities. Examples of potential release points include leakage from storage dams,

equipment failure and handling accidents. The quantity of chemical that might be released will vary according to the expected use and the characteristics of the well site. Where possible, this information should be supplied by the mining proponent.

Quantities may be estimated by reference to prior experience or by reasoned argument. All potential routes of exposure are considered in exposure assessment. For example, the likelihood of exposure of environmental organisms to the chemical through exposure to contaminated soil, water, air and / or food is evaluated.

The following questions are considered in the exposure assessment:

- The potential source of the exposure (leaks, spills, etc.)
- where is the chemical likely to be found: water, soil, air, food?
- are the organisms at risk aquatic or terrestrial or both?
- how will they be exposed (through drinking, eating, breathing, dermal contact)?
- what is the estimated environmental concentration of the chemical in the event of an accidental release?
- how long will the exposure last?

7.2.4 Qualitative risk analysis

As discussed above, qualitative risk assessment involves analysing and integrating the scientific data that informs the hazard assessment with the exposure assessment. Reasoned scientific argument and expert judgement are required. The conclusion should address the following matters:

- the expected consequences of release of the chemical from coal seam gas operations
- potential problems associated with the use of the chemical for coal seam gas extraction
- the level of concern about potential environmental harm.

Consideration should be given to the acute and chronic toxicity of the chemicals, taking into account their environmental persistence, bioaccumulation and transport, combined with information about exposure pathways.

The aim is to determine if the substance in question may reach concentrations in the environment that will cause adverse effects. The approach taken depends on the particular properties, volume, and manner of use of the substance in question. Chemicals which are known to have low toxicity to aquatic or terrestrial organisms under a variety of conditions are generally considered to be of low concern, but consideration must be given to whether the substance will affect the environment by causing physico-chemical stress. For example, the chemical may alter the pH of a water body (e.g. sodium carbonate), or act as a nutrient for bacteria or algae (e.g. guar gum) and cause bacterial or algal blooms.

Exposure scenarios and exposure pathways must also be taken into account, together with the lifetime of the chemical. If a chemical is acutely toxic, but degrades rapidly in water, it may cause significant adverse effects if released directly into surface water as the result of a spill, but adverse effects will be localised due to its short half-life. Chronic toxicity of the substance is not relevant in this case.

Persistent chemicals are generally of higher concern, given the potential for organisms to be exposed for a longer period of time. Acute toxicity studies are not sufficient for persistent chemicals; chronic toxicity must be also taken into account due to the potential for long-term exposure. Many insoluble inorganic substances do not exhibit significant acute or chronic effects (e.g. sintered bauxite). For a persistent organic chemical, the potential to bioaccumulate (for example if the chemical has a log Kow > 4.2) increases the level of concern, and particular scrutiny should be given to whether the chemical exhibits chronic toxicity. A chemical that is persistent, bioaccumulative and toxic is of the highest concern.

Consideration should also be given to the partitioning behaviour of the substance in the environment. If a chemical is highly volatile and partitions primarily to air (e.g. nitrogen) then its toxicity to aquatic organisms is not relevant to the risk assessment.

The *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (DoEE 2017c; NICNAS 2017d), used three risk levels to describe the level of concern about a chemical and its potential for environmental harm:

- **chemicals of 'low concern'**. These chemicals are assessed to be unlikely to harm the environment if they are released from coal seam gas operations. Chemicals of low concern do not require specific risk management measures
- **chemicals of 'potential concern'**. These chemicals have the potential to harm the environment if they are released from coal seam gas operations. Specific risk management measures may be necessary to ensure that chemicals of potential concern do not harm the environment
- **chemicals of 'potentially high concern'**. These chemicals are likely to harm the environment if they are released from coal seam gas operations. Specific risk management measures are likely to be required to ensure that chemicals of potentially high concern do not harm the environment.

Detailed examples of qualitative risk assessments of chemicals are found in appendix D of this document and the appendices of the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (DoEE 2017d).

Examples of chemicals found to be of low concern after a qualitative risk assessment are summarised below:

- sodium carbonate. This chemical is considered to be of low concern. It has relatively low toxicity to environmental organisms but it does have the potential to substantially alter the pH of surface waters if released in large quantities. However, such changes are expected to be short lived.
- Gelatin. This chemical is considered to be of low concern. It could directly affect ecosystems and biota by adding excessive nutrients to water bodies resulting in oxygen depletion. However these effects are likely to be localised and short lived.
- Sintered bauxite. This substance is considered to be of low concern. At normal pH, this substance is highly insoluble and the toxicity to aquatic organisms is expected to be low. Bauxite is a naturally occurring, aluminium rich rock that is present in many terrestrial and aquatic environments.

An example of a group of chemicals found to be of potential concern:

- the group of boron compounds including borax. These chemicals are used in large quantities in CSG operations and exhibit some toxicity to plants. Boron chemicals that are released to the environment from CSG operations may cause localised toxic effects to terrestrial and aquatic plants.

7.3 Quantitative risk assessments

7.3.1 Using toxicity test data to calculate PNEC values

The endpoints from the ecotoxicity tests are used to calculate a Predicted No Effect Concentration (PNEC), which is the concentration of a chemical in an environmental compartment where no harmful effects to the particular organism are likely to occur. Quantitative environmental risk assessments use PNEC values and acute and / or chronic toxicity test endpoints such as:

- NOEC values
- EC₁₀ or LC₁₀ values (preferably chronic EC₁₀ or LC₁₀)

Where measured laboratory data are lacking, measured data from chemically similar compounds may be used (OECD 2007) or QSAR data, which provide estimates based on the chemical structure. When QSARs are used, the approach and its reliability should clearly be described in the assessment report (see Section 4.4.2 for further details). An example of QSAR approach in a coal seam gas context can be found in DoEE (2017b, 2017c, and 2017d).

PNECs can be calculated using different approaches using techniques such as (ANZECC and ARMCCANZ 2000a):

- species sensitivity distribution (SSD)
- assessment factor
- reference percentile.

Each of these techniques are further discussed below. Species sensitivity distribution (SSD) is the preferred approach (ANZECC and ARMCCANZ 2000a; Warne et al. 2014) as it can be applied within each of the different tier levels described in Section 2.2.3.

7.3.1.1 Deriving PNECs using species sensitivity distribution

If a large dataset for different taxonomic groups is available, statistical extrapolation methods such as SSD can be used to derive a PNEC. This is also the preferred approach for the derivation of PNECs. The principles are outlined in ANZECC and ARMCCANZ (2000a) and Warne et al (2014).

In general, ecotoxicity data are log-transformed and a prescribed percentile of a fitted distribution function is used as a criterion. Distribution functions proposed include a Burr Type III function, a log-logistic function, and a log-normal function. This usually results in calculation of the protective concentration (PC95) which is the estimated concentration of a chemical that protects 95% of species. Confidence intervals can be calculated. The data should be assessed on a case-by-case basis. Sensitive endpoints, sensitive species, and mode of toxic action, and / or knowledge from structure activity should be considered in the risk assessment (ANZECC and ARMCCANZ 2000a; Warne 2001; Warne et al. 2014). An advantage of SSD methods is that they use all the available data, and the whole sensitivity

distribution of the group of species representative of an ecosystem to derive a PNEC instead of taking the lowest long-term NOEC. Such methods make several assumptions (such as that the sensitivities of the test species reflect the distribution of sensitivities of the ecosystem of interest) which are further detailed in ANZECC and ARMCANZ (2000a), EPHC (2009a) and Warne et al. (2014). There are minimum requirements for the number of data points for the SSD approach (Warne et al. 2014).

7.3.1.2 Deriving PNECs using assessment factors (when ecotoxicity data are limited)

When ecotoxicity data are limited, derivation of a PNEC commonly relies on applying assessment or safety factors to the lowest (most sensitive) toxicity value, usually associated with the most sensitive species. A PNEC can be estimated from an effect concentration by dividing it by an appropriate assessment factor. Under the ANZECC and ARMCANZ (2000a) framework the most sensitive endpoint of the available ecotoxicity data should be used for this calculation. Generally, the more reliable the set of ecotoxicity data, the smaller the assessment factor applied.

Assessment factors reflect uncertainties such as:

- intra- and inter-specific variation
- the extrapolation of short- to long-term toxicity
- the extrapolation of laboratory results to the field.

Assessment factors used in Australia for estimating PNEC in industrial chemicals assessments are listed in Table 7.2 and are based on the principles in OECD (1995a, 2015c) and ANZECC and ARMCANZ (2000a), as described by EPHC (2009a, 2009b). DoEE (2017a) also discusses the calculation of PNECs using assessment factors for chemicals associated with coal seam gas extraction risk assessment scenarios. Ranges of assessment factors appropriate for various datasets are given in Table 7.2; further guidance on the specific choice of assessment factor is provided below.

Table 7.2 Summary of proposed assessment factors for estimating a PNEC in aquatic ecosystems (ANZECC and ARMCANZ 2000a and EPHC 2009b)

Case	Data available	Range of assessment factor	Description
a	EC ₅₀ algae (72 h) EC ₅₀ <i>Daphnia</i> (24–48 h acute test) LC ₅₀ fish (96 h)	100–1 000	When only acute toxicity data are available, an assessment factor of between 100 and 1000 is applied to the lowest EC or LC ₅₀
B	NOEC <i>Daphnia</i> (14–21d chronic toxicity test) NOEC algae (72 h) NOEC fish (chronic toxicity test)	10–100	When chronic toxicity data are available in addition to acute data, often an assessment factor of between 10 and 100 is applied to the lowest NOEC

These assessment factors are applied to derive the PNEC, according to the equation:

$$PNEC = \frac{\text{quantitative estimate of effect}}{\text{assessment factor}} \quad [\text{Equation 9}]$$

Where:

PNEC = Predicted No Effect Concentration

For chemicals with multiple ecotoxicity data (e.g. on multiple aquatic species), the lowest (most sensitive) ecotoxicity estimate of effect is generally used in the PNEC calculation, with the application of the assessment factor as in the equation above. This approach ensures that risks are considered for the most sensitive organism (NICNAS 2017d).

Particular care should be taken when applying assessment factors to:

- acute data for chemicals which are suspected of having a specific mode of action, such as high log K_{ow} chemicals known to significantly bioaccumulate / biomagnify
- data on chemicals of limited solubility and no observed toxicity, such as some inorganic salts or insoluble chemicals such as polystyrene or silicon.

These assessment factors may not be protective of endocrine-disrupting effects as suggested by OECD (2002a) and Cadwell et al. (2008). In addition, these assessment factors may not provide sufficient protection for chemicals present in mixtures where there may be additive, antagonistic, or synergistic toxicity effects. Mixture toxicity as well as potential for endocrine-disrupting effects should be considered in the hazard assessment as they have been shown to be relevant for the coal seam gas industry (Kassotis et al. 2014; 2015). As detailed in Section 4.4.2, direct toxicity assessment may be useful for determining mixture toxicity (van Dam and Chapman 2001).

Example scenarios for adjusting assessment factors based on the principles in OECD (1995b; 2015b) and ANZECC and ARMCANZ (2000a), as described by EPHC (2009a and 2009b) are shown below: For example, when only acute toxicity data are available, an assessment factor of between 100 and 1000 is applied to the lowest L(E)C₅₀ (case 'a' in Table 7.7). For acute toxicity data:

- an assessment factor of 1 000 is typically applied to the lowest acute L(E)C₅₀ when only limited acute data (e.g. one or two species) are available
- an assessment factor of 100 is applied when acute toxicity data covering the OECD (1995a) minimum pre-marketing dataset are available
- an assessment factor of 2 or 20 may be applied for essential elements with comprehensive datasets of chronic or acute data respectively (ANZECC and ARMCANZ 2000a) - if sufficiently comprehensive datasets are available, the SSD method should be used (for all chemicals, not just for essential elements)
- Evidence required to adjust the assessment factors would include (based on EPHC 2009a and 2009b):
 - availability of data from a wide variety of species including those which are considered to represent sensitive species (if so, use the SSD approach, provided data requirements are met)
 - information from structurally similar compounds or QSAR, to suggest that the acute to chronic ratio is likely to be low
 - information suggesting that: the chemical acts in a non-specific or narcotic manner, with little inter-specific variation in toxicity; the release of the chemical is short-term or intermittent; and the chemical would not persist in the environment.

When chronic toxicity data are available in addition to acute data, an assessment factor of between 10 and 100 is typically applied to the lowest NOEC or EC₁₀/EC₅ (case b in Table 7.7). The following aspects should be taken into account (ANZECC and ARMCANZ 2000a; OECD 2002c; EPHC 2009a; b):

- the lowest assessment factor of 10 could be applied to an adequate set of chronic data but, if there are sufficient data available, the SSD method should be used
- if the chemical does not have a narcotic mode of action and at least three chronic NOEC or EC10/EC5 data are available - an application factor of 20 is applied to the lowest of the chronic values
- if chronic data are available from only one or two species representing one or two trophic levels (i.e. fish, Daphnia or algae), a factor of 100 (one species) or 50 (two species) is applied to the lowest NOEC. In this case, a PNEC value derived from chronic data should be compared to that derived from the lowest acute data. It is then the lowest value that is used in the assessment
- if there are not sufficient data to satisfy the OECD Minimum Premarketing Dataset (MPD) requirements, a factor of 1 000 should be applied to the lowest acute L(E)C₅₀.

7.3.1.3 Deriving the PNEC using reference site percentiles

Predicted no effect concentrations may be derived using water quality or sediment data from reference sites in monitoring programs. The PNECs can be derived using probabilistic endpoints, such as 80th percentiles for sediment and / or water quality parameters from reference site measurements. Determining those values should follow the principles outlined in Section 8.3.5.5 of ANZECC and ARMCANZ (2000b).

The outputs of these activities can range from toxicity classifications or calculation of PNEC values with different degrees of uncertainty and confidence.

7.3.2 Risk characterisation

Characterisation of environmental risks should combine knowledge of the level of exposure with the knowledge of the concentrations that cause harmful effects. The risk of chemicals from coal seam gas operations to the receiving environment can be assessed by comparing PECs (from the exposure assessment) with the PNECs (from the hazard assessment) to derive a risk quotient (RQ) (this can also be known as hazard quotient).

The RQ calculation is:

$$RQ = \frac{\text{exposure}}{\text{toxicity}} = \frac{PEC}{PNEC} \quad \text{[Equation 4]}$$

Where:

RQ = the Risk Quotient

PEC = the Predicted Environmental Concentration [mg/L] (see Section 5.8), and

PNEC = the Predicted No Effect Concentration [mg/L] (see Section 7.3).

If the $RQ < 1$, the risk to the compartment under consideration is deemed acceptable and there is no need for further refinement of the PEC or PNEC. No risk / hazard reduction measures are required. There should be no need for further management controls on the chemical additional to those already in place.

Where the RQ approaches 1, the margins of safety are reduced and increases in volumes of use may result in a PEC / PNEC exceeding 1. Therefore, likely volumes and uses of the chemical should be considered. Also, assessors should carefully consider notification requirements (refer to the NICNAS Act and the Notifier's handbook (NICNAS 2013)).

If $RQ > 1$, the risk to the compartment requires further investigation. For existing industrial chemicals (i.e. already approved for use in Australia) two conclusions may be drawn from this outcome. The assessor should judge whether further information (including test data) would help to classify the risk (e.g. in the event the ratio was not significantly greater than 1), or if risk management measures are needed. Additional considerations include (modified from European Communities (EU 2003)):

- factors that affect chemical speciation, bioavailability and bioaccumulation potential
- the shape of the toxicity / time curve in ecotoxicity testing
- other adverse effects such as endocrine disruption
- data on structurally analogous chemicals
- toxicity of chemicals (or chemical mixtures) and site-specific factors.

Where the risk quotient is sufficiently high i.e. $RQ > 10$, the chemical is considered to be of concern, and further testing and / or stricter risk management options may be recommended prior to approving the use of the chemical.

Examples of the application of the RQ approach undertaken for chemicals associated with coal seam gas extraction are provided in (DoEE 2017c).

For higher tier assessments, the percentage of species at risk or probability distributions of extent of environmental detriment may be estimated instead of RQ. These approaches provide more detailed and nuanced information on the range of potential environmental consequences than the binary acceptable / not acceptable RQ approach.

7.3.3 Analytical processes and models for higher tiered assessments

Risk analysis can benefit greatly from expert systems and computational tools, particularly at higher tiers of assessment, where the data needs and the depiction of interactions and interdependencies between variables becomes more complex.

Most quantitative risk analyses make use of databases and statistical software. The computational effort required for more complex, higher tier analyses can become onerous, and particularly for probabilistic assessments, the analysis of multiple layers of conditional probabilities may be needed.

Statistical procedures used in quantitative risk assessments can include Monte Carlo methods⁵⁹ and Bayesian Belief networks⁶⁰. Monte Carlo methods use simulation models and repeated random sampling to build models of uncertain parameters and solve numerical problems. Bayesian Belief networks often use graphical descriptions of inter-dependencies between different factors and may incorporate qualitative information (Pollino and Hart 2005 and 2008).

There are also other less commonly used tools for simplifying probabilistic risk assessment at lower tiers. For example, Twining et al. (1999) described a tool, called AQUARISK,

⁵⁹ Monte Carlo methods (or Monte Carlo experiments) are a broad class of computational algorithms that rely on repeated random sampling to obtain numerical results. A Monte Carlo analysis is a computational methodology to estimate the most probable outcome from a simulation model with uncertain inputs by generating multiple simulation runs from sampling input parameters from known probability distributions.

⁶⁰ These Bayesian networks tools are increasingly popular for probabilistic risk assessment, partly because of the development of simple graphical user interfaces, but also due to the computational efficiency of the Bayesian approach. However, Monte Carlo approaches based on classical statistical approaches have been in use for a longer period and remain in use today, with these approaches having first been used for quantitative, probabilistic environmental risk assessments in the 1980s.

developed by the Australian Nuclear Science and Technology Organisation to assess the environmental risks of metals in sediments in Sydney Harbour. The tool can perform simple Tier 1 and 2 risk assessments for metals based on the ANZECC and ARMCANZ (2000a) ecotoxicity databases and probabilistic consideration of water quality variability over time.

The guidance manual does not endorse the use of any particular software tool, but notes that the use of such tools can greatly simplify computational tasks.

7.3.4 Risk description

During risk description, the results of the risk estimation are used to interpret the risk posed to ecological entities. The risk description should indicate the overall degree of confidence in the risk estimates, summarising uncertainties, citing evidence supporting the risk estimates, and interpreting the adversity of ecological effects.

7.4 Checklist

Table 7.3 Checklist for qualitative environmental risk characterisation – including hazard assessment and risk characterisation

Qualitative environmental risk characterisation		✓
Hazard assessment		
1	Evaluate relevant chemical and ecotoxicity data available (including appropriate test endpoints, appropriate species (aquatic and terrestrial), potential for bioaccumulation and endocrine disruption) (Sections 4.4.2 and 4.4.3)	
2	Collect or undertake tests for additional chemical and ecotoxicity data if the evaluation of the available data indicates that it is required	
3	Categorise by toxicity classification or if data available calculate the predicted no effect concentration (PNEC) using suitable methods based on the available data	
Risk Characterisation		
4	Compare exposure concentrations to relevant environmental and ecosystem-based guidelines (where appropriate) (Section 7.3.2)	
6	Undertake qualitative risk assessment if there are insufficient data for quantitative assessment (Section 7.2)	
5	Characterise risk to determine potential risk to the environment using the outcomes from the previous exposure assessment and hazard assessment	
7	Further investigate / refine PECs and PNECs using the tiered approach when risk outcomes and / or risk quotients exceed risk limits	
8	Delineate and report data uncertainties	
9	Consider likelihood and mitigation measures as part of risk characterisation	

Table 7.4 Checklist for quantitative environmental risk characterisation – including hazard assessment and risk characterisation

Quantitative environmental risk characterisation		✓
Hazard assessment		
1	Evaluate relevant chemical and ecotoxicity data available (including appropriate test endpoints, appropriate species (aquatic and terrestrial), potential for bioaccumulation and endocrine disruption) (Sections 4.4.2 and 4.4.3)	

Quantitative environmental risk characterisation		✓
2	Collect or undertake tests for additional chemical and ecotoxicity data if the evaluation of the available data indicates that it is required	
3	Categorise by toxicity classification or if data available calculate the predicted no effect concentration (PNEC) using suitable methods based on the available data	
Risk Characterisation		
4	Compare exposure concentrations to relevant environmental and ecosystem-based guidelines (where appropriate) (Section 7.3.2)	
5	Characterise risk to determine potential risk to the environment using the outcomes from the previous exposure assessment and hazard assessment	
6	Undertake qualitative risk assessment if there are insufficient data for quantitative assessment (Section 7.2)	
7	Further investigate / refine PECs and PNECs using the tiered approach when risk outcomes and / or risk quotients exceed risk limits	
8	Delineate and report data uncertainties	
9	Consider likelihood and mitigation measures as part of risk characterisation	

8 Risk communication and management

Risk communication and management are important components established in AS/NZS ISO 31000: 2009 – *Risk Management Principles and Guidelines*⁶¹. Other hazardous substance regulations and guidance documents can also aid in the design and implementation of a tailored risk management approach. The following sections consider risk communication and management for chemicals associated with coal seam gas extraction.

The communication of risk is critical throughout the risk assessment process and in the development of management and mitigation measures. Monitoring and review of the risk management strategy are also critical to ensure identification of emerging risks and adaptive management. Further, the risk assessment may require revision, based on new information, including monitoring and reporting data.

8.1 Risk communication

Clear articulation of the reasons for the conclusions of a risk assessment allows risk managers, policy-makers and other stakeholders to understand and make informed decisions based on the risk assessment.

Open and transparent communication at all stages of the risk assessment supports actions in accordance with the risk. Perceptions of risk are strong drivers of stakeholder behaviour (enHealth 2012a). Effective internal and external communication ensures that those accountable for managing risk and other stakeholders understand the basis for decisions and actions.

A risk communications plan involves (adapted from AS/NZS 2009):

- establishing the context – this considers the context of the risk assessment, including management goals, capabilities, roles and accountabilities, political, legal and regulatory context, perceptions and values. It is also important to establish and communicate the specific context of the risk assessment and where it fits in an overall development or plan
- ensuring risks are adequately identified and described– seeking input from a variety of disciplines, expert and lay knowledge to ensuring different views are appropriately considered when defining risk criteria and evaluating risks. This can greatly assist in understanding and managing perceptions of risk perception among a broader community or external stakeholders (enHealth 2012a)
- engaging stakeholders – ensuring stakeholders are adequately consulted throughout the risk assessment process is important to ensure ‘buy in’ to a risk assessment from all stakeholders.

Peer review is also important to allow for independent evaluation of the judgements, scientific reasoning and conclusions of the risk assessment.

⁶¹ AS/NZS ISO 31000: 2009 can be accessed by purchasing via:
<https://www.iso.org/standard/43170.html>.

The reporting of identified risks and risk assessment results is an essential component of risk communication and may be required by regulation. If diverse stakeholders are to have confidence in the results and conclusions drawn from risk assessments, key information needs to be provided in a transparent and traceable manner that recognises that different stakeholders will have different needs, expectations, and concerns. One way to achieve this is to publish the risk assessment report and the accompanying risk sheets (see Appendix E). Risk assessment reports and their associated risk sheets should be written in a transparent manner that enables readers to gain a clear picture of what has been done, what the results are, and why the results are as they are. Traceability is an unambiguous and complete record of the decisions and assumptions made, and of the models and data used in arriving at a given set of results.

8.2 Communicating uncertainty, variation, and sensitivity

8.2.1 Uncertainty and variation

Uncertainty in chemical risk assessment is caused by lack of knowledge about the ‘correct’ value, such as a specific exposure measure or estimate (NEPM 2013; enHealth 2012a). Additional measurements can assist in reducing uncertainty.

Variability refers to differences in attributes due to diversity or heterogeneity – like how tall people are, or how much they weigh, or the mix of organisms that might be present at a site. It doesn’t matter how many times such attributes are measured, it will always yield a snapshot of the mix of possible results. Variability cannot be reduced by further measurement or study, although it can be more accurately characterised (NEPM 2013; enHealth 2012a; NRC 2008).

There are three broad types of uncertainty (NEPM 2013; US EPA 1992) (see Section 4.5.3):

- *Scenario uncertainty* is uncertainty arising from missing or incomplete information such as descriptive errors, aggregation errors, errors in professional judgement, and incomplete analysis
- *Parameter uncertainty* is uncertainty affecting a particular parameter such as measurement errors, sampling errors, variability, and use of generic or surrogate data
- *Model uncertainty* is uncertainties in scientific theory affecting the ability of a model to make predictions.

It is important to document uncertainty and variability in a risk assessment and to explain what impact it may have on results. For example, when a risk is estimated to be very low, even if there is moderate uncertainty in the results, it probably won’t change the conclusion (that is, that a chemical is of low concern). The same applies when the risk is estimated to be very high – the results are unlikely to change from being a chemical of concern to, for example, low concern. However, there is a possibility that less conservative (higher tier) assessments may render a chemical which was assessed initially of concern to be not a concern. Uncertainty, variability, and sensitivity are critical when in the middle zone – where something may or may not be a risk. For example, small changes in some of the parameters can then make a big difference to the conclusions.

A clear qualitative analysis is sufficient in most cases to communicate the levels of uncertainty associated with an assessment (NEPM 2013). The NRC (2008) provided a detailed evaluation of the techniques provided in US EPA guidance and concluded that although a number of usable methodologies were available, it is unclear what level of detail was required to capture and communicate key uncertainties (NEPM 2013). Furthermore, quantitative methods suffer from the difficulty in sensibly quantifying all uncertainties; and

that the apparent precision of quantitative analysis for some uncertainties may distract attention from other, possibly equally important but unquantifiable, uncertainties (NEPM 2013).

Further discussion and guidance on uncertainty is provided in NEPM (2013) and enHealth (2012a). NRC (2008) and WHO (IPCS 2008 and 2014) provide the following additional guidance on the principles for uncertainty analysis, which have been adapted for contaminated land risk assessment (NEPM 2013) and are equally relevant to coal seam gas extraction activities:

- chemical risk assessments should provide qualitative (as a minimum) or quantitative description of uncertainty and variability consistent with available data. The information required to conduct detailed uncertainty analysis may not be available in all situations
- the uncertainty analysis should seek to communicate which uncertainties are most important to the conclusions of the risk assessment
- the level of detail of the uncertainty analysis should be commensurate with the scope of the risk assessment (and the estimated level of risk)
- uncertainty analysis should be expressed in terms that can be understood by the risk owner, the risk manager, and other stakeholders
- sensitive populations should be considered to the extent that they are not covered by the selected toxicity criteria (generally they will be)
- uncertainty and variability should be kept conceptually separate

Consistent with the guidance in NEPM (2013) and enHealth (2012a), an analysis of uncertainty might include the following important information:

- the relevant section in the risk assessment report that the uncertainty analysis applies to (ie, problem formulation, hazard identification, conceptual modelling)
- a description of the uncertainty
- the relative magnitude of the uncertainty (eg, very low, low, medium, high, very high); and
- the relative effects the uncertainty has on the risk characterisation (eg, a low, medium, or high potential to under-estimate or over-estimate risks).

8.2.2 *Sensitivity analysis*

Sensitivity analysis provides a quantitative estimate of the effect of uncertainty and / or variability in the input parameters on the results of the risk assessment. Sensitivity analysis can be used to identify which parts of the risk assessment results are least sensitive to variation in input parameters, and / or which parts are most sensitive to varied inputs (NEPM 2013). Sensitivity analysis is the process of changing one variable within a defined range while leaving the others constant and determining the effect on the output. The procedure involves fixing each uncertain quantity, one at a time, at its credible lower-bound and then its upper bound (holding all other at their medians), and then computing the outcomes for each combination of values (US EPA 1992). It can be used to test the effects of both uncertainty and variability in input values, as was done in the *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* (see, for example, Mallants et al. 2017b and NICNAS 2017d).

Sensitivity analyses can be used to identify important input variables (or groups of variables), or to develop bounds on the distribution of exposure or risk (NEPM 2013). A sensitivity

analysis can also estimate the range of exposures or risk that result from combinations of minimum and maximum values for some parameters and mid-range values for others (US EPA 1989). Effort may then be directed to the collection of additional data for these important variables; as additional data is collected, the uncertainty in the 'true' value is reduced, and it may be possible to define a smaller range for a given parameter. The uncertainty in the results of the risk assessment may therefore be reduced.

Clear documentation of uncertainty is critical to communication of the reliability and confidence in the risk assessment. For further details on uncertainty management see Section 4.7.3. Risk assessment and reporting benefits those undertaking the assessment, external stakeholders and regulatory agencies. This practice provides publicly accessible evidence of a systematic approach to risk management by:

- demonstrating that the assessment was conducted properly
- providing a record of risks about which an organisation has knowledge
- reducing duplication of assessment effort
- improving accountability
- facilitating monitoring and review
- providing a platform for the sharing and communication of information.

The above points contribute to accountability and transparency of coal seam gas operations and the management of associated risks. Publishing risk assessment reports and their associated risk sheets (Appendix E) can also help guide future research and monitoring efforts as knowledge gaps are identified.

8.3 Implementing mitigating measures and managing risk

Risk assessments are designed to estimate the extent of risk and inform the management of risk. Where risks are estimated to be above acceptable levels, mitigation measures must be considered. Mitigation measures are usually based on changing the potential for exposure, the intensity of the exposure, or its frequency and duration⁶². In most situations, it is not possible to change the effects of a chemical at a particular concentration (occasionally changing the pH or other environmental conditions may change toxicity). The process of risk assessment allows an understanding of what exposure pathways are most relevant in order to better target mitigation measures (and to avoid any unnecessary mitigation).

Where there are no acceptable mitigation measures to achieve an acceptable level of chemical risk, the need to use the relevant chemical, or suite of chemicals, must be reassessed.

The framework for implementing risk management should include (from AS/NZS, 2009):

- defining the appropriate timing and strategy for implementation
- applying the framework for environmental and / or human health risk assessment to the chemicals being assessed

⁶² Chemical risk control measures generally are designed to control or limit exposure and fall into a hierarchy consisting of: elimination, substitution, isolation, engineering controls, and administrative controls (DoE 2016; SWA 2012).

- complying with legal and regulatory requirements
- ensuring decision-making, including the development and setting of objectives, is aligned with outcomes from the risk assessment
- holding information and training sessions
- communicating and consulting with stakeholders to ensure that the risk management framework remains appropriate
- providing additional guidance about ongoing monitoring to improve data availability.

8.4 Compliance and risk management

Compliance methods will be specific to each risk assessment, but the overarching framework is based on AS/NZS (2009).

Regulatory and internal corporate compliance should be a planned part of risk management and involve monitoring or surveillance on a regular periodic or as needed basis, in response to events and incidents. Internal compliance processes should encompass all aspects of the risk management process for the purposes of:

- ensuring that controls / management options are effective and efficient in both design and operation (including proposed new technologies and chemicals)
- obtaining further information to improve risk assessment
- analysing and learning lessons from events (such as, compliance reports, incidents, near-misses), changes, trends, successes and failures
- detecting changes, including changes in the acceptability of risk to stakeholders, to risk criteria, and the risk itself (for example, the chemical formulation or level of exposure) which can require revision of risk controls and priorities
- identifying emerging risks.

It is important to implement regular performance monitoring as part of risk management. This includes monitoring of the identified risks, the effectiveness of the risk controls, and the appropriateness of the management system set up to control implementation. This ensures that performance shortfalls are identified promptly. It also allows for identification and assessment of new risks and changing risk profiles. Monitoring can also provide a more robust dataset to refine models and risk assessments and better target risk management effort, increasing confidence in risk assessment and management.

Risk management is an iterative process. With each iteration, risk assessment can be strengthened to achieve progressively better risk management.

8.5 Documentation

A risk assessment report should be prepared for each assessment which covers all aspects of the risk assessment process. Risk dossiers, as outlined in Appendix E, should be developed for each chemical.

8.6 Checklist

Table 8.1 Checklist for risk communication and management

Risk Management and Communication		
1	Define the risk management strategy and implementation	
2	Communicate and consult with stakeholders to ensure the risk management framework is appropriate	
3	Document the uncertainty, variability and the results of the sensitivity analysis; and describe their effects on the results of the assessment	
4	Apply the risk assessment framework for the chemicals being assessed, complying with relevant legal and regulatory requirements	
5	Undertake monitoring and review of risk management strategy and framework on an appropriate basis to ensure identification of emerging risks and continual improvement	
6	Communicate and discuss results with risk owners and managers, and if required, with regulators	

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Appendix A: Example list of coal seam gas water quality parameters

An example list of standardised water quality monitoring parameters that can be used for water and fluid samples collected from coal seam gas related monitoring sites is provided below. The analytical suite of parameters (referred to as analytes) are designed for sampling, analysis, and reporting of formation water, drilling and fracturing fluids, flowback water, produced water, reverse osmosis (RO) permeate and brines, and / or coal seam gas water prior to and after groundwater reinjection.

The analytes listed below are examples only. They are intended to be sampled in water from sources such as:

- drilling muds and hydraulic fracturing fluids
- wellheads and separators, including exploration, appraisal, pilot, production, and monitoring wells
- ponds and storages, such as drilling and flowback ponds, produced water ponds, gathering ponds, buffering or overflow ponds, and treated water storages and tanks
- pipelines and gathering lines, including low point drains.

The analytes listed in this example are designed to provide a standardised suit of analytical parameters that are capable of more fully characterising coal seam gas waters and fluids, be used to detect any potential contamination, and inform water quality monitoring programmes. Sampling should be undertaken in accordance with a carefully designed water quality monitoring programme. Further guidance on water quality monitoring is available in the *Australian Guidelines for Water Quality Monitoring and Reporting 2000* (ANZECC and ARMCANZ 2000b).

Listed parameters are based on monitoring parameters outlined in:

- Appendix 3 of the QGC CSG Fraccing Fluid Ecotoxicity Work Plan 2013 (Hydrobiology 2013)
- Section 3.4.5 of AGL's *Waukivory Pilot Project Surface Water and Groundwater Monitoring Report to 30 September 2015* (Parsons Brinckerhoff 2015).

The indicative list provided here is a guide to the types and range of data needed to assist in the assessment of coal seam gas extraction activities. The list should not be seen as prescriptive and may require tailoring to specific project requirements and the chemical and water quality issues under consideration. Importantly, the analytes being monitored should be sufficient to detect and measure any changes in groundwater quality over time and space and, importantly, should include both anthropogenic drilling and hydraulic fracturing chemicals (including their breakdown products and derivatives) as well as geogenic chemicals.

Table 1: Physico-chemical Parameters

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Dissolved oxygen (DO)	% saturation and mg/L	0.01	Can be measured in situ
Electrical Conductivity (EC)	µS/cm	1	Can be measured in situ
Total Dissolved Solids (TDS)	mg/L	1	
Total Suspended Solids (TSS)	mg/L	1	
Free and total residual chlorine	mg/L	0.1	Can be measured in situ
Oxidation-reduction potential (redox potential - ORP)	mV		Can be measured in situ
pH	pH Units	0.1	Can be measured in situ
Sodium Adsorption Ratio	Ratio	1	No units of measure
Temperature	°C	0.1	Can be measured in situ
Turbidity	NTU	1	Can be measured in situ

Table 2: Nutrients

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Nitrate	% saturation and mg/L	0.01	Can be measured in situ
Nitrite			
Total Nitrogen			
Total Kjeldahl Nitrogen			
Ammonia			
Reactive Phosphorous			
Total Phosphorous			

Table 3: Anions

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Sulfate (SO ₄ ²⁻)	mg/L	1	
Chloride (Cl ⁻)	mg/L	1	
Carbonate (CO ₃ ²⁻)	mg/L	1	

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Bicarbonate (HCO_3^-)	mg/L	1	
Carbonate Alkalinity	mg/L	1	As CaCO_3 equivalent
Bicarbonate Alkalinity	mg/L	1	As CaCO_3 equivalent
Hydroxide Alkalinity	mg/L	1	As CaCO_3 equivalent
Total Alkalinity	mg/L	1	As CaCO_3 equivalent
Nitrite (NO_2^-)	mg/L	0.001	
Nitrate (NO_3^-)	mg/L	0.001	
Fluoride (F^-)	mg/L	0.1	
Bromide (Br^-)	mg/L	1	
Total Cyanide	mg/L	0.004	

Table 4: Major Cations

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Sodium (Na^+)	mg/L	0.05	
Magnesium (Mg^{2+})	mg/L	0.05	
Potassium (K^+)	mg/L	0.05	
Calcium (Ca^{2+})	mg/L	0.05	

Table 5: Metals and metalloids (total and dissolved)

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Aluminium	mg/L	0.001	
Antimony	mg/L		
Arsenic	mg/L	0.001	Potentially also consider As (III) and As (V)
Barium	mg/L	0.001	
Beryllium	mg/L	0.001	
Boron	mg/L	0.001	
Cadmium	mg/L	0.0001	
Chromium	mg/L	0.001	Potentially also consider Cr (III) and Cr (VI)
Cobalt	mg/L	0.001	
Copper	mg/L	0.001	
Iron	mg/L	0.001	
Lead	mg/L	0.001	
Manganese	mg/L	0.001	

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Mercury	mg/L	0.0001	
Molybdenum	mg/L	0.001	
Nickel	mg/L	0.001	
Selenium	mg/L	0.001	
Silica	mg/L	0.001	
Silver	mg/L	0.001	
Strontium	mg/L	0.001	
Thorium	mg/L	0.001	
Tin	mg/L	0.001	
Uranium	mg/L	0.001	
Vanadium	mg/L	0.001	
Zinc	mg/L	0.001	
Other radionuclides and gross alpha, beta, and gamma radiation	Bq/L		

Table 6: Benzene, Toluene, Ethylbenzene, Xylenes (BTEX)

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Benzene	mg/L	0.001	
Toluene	mg/L	0.001	
Ethylbenzene	mg/L	0.001	
m and p Xylene	mg/L	0.001	
o Xylene	mg/L	0.001	
Total Xylenes	mg/L	0.002	

Table 7: Total Recoverable Petroleum Hydrocarbons (TPH) – ASC NEPM (2013) fractions

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
TPH C ₆ – C ₁₀	mg/L	0.02	
TPH C ₆ – C ₁₀ less BTEX	mg/L	0.02	
TPH >C ₁₀ – C ₁₆	mg/L	0.02	
TPH >C ₁₀ – C ₁₆ less Naphthalene	mg/L	0.02	
TPH >C ₁₆ – C ₃₄	mg/L	0.05	
TPH >C ₃₄ – C ₄₀	mg/L	0.05	
Total TPH C ₆ – C ₄₀	mg/L	0.05	

Table 8: Polycyclic Aromatic Hydrocarbons (PAH)

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
3-Methylcholanthrene	mg/L	0.001	
7,12-Dimethylbenz(a)anthracene	mg/L	0.001	
Acenaphthene	mg/L	0.001	
Acenaphthylene	mg/L	0.001	
Anthracene	mg/L	0.001	
Benzo (a) pyrene	mg/L	0.001	
Benzo (b) fluoranthene	mg/L	0.001	
Benzo (ghi) perylene	mg/L	0.001	
Benzo (k) fluoranthene	mg/L	0.001	
Benzo(a)anthracene	mg/L	0.001	
Chrysene	mg/L	0.001	
Dibenz (ah) anthracene	mg/L	0.001	
Fluoranthene	mg/L	0.001	
Fluorene	mg/L	0.001	
Indeno (1,2,3-cd) pyrene	mg/L	0.001	
Naphthalene	mg/L	0.001	
Phenanthrene	mg/L	0.001	
Pyrene	mg/L	0.001	
Carcinogenic PAHs (benzo[a]pyrene equivalents)			See ASC NEPM (2013) for potency factors
Total PAH	mg/L	0.001	

Table 9: Phenols

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
2,3,4,6-Tetrachlorophenol	mg/L	0.001	
2,4,5-Trichlorophenol	mg/L	0.001	
2,4,6-Trichlorophenol	mg/L	0.001	
2,4-Dichlorophenol	mg/L	0.001	
2,4-Dimethylphenol	mg/L	0.001	
2,4-Dinitrophenol	mg/L	0.001	
2,6-Dichlorophenol	mg/L	0.001	

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
2-Chlorophenol	mg/L	0.001	
2-Methyl-4,6-dinitrophenol	mg/L	0.001	
2-Nitrophenol	mg/L	0.001	
4-Chloro-3-methylphenol	mg/L	0.001	
4-Nitrophenol	mg/L	0.001	
Dinoseb	mg/L	0.001	
Hexachlorophene	mg/L	0.001	
m- and p-Cresol	mg/L	0.001	
o-Cresol	mg/L	0.001	
Pentachlorophenol	mg/L	0.001	
Phenol	mg/L	0.001	

Table 10: Organic Carbon

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Dissolved Organic Carbon (DOC)	mg/L	1	
Total Organic Carbon (TOC)	mg/L	1	

Table 11: Dissolved Gasses

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Dissolved Oxygen (DO)	% saturation and mg/L	0.01	
Carbon Dioxide	mg/L	5	
Methane	mg/L	0.01	
Un-ionised hydrogen sulfide	mg/L		

Table 12: Other Analytes

Parameter	Reporting Units	Limit Of Reporting (<LOR)	Notes
Bromide	mg/L	0.01	
Chlorine/Chloride	mg/L	0.01	
Monoethanolamine (MEA) borate, as ethanolamine	mg/L	0.01	

Tetrakis (hydroxymethyl) phosphonium sulfate (THPS)	mg/L		
Formaldehyde	mg/L		
Total residual chlorine	ppm		

Table 13: Environmental Isotopes

Parameter	Analysis	Notes
Tritium (^3H)	Tritium analyses	Provides information about younger groundwater ages and mixing; can be used to confirm the presence or absence of younger groundwater
Chlorine-36 and Chlorine-37 (^{36}Cl and ^{37}Cl)	Chlorine analyses	Provides information about older groundwater ages and mixing
Helium-4 (^4He)	Helium-4 analyses	Provides information about vertical groundwater flow through aquifers and aquitards (K_v) over time, formation-scale porosity, groundwater flow rates, and paleoclimatic conditions
Oxygen-18 (^{18}O)	Oxygen-18 and Deuterium analyses	Provides information about the origin of natural waters and processes that have affected groundwater since it entered the groundwater system
Deuterium (^2H)		
Strontium-87 (^{87}Sr)	Strontium-87 and Strontium-86 analyses	Provides information on water-rock interactions and the provenance of aquifer rock formations;
Strontium-86 (^{86}Sr)		
Carbon-13 ($^{13}\text{C}_{\text{DIC}}$)	Carbon-13 and methane isotope analyses	Provides information about groundwater age
Radiocarbon (^{14}C)	Radiocarbon aging analysis	Provides information about groundwater age
Methane ($^{13}\text{C}-\text{CH}_4$)	Carbon-13 and methane isotope analyses	Provides information about thermogenic or biogenic origins of dissolved methane in groundwater
Methane ($^2\text{H}-\text{CH}_4$)		
Boron-11 (^{11}B) Sulfur-32 and Sulfur-34 (^{32}S , ^{34}S) Lithium-7 (^7Li) Radon-222 (^{222}Rn), CFCs (CFC-11, CFC-12), Sulfur hexachloride (SF-6) Noble gasses: ^4He , ^{20}Ne , ^{36}Ar , ^{85}Kr	Other geochemical, isotopic, CFC tracer, and noble gas analytes	Distinguishes the presence, source, and tracks the crustal movement of gas and fluids through time; identifies and quantifies surface water-groundwater interaction and hyporheic exchange rates; ages younger groundwater

Appendix B: Checklists

Table C.1 Planning and problem formulation (for both human health and environmental risk assessment)

Planning and problem formulation		✓
1	Define the management goals of the risk assessment and applicability of regulatory requirements	
2	Define the scope and objectives of the risk assessment to clearly identify the problem	
3	Generate conceptual models representing predicted key relationships between stressors, exposure and assessment endpoints	
4	Identify the methodology and complexity (tier level) for analysing the risk (exposure and hazard), keeping in mind this may evolve as the assessment progresses	
5	Consider multiple hazards and cumulative impacts	
6	Are the data available and accessible? What are the data quality criteria? What are the data gaps and uncertainties?	
7	Have the interests and concerns of affected parties been considered in formulating the problem?	

Table C.2 Data requirements (for both human health and environmental risk assessment)

Data requirements		✓
1	Identify the chemical, mixtures or chemical identities in mixtures / flowback / produced water / wastewater (Section 4.1)	
2	Obtain chemical information, along with information of fate and behaviour of the chemical(s) in the environment (Section 4.2)	
3	Gather data for the exposure assessment (i.e. chemical quantities and concentrations, exposure routes and compartments) (Section 4.3)	
4	Gather data for the hazard assessment (Section 4.4)	
5	Evaluate data quality (Section 4.6) and determine if further data are required	
6	Determine, analyse and report on the uncertainty within the acquired data (Section 4.7.3)	
7	Analyse weight of evidence to determine the adequacy of the available data as a whole (Section 4.7.4)	

Table C.3 Human Health Exposure Assessment

Human health exposure assessment		✓
1	Identify the chemical sources and define points of release of chemical(s).	
2	Identify and define transfer pathways for the chemical(s)	
3	Identify and define the receptors and exposure routes (occupational exposure and public exposure) applicable to the situation being assessed.	
4	Describe, measure and / or calculate exposure concentrations for occupational exposure and public exposure.	

5	Describe approach, models used and uncertainties around the data used.	
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Table C.4 Environmental Exposure Assessment

Environmental exposure assessment		✓
1	Identify the chemical sources and define points of release of chemical(s) or mixtures.	
2	Identify and define transfer pathways for the chemical(s).	
3	Identify and define the environmental receptors that may be at risk of exposure applicable to the situation being assessed.	
4	Describe, measure and / or calculate the potential or predicted environmental concentration (PECs) of the chemical(s) for the identified environmental compartment(s) using the scenarios developed during point of release, transfer pathway and receptor assessments. Quantities of release, concentrations and probability of occurrence should be integrated here.	
5	Describe approach, models used and uncertainties around the data used.	

Table C.5 Human Health Risk Assessment

Human Health risk characterisation		✓
Screening		
1	Identify chemicals of low concern/potential concern and collate available information on the human health hazards using NICNAS validation rules described in Section 6.4.1	
Hazard assessment		
2	Collate and evaluate relevant toxicity data and dose response relationships from toxicology studies. Identify the critical health effect, the dose for the point of departure (e.g. NOAEL), and develop toxicological profiles for the chemicals of potential concern.	
3	Determine whether carcinogenic chemicals are present, whether these are genotoxic, and follow described methodology using threshold or non-threshold assessment.	
Exposure assessment		
4	Estimate the internal dose from the monitoring data or the PEC from the modelled data	
Risk Characterisation		
5	Characterise public and occupational health risks by combining the estimated exposure doses from the exposure assessment with the toxicological values from the hazard assessment	
6	For threshold approach - calculate margin of exposure (MoE) or hazard quotient (HQ) to characterise risk (Section 6.4.1) Delineate data uncertainties and determine appropriate uncertainty / safety factors for interpretation of MoE or derivation of TRV.	
7	For non-threshold approach - utilise non-threshold risk characterisation methods (Section 6.4.2)	

Table C.6 Environmental Risk Assessment

Quantitative environmental risk characterisation		✓
Hazard assessment		

1	Evaluate relevant chemical and ecotoxicity data available (including appropriate test endpoints, appropriate species (aquatic and terrestrial), potential for bioaccumulation and endocrine disruption)	
2	Collect or undertake tests for additional chemical and ecotoxicity data if the evaluation of the available data indicates that it is required	
3	Categorise by toxicity classification or if data available calculate the predicted no effect concentration (PNEC) using suitable methods based on the available data	
Risk Characterisation		
4	Compare exposure concentrations to relevant environmental and ecosystem-based guidelines (where appropriate)	
5	Characterise risk to determine potential risk to the environment using the outcomes from the previous exposure assessment and hazard assessment	
6	Further investigate / refine PECs and PNECs using the tiered approach when risk outcomes and / or risk quotients exceed risk limits	
7	Delineate and report data uncertainties	
8	Consider likelihood and mitigation measures as part of risk characterisation	

Table C.7 Risk management and communication (for both human health and environmental risk assessment)

Risk Management and Communication		✓
1	Define the risk management strategy and implementation.	
2	Communicate and consult with stakeholders to ensure the risk management framework is appropriate.	
3	Apply the risk assessment framework for the chemicals being assessed, complying with relevant legal and regulatory requirements.	
4	Undertake monitoring and review of risk management strategy and framework on an appropriate basis to ensure identification of emerging risks and continual improvement.	
5	Communicate and discuss results with risk owners and managers, and if required, with regulators.	

Appendix C: Equations referred to in the manual

	Equation	Purpose
1	<i>Risk = function (hazard × exposure)</i>	General formula for calculating chemical risk.
2	$I = \frac{C \times CR \times EFD}{BW} \times \frac{1 \times CF}{AT}$ <p>Where:</p> <p>I = intake of chemical (usually expressed as mg/kg bw/day).</p> <p>C = average chemical concentration in media over the exposure period (e.g. mg/L, mg/kg, or mg/m³).</p> <p>CR = contact rate; the amount of contaminated media contacted per unit of time or event (e.g. L/day, m³/day).</p> <p>EFD = exposure frequency and duration (how long and how often exposure occurs). EFD may be based on the product of two parameters: EF (exposure frequency, e.g. days/year) and ED (exposure duration, e.g. years).</p> <p>BW = life stage body weight, usually averaged over the exposure period (kg).</p> <p>AT = averaging time, period over which the exposure is averaged (e.g. hours, days, months, years). This will depend on the nature of the adverse effect (e.g. acute or chronic) being assessed and the exposure scenario predicted. For non-threshold adverse effects (e.g. genotoxic carcinogenesis) where exposure may be assumed to be over a lifetime the AT value most commonly used is 70 years. For threshold effects AT values of 36 years (30 as an adult and 6 as a child) for public exposure and 30 years for worker exposure are recommended (enHealth 2012a and 2012b; ASC NEPM 2013 B4 and B7).</p> <p>CF = conversion factor, if units in above parameters do not match.</p>	General formula for calculating chemical intake from various media.
3	$PEC = \frac{Q}{V}$ <p>Where:</p> <p>Q = the quantity of a chemical released into the environment</p> <p>V = the volume of the receiving environment medium.</p>	General formula for calculating the environmental concentration in receiving environments.
4	$RQ = \frac{exposure}{toxicity} = \frac{PEC}{PNEC}$ <p>Where:</p> <p>RQ = the Risk Quotient</p> <p>PEC = the Predicted Environmental Concentration [mg/L], and</p> <p>PNEC = the Predicted No Effect Concentration [mg/L].</p>	General formula for calculating a risk quotient.

5	$MoE = \frac{PoD}{human\ dose}$ <p>Where: MoE = Margin of Exposure PoD = Point of Departure (e.g. NOAEL) in mg/kg/d Intake = Intake in mg/kg/day from all exposure routes</p>	Formula used to derive the margin of exposure during human health risk characterisation.
6	$RQ = \frac{Human\ Dose}{T - TRV}$ <p>Where: RQ = Risk Quotient Intake = Intake in mg/kg/day T-TRV = Threshold Toxicity Reference Value (TRV) in mg/kg/day</p>	Formula used to derive the risk quotient during human health risk characterisation.
7	$Overall\ RI = \sum RQ\ for\ each\ exposure\ pathway$ <p>Where: Overall RI = \sumRQ for each exposure pathway RQ = Risk Quotient</p>	Formula used to derive the risk index during human health risk characterisation.
8	$ILRC = Human\ Dose\ or\ Exposure\ Concentration \times TRV$ <p>Where: ILCR = Increased lifetime cancer risks Intake = Intake in mg/kg/day Exposure concentration = Exposure concentration in mg/m³ TRV = Toxicity Reference Value mg/kg/day</p>	Formula used to derive the increased lifetime cancer risk during human health risk characterisation.
9	$PNEC = \frac{quantitative\ estimate\ of\ effect}{assessment\ factor}$ <p>Where: PNEC = Predicted No Effect Concentration Assessment factor = safety or uncertainty factor</p>	General formula for calculating a Predicted No Effect Concentration.
-	$MATC = \sqrt{(NOEC)(LOEC)}$ <p>Where: MATC = Maximum Acceptable Toxicant Concentration NOEC = No Observable Effects Concentration LOEC = Lowest Observable Effects Concentration</p>	General formula for calculating the Maximum Acceptable Toxicant Concentration (MATC) Included here, for information only. Its use is not recommended (previously used in effects assessment – reported as the geometric mean between NOEC and LOEC)

Appendix D: Qualitative risk assessment – examples

The following examples are for environmental hazards only and exclude human health hazards.

Examples of qualitative screening assessments

The *National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia* considered the risks to the environment from 113 chemicals associated with coal seam gas extraction in the period 2010 to 2012. Qualitative assessments for 54 of these chemicals used an approach that was similar to that developed for the IMAP assessment framework⁶³. For example, risk assessment sheets for hydrogen peroxide and tetrasodium EDTA are set out in Appendix G of DoEE (2017b). The application of qualitative risk assessment approaches, again to hydrogen peroxide and tetrasodium EDTA, are provided below, for information.

Data and information gathered from the scientific literature informed the background section of the screening assessment of hydrogen peroxide and tetrasodium EDTA. The information was carefully analysed to ensure that the weight of available evidence supported its inclusion in the assessment (see, for example, Section 4.5.4 of this Guidance Manual, ECHA 2010, and Environment Canada 2003).

The background section for both chemicals includes information on:

- general characteristics
- the particular use of the chemical in the coal seam gas industry
- chemical properties that are relevant to the environment, especially those that are potentially harmful
- natural and anthropogenic sources of the chemical in the environment, including information on background concentrations.

The background discussion for these chemicals highlighted key factors for consideration in the qualitative screening assessments. For instance, hydrogen peroxide readily degrades in the environment to harmless by-products, while tetrasodium EDTA may mobilise toxic metals in contaminated aquatic ecosystems.

In the case of tetrasodium EDTA, speciation is of primary importance. It undergoes exchange reactions with transition metal ions. This poses a potential hazard because tetrasodium EDTA has the potential to mobilise toxic metals that would otherwise be insoluble. Speciation of tetrasodium EDTA also has a profound effect on the persistence of the chemical; tetrasodium EDTA is not readily biodegradable, but as an iron (III) complex the EDTA ligand is photolytically unstable ($DT_{50} \approx 20$ days).

In the case of hydrogen peroxide, partitioning behaviour is not relevant to the assessment since the chemical rapidly disproportionates (a type of degradation) into water and oxygen under environmental conditions. In this case, it is the lack of persistence that is the dominating characteristic.

⁶³ <https://www.nicnas.gov.au/chemical-information/imap-assessments/the-imap-framework>

Persistence data was available for hydrogen peroxide for biotic and abiotic degradation in various media. The data demonstrated that hydrogen peroxide is not persistent in the environment. The qualitative consideration of tetrasodium EDTA was more subtle. The tetrasodium EDTA complex is persistent, but on complexation with ferric ions in the environment (that is, Iron III), the EDTA ligand is photolytically unstable. This behaviour suggests that tetrasodium EDTA is unlikely to persist in the environment. This could then be confirmed by on-site monitoring. In the case of tetrasodium EDTA, the available data indicate that the chemical has a low potential to bioaccumulate, and for hydrogen peroxide, the chemical degrades so fast in the environment that bioaccumulation is not a relevant consideration. Hence neither chemical falls into the PBT category (see Table 7.5).

When released to the environment, hydrogen peroxide has a very short half-life, so there is no potential for long-range environmental transport of this chemical.

Tetrasodium EDTA will complex with metal ions in the environment. It binds almost irreversibly with ferric ions, which are usually abundant. In this complex, the EDTA ligand is susceptible to photolysis. This limits the potential of tetrasodium EDTA to undergo long-range transport in most aquatic systems. However, the transport of the EDTA ligand is dependent on the metal to which it is bound. Consequently, there is some potential for long-range transport of certain EDTA-metal complexes.

A summary of critical environmental effects can help document and communicate the key causal and process factors that contribute to the ecotoxicity of a chemical. For instance, the relative toxicity of tetrasodium EDTA and its metal-complex derivatives is summarised in the qualitative risk assessment.

Qualitative screening assessments for both hydrogen peroxide and set out below, for information (see DoEE 2017d for details, including references).

Hydrogen peroxide

Background

Hydrogen peroxide is a naturally occurring chemical, and is produced by almost all cells as a part of normal metabolic processes (OECD 1999). It is also commercially available as aqueous solutions varying in concentration from 2 to 90% w/w, and is used as an oxidant for dyeing hair, as a topical disinfectant, in pulp bleaching, in textile bleaching, in chemical processing, and in wastewater treatment (EC CAB 2000; EC 2003). Hydrogen peroxide is used in the coal seam gas industry as a 'breaker' to chemically degrade the gel in hydraulic fracturing fluids in order to reduce the viscosity back to that of water (DotE 2014). According to information from the Queensland Government, its use within the Australian coal seam gas industry is for gel management (DoEHP QG 2015).

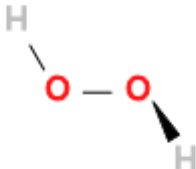
Hydrogen peroxide is formed and transformed by natural processes in each compartment of the environment through biotic and abiotic reactions, with irradiation of water producing 2 to 12 µg per hour per litre in freshwater ecosystems (Wetzel 2001; EC CAB 2000). The mean measured background concentration of hydrogen peroxide in air and lake water has been reported as 0.14 to 1.4 µg/m³ (0.1 to 1 ppb) and 1 to 30 µg/L, respectively. The peak concentration of hydrogen peroxide in air and lake water has been reported as 10 µg/m³ (7 ppb) and >100 µg/L, respectively (EC 2003).

Hydrogen peroxide is a reactive colourless liquid at room temperature (ATSDR 2002). It is a strongly oxidising chemical that undergoes a variety of rapid redox reactions in aqueous solution that result in its decomposition. An important route of degradation of hydrogen peroxide in surface waters is the highly exothermic disproportionation of hydrogen peroxide

to water and molecular oxygen (dioxygen). This reaction proceeds by both abiotic and biotic pathways in environmental waters. The abiotic disproportionation of hydrogen peroxide is catalysed by a variety of environmental species, especially transition metal ions. The disproportionation of hydrogen peroxide is also catalysed by catalase enzymes, which are ubiquitous in the cells of aerobic life forms (EC 2003).

The reactive nature of hydrogen peroxide means that it can cause oxidative stress in exposed organisms. In addition, its reactions with water constituents can increase water temperatures abruptly (ATSDR 2002) and potentially burn any organisms which come into contact before it breaks down into water and oxygen. However, the short lifetime of hydrogen peroxide in soil and water and further normal biogeochemical regulation mechanisms are expected to limit the potential for the chemical to cause any such effects in the environment.

Chemical name and identification

CAS Name	Hydrogen peroxide (H ₂ O ₂)
CAS RN	7722-84-1
AICS name	Hydrogen peroxide (H ₂ O ₂)
Synonyms	Hydrogen peroxide Dihydrogen dioxide
Structural formula	
Molecular formula	H ₂ O ₂
Molecular weight	34.01 g/mol
SMILES	OO

Physico-chemical properties

Pure hydrogen peroxide is stable at normal temperature and pressure. Commercial solutions must be stabilised with additives to prevent possibly violent decomposition due to catalytic impurities or elevated temperatures and pressures. Stability is at a maximum at pH 3.5 to 4.5. Hydrogen peroxide is not flammable, however, it presents a fire hazard because as a strong oxidizer it can enhance the combustion of other substances (EC 2003):

Property	
Physical form	Colourless, clear syrupy liquid and highly volatile under ambient conditions (EC 2003)
Melting point	-0.41°C (Hess 1999)
Boiling point	150–152°C (EC 2003)
Density (relative to water)	1.4425 g/cm ³ at 25°C (EC 2003)
Water solubility	Miscible in all proportions (Hess 1999)
pK _a	11.62 at 25°C (EC 2003)
Log K _{ow}	Not applicable
Vapour pressure	300 Pa at 25°C (EC 2003)

Domestic and international regulatory information

A review of international and national environmental regulatory information was undertaken. No specific environmental regulatory controls or concerns were identified within Australia and internationally for hydrogen peroxide:

Pre-assessment profile	
Montreal	No
SGG	No
Rotterdam	No
Stockholm	No
Reach (SVHCs)	No
EDC (US EPA)	No
EDC (Europe)	No

Environmental fate summary

Dissolution, speciation and partitioning

Hydrogen peroxide is stable under ambient conditions as a pure liquid, however, aqueous solutions are unstable with respect to spontaneous decomposition to oxygen and water (Hess 1999; Cotton and Wilkinson 1988). Under environmental conditions, hydrogen peroxide is expected to decompose rapidly. Therefore, partitioning of the chemical beyond the compartment of release is not expected.

The decomposition of hydrogen peroxide in aqueous solution is a disproportionation reaction (Equation G1), which is catalysed by transition metal ions, dust, and alkali (EC 2003):



Hydrogen peroxide is a strong oxidant in acid and basic solution. It can also react as a modest reductant, although only towards powerful oxidants such as Cl₂. The rate of oxidation by hydrogen peroxide is slow in acid solution and fast in basic solution (Cotton and Wilkinson 1988). Hydrogen peroxide also undergoes substitution chemistry.

Persistence

Hydrogen peroxide is biologically degradable by aerobic organisms. Degradation of the chemical is therefore highly dependent on biological composition, as well as the presence of metal catalysts (EC 2003). The half-life of hydrogen peroxide in soil without microbiological activity and few minerals has been reported as 15 hours as compared with only several minutes in soil with 10^8 to 10^9 cells/g total solids and which also contained iron and manganese at catalysts. The half-life for hydrogen peroxide in ground water was in the range 7 to 70 minutes (ECETOC 1993).

In surface waters, hydrogen peroxide undergoes abiotic degradation through disproportionation and redox reactions. It is also degraded by algae and microorganisms, and the lifetime of H_2O_2 in natural surface waters is therefore strongly influenced by the biological composition of the water body (ECETOC 1993). The half-life in water depends on the exposure conditions, but a short half-life has been reported at pH 7 (US EPA 2007).

The degradation half-life for hydrogen peroxide in the atmosphere has been variously estimated as in the range 10 to 20 hours for the troposphere (ECETOC 1993) to an average of 24 hours (EC 2003). Based on the above experimental values hydrogen peroxide is not considered persistent in the environment.

Bioaccumulation

There are no experimental results on bioaccumulation available, however, the potential for hydrogen peroxide to bioaccumulate is mitigated by enzymes such as catalase which naturally regulate the levels of hydrogen peroxide in aerobic organisms. Therefore, no bioaccumulation is expected.

Transport

Hydrogen peroxide is a naturally occurring, globally distributed chemical. The chemical rapidly degrades in all environmental compartments as a result of biotic and abiotic reactions. No significant potential for long-range transport is expected.

Environmental effects summary

Critical environmental effects

Acute toxicity endpoints for aquatic organisms

The median lethal concentration (LC_{50}) and median effective concentration (EC_{50}) values for model organisms across three trophic levels were used to characterise the acute effects of this chemical (EC 2003):

Taxon	Endpoint	Method
Fish	96 h LC_{50} = 16.4–37.4 mg/L	Experimental Pimephales promelas
Invertebrates	96 h EC_{50} = 2.3–17.7 mg/L	Experimental Daphnia spp.
Algae	EC_{50} = 1.6–43 mg/L	Experimental Anabaena A4

The effects of hydrogen peroxide on micro-organisms have been assessed. The EC_{50} of 466 mg/L for inhibition of microbial respiration in sludge micro-organisms indicates hydrogen peroxide is non-inhibitory to microbial respiration (EC 2003).

Chronic toxicity endpoints for aquatic organisms

The following No-Observed-Effect-Concentration (NOEC) values for model organisms from two major aquatic trophic levels were used to characterise the chronic effects of this chemical (EC 2003):

Taxon	Endpoint	Method
Fish	Not available	-
Invertebrates	56 d NOEC = 2 mg/L	Experimental Zebra mussels (species not specified)
Algae	72 h NOEC = 0.1–0.63 mg/L	Experimental <i>Chlorella vulgaris</i>

Based on the above toxicity data, hydrogen peroxide is not categorised as toxic to aquatic life according to domestic toxicity criteria.

Categorisation and other characteristics of concern

PBT categorisation

The chemical is not a PBT substance according to domestic environmental hazard criteria.

Other characteristics of concern

No other characteristics of concern for the environment were identified for this chemical.

Screening assessment

Assessment

Hydrogen peroxide is a naturally occurring and ubiquitous chemical in the environment. It is naturally produced and degraded through a range of biotic and abiotic reactions. Under typical environmental conditions, the chemical is expected to degrade rapidly in soil and water and does not persist in the environment. The chemical also does not bioaccumulate. Hydrogen peroxide has some moderate acute toxicity to aquatic organisms, but all aerobic aquatic organisms are naturally adapted to fluctuating background concentrations of hydrogen peroxide in natural waters.

Release of large volumes of hydrogen peroxide directly into the environment may create physico-chemical stressors. For example, its reactions with water constituents can increase water temperatures abruptly (ATSDR 2002) and potentially burn any organisms which come into contact before it breaks down into water and oxygen. Release of hydrogen peroxide can also affect the oxidation state and speciation of metal ions in the environment. However, normal biogeochemical regulation mechanisms are expected to be able to limit the effects of moderate fluctuations in the concentrations of hydrogen peroxide in aquatic ecosystems. The chemical is highly reactive in soil and any direct releases to soil are expected to result in spontaneous and rapid degradation of hydrogen peroxide to water and dioxygen. Hence, indirect emissions of H₂O₂ to surface waters as a result of releases of the chemical to the soil compartment through spills or use in coal seam gas extraction are not expected to occur.

Outcome

A Tier 1 assessment of the environmental risks from the use of hydrogen peroxide is not required.

Tetrasodium EDTA

Background

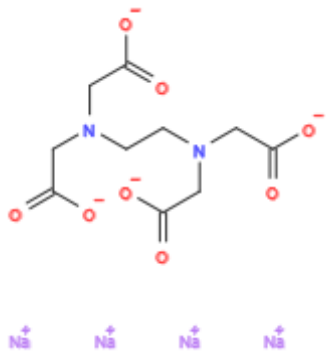
Glycine, *N*, *N'*-1,2-ethanediylbis [*N*-(carboxymethyl)-, tetrasodium salt (tetrasodium ethylenediaminetetraacetic acid; tetrasodium EDTA) is a strong chelating agent, and can form complexes with many metal ions (Nowack et al. 2001). It has uses in a wide range of industrial and domestic applications, including household and commercial detergents, textile finishing and paper processing. In the coal seam gas industry, tetrasodium EDTA is used for iron control. Iron is naturally abundant in the environment and is a key nutrient for plants and animals, but can form problematic precipitates in coal seam gas operations (ANZECC and ARMCANZ 2000; Frenier et al 2003).

Ethylenediaminetetraacetic acid (EDTA) is a synthetic aminocarboxylic acid polydentate ligand with a strong affinity for a range of metal ions. Release of uncomplexed EDTA to aquatic ecosystems can cause moderate indirect ecotoxicity effects due to its ability to sequester essential trace metals (e.g., zinc(II) and copper(II)). However, EDTA is typically released to the environment in the form of metal complexes, as its chelating action is the functionally relevant characteristic. When complexed to nutrient metals, the toxicity of EDTA is low (Nowack et al. 2001; ECB 2004).

As a result of its extensive industrial use, EDTA is routinely detected in environmental waters at concentrations between 0.1 and 1 mg/L (ECB 2004). These background concentrations have previously been identified as of concern, as this may allow mobilisation of toxic heavy metals in contaminated aquatic ecosystems (Nowack 2002; ECB 2004). However, further studies have concluded that significant remobilisation of existing contaminants is only expected to occur in extreme cases when high volumes of EDTA are released (Nowack et al 2001; ECB 2004).

Chemical name and identification

CAS Name	Glycine, <i>N</i> , <i>N'</i> -1,2-ethanediylbis [<i>N</i> -(carboxymethyl)-, sodium salt (1:4)
CAS RN	64-02-8
AICS name	Glycine, <i>N</i> , <i>N'</i> -1,2-ethanediylbis [<i>N</i> -(carboxymethyl)-, tetrasodium salt
Synonyms	Tetrasodium EDTA Tetrasodium ethylenediaminetetraacetic acid

CAS Name	Glycine, N, N'-1,2-ethanediylbis [N-(carboxymethyl)-, sodium salt (1:4)
Structural formula	
Molecular formula	C ₁₀ H ₁₂ N ₂ Na ₄ O ₈
Molecular weight	380.17 g/mol
SMILES	C(=O)([O-])CN(CC(=O)[O-])CCN(CC(=O)[O-])CC(=O)[O-].[Na+].[Na+].[Na+].[Na+]

Physico-chemical properties

Properties	
Melting point	>300.0 °C (LMC 2014)
Boiling point	Not available
Water solubility	500 g/L (LMC 2014)
pK _a	pK _{a1} = 1.95 pK _{a2} = 2.68 pK _{a3} = 6.11 pK _{a4} = 10.17 (Butler 1998)
Log K _{ow}	Not available
Vapour pressure	Not available

Domestic and international regulatory information

A review of international and national environmental regulatory information was undertaken. No specific environmental regulatory controls or concerns were identified within Australia and internationally for tetrasodium EDTA.

Environmental fate summary

Dissolution, speciation and partitioning

EDTA is typically released to the environment in its complexed form (Nowack et al. 2001). The speciation of metal complexes is determined by the complex released, and metal exchange reactions mediated by its interactions with the chemistry of the receiving water compartment (Nowack 2002; ECB 2004). However, complexes of EDTA with iron(III) are often detected in river water due to the ubiquity of iron(III) and the slow kinetics of relevant metal exchange reactions (half life approximately 20 days) (Nowack 2002).

Partitioning of complexed EDTA between water and sediment compartments is dependent on the metal ion complexed. For example, EDTA complexed with cobalt(III) and iron(III)

partitions predominately to the water compartment, while lead(II) EDTA complexes adsorb strongly to sediment (Nowack 2002).

Persistence

EDTA is not readily biodegradable. Various studies conducted to standardised ready biodegradation test guidelines have found biodegradation to range between 0% and 10% in 28 days. The chemical is also resistant to hydrolysis (ECB 2004; NITE 2015). The chemical is considered to be persistent in the environment according to domestic hazard criteria (EPHC 2009).

However, EDTA is photolytically unstable when complexed with iron(III) ions. The complex is reported to have a half life of 5 hours in central Europe in summer, with a worst-case half life of 20 days. A number of degradation products are expected, which are expected to be inherently biodegradable (ECB 2004).

Bioaccumulation

Measured bioconcentration factors available for EDTA in fish are less than 15 L/kg (ECB 2004; NITE 2015), indicating low potential to bioaccumulate. The chemical is not considered to be bioaccumulative according to domestic hazard criteria (EPHC 2009).

Transport

Environmental transport of EDTA will be determined by the metal ions it is complexed with. Most studies investigating the transport of EDTA complexes compare this to transport of the uncomplexed metal. Generally, EDTA is found to decrease adsorption of metals and therefore increase its potential for transport in the environment (ECB 2004).

Environmental effects summary

Critical environmental effects

The toxicity of complexing agents is determined by the presence of metal ions and other factors affecting speciation, such as pH. The chemical is most toxic to aquatic organisms when released to the environment uncomplexed. When uncomplexed, EDTA chelates key nutrients from ecosystems and causes nutrient deficiency (ECB 2004). Available ecotoxicity data indicate that uncomplexed EDTA is not toxic according to domestic hazard criteria (EPHC 2009). However, assuming at least stoichiometric amounts of nutrients are present, actual toxicity in the environment is expected to be lower (ECB 2004).

Acute toxicity endpoints for aquatic organisms

The following measured median effective concentration (EC50) and median lethal concentration (LC50) values for model organisms were identified for EDTA. Studies were conducted in accordance with OECD test guidelines. No modification of test media to increase nutrient concentrations was reported:

Taxon	Endpoint	Method
Fish	96 h LC50 = 74 mg/L	Experimental <i>Oryzias latipes</i> (NITE 2015)
Invertebrates	48 h EC50 = 57 mg/L	Experimental <i>Daphnia magna</i> (NITE 2015)
Algae	72 h EC50 = 6 mg/L	Experimental <i>Pseudokirchneriella subcapitata</i> (NITE 2015)

Chronic toxicity endpoints for aquatic organisms

The following no-observed-effect concentration (NOEC) values for model organisms were identified for EDTA. Studies were conducted in accordance with OECD test guidelines. No modification of test media to increase nutrient concentrations was reported:

Taxon	Endpoint	Method
Fish	35 d NOEC > 26 mg/L	Experimental <i>Danio rerio</i> (ECB 2004)
Invertebrates	21 d NOEC = 5.5 mg/L	Experimental <i>Daphnia magna</i> (NITE 2015)
Algae	72 h NOEC = 0.32 mg/L	Experimental <i>Pseudokirchneriella subcapitata</i> (NITE 2015)

Categorisation and other characteristics of concern

PBT categorisation

The chemical is not a PBT substance according to domestic environmental hazard criteria.

Other characteristics of concern

No other characteristics of concern for the environment were identified for this chemical.

Screening assessment

Assessment

Tetrasodium EDTA is a common chelating agent, and is released to the environment as a result of a wide number of domestic and industrial uses. Metal complexes of EDTA are consequently routinely detected in the environment. Due to its potential to modify the behaviour of metals in the environment, EDTA has previously been identified as of potential concern internationally.

Use of tetrasodium EDTA in coal seam gas is expected to result in the formation of EDTA metal complexes, most likely with iron(III). Some EDTA complexes with heavy metals and radionuclides could also be formed, resulting in the mobilisation of these species. However, these potential indirect effects are beyond the scope of this assessment.

Release of EDTA complexed with metals such as iron(III) to the environment will have limited direct ecotoxic effects. Metal exchange reactions may result in the mobilisation of heavy metal contaminants, if present in the receiving compartment. However, the potential for this to occur is expected to be limited, given the slow kinetics of metal exchange reactions for the iron(III) EDTA complex and the photolytic half life of this compound.

Accidental spills of tetrasodium EDTA during transport to coal seam gas operations could result in release of significant quantities of uncomplexed EDTA to the environment. Although large quantities of uncomplexed EDTA could mobilise heavy metal contaminants and/or sequester key nutrients in aquatic ecosystems, such impacts are not expected to occur before clean-up of accidental spills can occur.

Outcome

A Tier 1 assessment of the environmental risks from the use of tetrasodium EDTA is not required.

Appendix E: Risk Assessment Dossier

Suggested content for a coal seam gas Chemical Risk Assessment Dossier is provided below. A dossier should be developed for each chemical. Suggested contents include:

- A chemical information sheet
- A human health hazard assessment sheet
- A human health risk assessment sheet
- An environment exposure and hazard assessment sheet
- An environment risk assessment sheet
- A risk communication and management sheet
- References, abbreviations and acronyms.

The suggested headings, information, and layout for a coal seam gas Chemical Risk Assessment Dossier are attached. Suggested content is provided as guidance and is not intended to be prescriptive.

1 Chemical Name [as listed in AICS or by CAS]

1.1 Chemical name, identity, physical properties, and industrial use

1.1.1 [insert Chemical name]

Table 1 Chemical name and identity

CAS No.	CAS Name

NOTES: [insert text]

This assessment is conducted for [chemical name] (chemical formula: [insert chemical formula]), more commonly referred to as [insert common names, if any].

1.1.2 Chemical synonyms and structure

The following chemical identity information in Table 2 is obtained from [insert citations].

Table 2 Chemical properties

	Chemical
AICS name(s)	[insert name(s)]
Synonyms	[insert name(s)]
Structural formula	[insert chemical structure diagram]
Molecular formula	[insert formula]
Molecular weight	[insert molecular weight]
Physical form, appearance, and odour at 20°C and 1.013 hPa	[insert colour] [insert physical form: solid (eg, powder / granules, pellets / crystals / etc) / liquid / gas] [insert odour].
SMILES notation	[insert SMILES]

NOTES: [insert text]

[insert text]

1.1.3 Physico-chemical properties

Table 3 Physical properties

	Units of Measure
Melting point	°C [at kPa]
Boiling point	°C [at kPa]
Vapour pressure	Pa [at °C]
Relative density	kg/m ³ [at °C]
Water solubility	g/L at °C [at pH]
Henry's Law Constant (K _H)	Pa m ³ /mol [at °C]
Partitioning coefficients (K _{ow} , K _{oc} , K _p)	n-octanol / water partition coefficient, log K _{ow} [at °C, pH] organic carbon adsorption coefficient, K _{oc} [at °C, pH] soil-water partition coefficient, K _p at [at °C, pH]
Dissociation constant (pK _a , pK _b)	pK [at pH]
Degradation rate (DT ₅₀)	days

NOTES: [insert text]

[insert text]

1.1.4 Current regulatory controls

1.1.4.1 Existing International controls

A review of international and national environmental regulatory information was undertaken. The following environmental regulatory controls or concerns were identified within Australia and internationally for [insert chemical name]:

Table 4 Existing international controls

Convention, Protocol or other international control	Listed (yes / no)
Stockholm Convention ^a	
EDC – Europe ^b	
EDC – USA ^c	
EU REACH (Annexes XIII, XIV, XVII) ^d	
Kyoto Protocol ^e	
Montreal Protocol ^f	

Convention, Protocol or other international control	Listed (yes / no)
Rotterdam Convention ^g	
Basel Convention ^h	

NOTES: a. Stockholm Convention on Persistent Organic Pollutants. b. European Commission priority list of substances for further evaluation of their role in endocrine disruption. c. US EPA lists of chemicals for tiered screening under the US EPA's Endocrine Disruptor Screening Program. d. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). e. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). f. The Kyoto Protocol is an international agreement linked to the United Nations Framework Convention on Climate Change. g. The Montreal Protocol on Substances that Deplete the Ozone Layer (a protocol to the Vienna Convention for the Protection of the Ozone Layer). h. Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade). i. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal.

1.1.4.2 Existing Australian Controls

Table 5 Existing Australian controls

Pre-assessment profile	Listed (yes / no)
AICS (NICNAS) ^a	
HCIS (SWA) ^b	
CWC declarable chemical (DFAT) ^c	
Food standards (FSANZ) ^d	
Proposed National Standard for Environmental Risk Management of Industrial Chemicals (CoAG) ^e	
NPI (DoEE) ^f	
NWQMS Doc 4 – (ANZECC and ARMCANZ) ^g	
NWQMS Doc 6 – ADWGs (NHMRC) ^h	
SUSMP (TGA) ⁱ	

NOTES: a. Australian Inventory of Chemical Substances (AICS). b. Hazardous Chemicals Information System (HCIS). c. Chemical Weapons Convention (CWC): A Guide for Australian Industry Producing, Using, or Trading Chemicals – Schedule 1, 2, 3, and DO Chemicals. d. Australia New Zealand Food Standards Code. e. Proposed CoAG National Standard for Environmental Risk Management of Industrial Chemicals – Proposed Schedules 2-8. f. National Pollution Inventory (NPI). g. National Water Quality Management Strategy: Australian and New Zealand Guidelines for Fresh and Marine Water Quality 2000. h. National Water Quality Management Strategy: Australian Drinking Water Guidelines. i. Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

[insert text]

1.1.4.2.1 Hazard classification(s) for occupational health and safety (HSIS / HCIS / GHS)

[insert text]

1.1.4.2.2 Occupational exposure standards (HSIS / HCIS / GHS)

[insert text]

1.1.4.2.3 Australian food standards (FSANZ)

[insert text]

1.1.4.2.4 Australian drinking water guidelines (NHMRC)

[insert text]

1.1.4.2.5 Australian and New Zealand Guidelines for Fresh and Marine Water Quality (ANZECC and ARMCANZ 2000)

[insert text]

1.1.4.2.6 Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) (TGA)

[insert text]

1.1.5 *Chemical use, quantities and concentrations*

1.1.5.1 Industrial Use

The chemical is used in the production of unconventional fossil fuels ([insert: OECD Product Category: eg, PC41 - Oil and gas exploration or production products]). The chemical is used in coal seam gas extraction for drilling / cementing / well cleanout / hydraulic fracturing / monitoring.

The function of the chemical is to [insert text] ([insert OECD Technical Function value: eg, biocide]).

1.1.5.2 Release Quantities

Table 6 Chemical quantities

Chemical lifecycle stage	Type of container / packaging	Mass / Volume of each container (L or kg)	Number of containers (per well)	Total quantity (per well)
As delivered to work site				

NOTES: [insert text]

[insert text]

1.1.5.3 Release Concentrations

Table 7 Chemical concentrations

Chemical lifecycle stage	Concentrations (%)	Concentrations (g/L or g/kg)	Range (R) or Upper bound value (U)
As delivered to work site			
In mixed drilling / hydraulic fracturing fluid			
In flowback water			
In produced water			

NOTES: [insert text]

[insert text]

1.2 Human health hazard characterisation

1.2.1 *Toxicokinetics and Metabolism*

This section covers the absorption, distribution, metabolism and excretion of the chemical in humans or laboratory animals.

1.2.1.1 Oral adsorption

[insert text]

1.2.1.2 Dermal adsorption

[insert text]

1.2.1.3 inhalation adsorption

[insert text]

1.2.1.4 Distribution

[insert text]

1.2.1.5 Metabolism

[insert text]

1.2.1.6 Excretion

[insert text]

1.2.2 *Acute toxicity (animal toxicity studies)*

[insert text]

Table 8 Repeated dose toxicity studies

Species	Duration Method	Dosage	LOAEL NOAEL	Endpoint Remarks	Reference	KI score

Species	Duration Method	Dosage	LOAEL NOAEL	Endpoint Remarks	Reference	KI score

NOTES:

1.2.2.1 Oral

[insert text]

1.2.2.2 Dermal

[insert text]

1.2.2.3 Inhalation

[insert text]

1.2.3 Acute toxicity (observations in humans)

[insert text]

1.2.3.1 Irritation / Corrosivity

Skin irritation

Eye irritation

Respiratory irritation

1.2.3.2 Sensitisation

Skin sensitisation

Respiratory sensitisation

1.2.3.3 Inhalation

[insert text]

1.2.4 Repeat dose toxicity

[insert text]

Table 9 Repeated dose toxicity studies

Species	Duration Method	Dosage	LOAEL NOAEL	Endpoint Remarks	Reference	KI score

NOTES:

1.2.4.1 Oral

[insert text]

1.2.4.2 Dermal

[insert text]

1.2.4.3 Inhalation

[insert text]

1.2.5 Genotoxicity

[insert text]

1.2.6 Carcinogenicity

[insert text]

1.2.7 Reproductive toxicity

Fertility [insert text]

Developmental toxicity [insert text]

1.2.8 Other health effects

[insert text]

1.2.9 Health hazard summary

1.2.9.1 Critical health effects

[insert text]

1.2.10 Hazard classification

[insert text]

Table 10 Recommended hazard classification for [insert chemical name]

	GHS ^a Classification

NOTES: a. Globally Harmonised System (UNECE 2009).

[insert text]

1.2.11 Hazard Labelling

[insert GHS labelling text]

1.2.12 Hazard pictograms

[insert GHS pictogram(s)]

1.3 Human health risk assessment

1.3.1 Human health exposure assessment

1.3.1.1 Occupational exposure

[insert text]

Table 11 Internal doses for ADULT WORKERS associated with drilling chemical exposure / hydraulic fracturing chemical exposure

Adult worker exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	[insert text]	E _{total} (mg/kg bw/day)
[insert scenario name]				
Mixing / blending				
Cleaning and maintenance				
Combined exposure from all exposure sources and routes				

NOTES: E_{oral} = internal dose from oral exposure. E_{derm} = internal dose from dermal exposure. E_{total} = total internal dose from all routes. N/A = not an applicable exposure route. N/C = not a complete exposure pathway.

[insert text]

1.3.1.2 Public exposure

[insert text]

Table 12 Internal doses for ADULTS associated with drilling chemical exposure / hydraulic fracturing chemical exposure

Adult exposure scenario	E _{oral} (mg/kg bw/day)	E _{derm} (mg/kg bw/day)	[insert text]	E _{total} (mg/kg bw/day)
[insert scenario name]				
Drinking				
Bathing				
Swimming				
Dusts				
Irrigated foods				
Inhalation				
Soil ingestion and dermal exposure				
Combined exposure from all exposure sources and routes				

NOTES: E_{oral} = internal dose from oral exposure. E_{derm} = internal dose from dermal exposure. E_{total} = total internal dose from all routes. N/A = not an applicable exposure route. N/C = not a complete exposure pathway.

[insert text]

Table 13 Internal doses for CHILDREN associated with drilling chemical exposure / hydraulic fracturing chemical exposure

Child exposure scenario	E_{oral} (mg/kg bw/day)	E_{derm} (mg/kg bw/day)	[insert text]	E_{total} (mg/kg bw/day)
[insert scenario name]				
Drinking				
Bathing				
Swimming				
Dusts				
Irrigated foods				
Combined exposure from all exposure sources and routes				

NOTES: E_{oral} = internal dose from oral exposure. E_{derm} = internal dose from dermal exposure. E_{total} = total internal dose from all routes. N/A = not an applicable exposure route. N/C = not a complete exposure pathway.

[insert text]

1.3.2 Human health risk characterisation

1.3.2.1 Uncertainty factors (assessment or safety factors)

For this risk assessment using a Margin of Exposure (MoE) approach, conservative default uncertainty factors (UFs) for intra- species and inter-species variability are assumed to be [insert value, eg, x10] each. Additional uncertainty factors (enHealth 2012a; EC 2003; US EPA 1993) are considered necessary to account for uncertainties such as:

- intra- species variability (UF_H): [insert value, eg, x 10]
- inter-species variability (UF_A): [insert value, eg, x 10]
- use of LOAEL instead of NOAEL (UF_L): [insert value, eg, x 10]
- use of sub-chronic instead of chronic (UF_S): [insert value, eg, x 10]
- data / database inadequacies (UF_D): [insert value, eg x 1-10]
- Use of professional judgement to address uncertainties and data gaps (MF_X): [insert value, eg, x 0.1-10]

Consequently, in the risk characterisation, an MoE of less than [insert value] is considered a concern.

1.3.2.2 Occupational health risks

1.3.2.2.1 Acute health risks

[insert text]

1.3.2.2.2 Chronic long-term health risks

[insert text]

Table 14 Margins of Exposure calculated for ADULT WORKERS associated with drilling chemical exposure / hydraulic fracturing chemical exposure

Activity	Margin of Exposure (MoE)
Mixing / blending of drilling chemicals	
Cleaning and maintenance	
Combined exposure Mixing / blending and cleaning and maintenance	

NOTES: NA = not assessed. ND = not determined. nd = not disclosed. N/A = not an applicable. N/C = not a complete exposure pathway.

[insert text]

1.3.2.3 Public exposure

1.3.2.3.1 Acute health risks

[insert text]

1.3.2.3.2 Chronic long-term health risks

[insert text]

Table 15 Margins of Exposure calculated for ADULTS / CHILDREN associated with drilling chemical exposure / hydraulic fracturing chemical exposure

Activity	Margin of Exposure (MoE) ADULTS	Margin of Exposure (MoE) PREGNANT WOMEN	Margin of Exposure (MoE) CHILDREN
[insert scenario name]			
Drinking			
Bathing			
Swimming			
Dusts			
Irrigated foods			
Combined exposure From all exposures			

NOTES: NA = not assessed. ND = not determined. nd = not disclosed. N/A = not an applicable. N/C = not a complete exposure pathway.

[insert text]

1.3.3 Conclusions

1.3.3.1 Occupation health risks

[insert text]

1.3.3.2 Public health risks

[insert text]

1.3.4 Uncertainties and data gaps

1.3.4.1 Sensitivity Analyses

[insert text]

1.3.4.2 Uncertainty Analyses

[insert text]

1.3.4.3 Data gaps

Monitoring: [insert text]

Reporting: [insert text]

1.4 Environment exposure and hazard assessment

1.4.1 Exposure 1

Release Scenario 1: [describe Release Scenario 1 and associated Release Point(s)]

Release Point 1: [insert Release Point]

Release quantity estimation (Q) 1: [insert estimated release quantity, in kg]

Release concentration 1: [insert estimated release quantity]

Estimation method: [describe data, methods, and any formula used to estimate release quantity at release point 1]

Release duration: [insert release duration, frequency information]

[insert text]

1.4.2 Exposure 2

Release Scenario 2: [describe Release Scenario 2 and associated Release Point(s)]

Release Point 2: [insert Release Point]

Release quantity estimation (Q) 2: [insert estimated release quantity, in kg]

Release concentration 2: [insert estimated release quantity]

Estimation method: [describe data, methods, and any formula used to estimate release quantity at release point 1]

Release duration: [insert release duration, frequency information]

[insert text]

1.4.3 Exposure 3

Release Scenario 3: [describe Release Scenario 3 and associated Release Point(s)]

Release Point 3: [insert Release Point]

Release quantity estimation (Q) 2: [insert estimated release quantity, in kg]

Release concentration 3: [insert estimated release quantity]

Estimation method: [describe data, methods, and any formula used to estimate release quantity at release point 1]

Release duration: [insert release duration, frequency information]

[insert text]

1.4.4 Environmental Fate and behaviour

Dissolution: [insert text]

Speciation: [insert text]

Partitioning: [insert text]

Abiotic degradation: [insert text]

Biodegradation: [insert text]

1.4.5 PBT Assessment

Persistence: [insert text]

Bioaccumulation: [insert text]

Toxicity: [insert text]

PBT Assessment: [insert text]

1.4.6 Estimation of Predicted Environmental Concentrations (PECs)

[insert text]

1.4.6.1 Calculation of PEC (water / soil / sediment / air)

[Insert formula and symbols, with metric / SI units of measure]

[insert text]

1.4.7 Estimation of Predicted No Effect Concentration (PNEC)

1.4.7.1 Acute and Chronic Aquatic Toxicity studies

Table 16 Acute ecotoxicology studies

Species	Endpoint (acute)	Method (OECD DTG)	Results (mg/L or µg/L)	Reference	Klimisch score

NOTES: [insert text]

[insert text]

Table 17 Chronic ecotoxicology studies

Species	Endpoint (acute)	Method (OECD DTG)	Results (mg/L or µg/L)	Reference	KI score

NOTES: [insert text]

[insert text]

1.4.7.2 Acute and Chronic Terrestrial Toxicity studies

[insert text]

LC/EC50 - Acute: [insert value, with units of measure eg, mg/L or µg/L]

LC/EC10 - Chronic: [insert value, with units of measure eg, mg/L or µg/L]

LC/EC30 - Soil chronic: [insert value, with units of measure eg, mg/L or µg/L]

LOEC: [insert value, with units of measure eg, mg/L or µg/L]

NOEC: [insert value, with units of measure eg, mg/L or µg/L]

MATC: [insert value, with units of measure eg, mg/L or µg/L]

1.4.8 Calculation of Acute, Chronic PNECs

1.4.8.1 Species Sensitivity Distribution (SSD)

[insert text]

[Insert formula and symbols, with Uncertainty Factors (UFs) and metric / SI units of measure]

PNEC (water): [insert values, with units of measure eg, mg/L or µg/L]

PNEC (sediment): [insert values, with units of measure eg, mg/L or µg/L]

PNEC (soil): [insert value, with units of measure eg, mg/L or µg/L]

PNEC (air): [insert value, with units of measure eg, mg/L or µg/L]

1.4.8.2 Uncertainty factors (assessment or safety factors)

For this risk assessment using semi-quantitative deterministic approaches, conservative default uncertainty factors (UFs), often referred to as assessment factors or safety factors (EPHC 2009a and 2009b; EC 2003), are considered necessary to account for uncertainties such as:

- one acute / short-term L(E)C₅₀ for acute toxicity from one trophic level (fish, *Daphnia*, algae): eg, x 1 000

- at least one short-term L(E)C₅₀ from each of the three trophic levels (fish, *Daphnia*, algae): eg, x 100]
- One chronic / long-term NOEC (either fish or *Daphnia*): eg, x 100
- Two chronic / long-term NOEC from species representing two trophic levels (fish and / or *Daphnia* and /or algae): eg, x 50]
- Three or more chronic / long-term NOEC from at least three species representing three trophic levels (fish and / or *Daphnia* and /or algae): eg, x 10]
- Field data or model ecosystems (UF_{FIELD}): [insert value, eg, x 1]
- data / database inadequacies (UF_D): [insert value, eg x 10⁻¹]
- Species sensitivity distribution (SSD) calculation method (UF_{SSD}): eg, x 5-1
- Use of professional judgement to address uncertainties and data gaps (MF_x): [insert value, eg, x 0.1-10]

[insert text]

1.5 Environment Risk Assessment

1.5.1 Risk quotient

PEC: [insert PEC]

PNEC: [insert PNEC]

Risk Quotient: [insert RQ]

Risk Classification: $RQ \leq 1$ (CSG chemical of low concern), or $RQ = 1$ to 10 (CSG chemical of potential concern), or $RQ > 10$ (chemicals of potentially high concern)

[insert text]

1.5.2 Environmental risks

1.5.2.1 Acute Exposure Risks

[insert text]

1.5.2.2 Chronic Exposure Risks

[insert text]

1.5.2.3 Long-term Exposure Risks

[insert text]

1.5.3 Conclusions

1.5.3.1 Estimated exposure concentrations, frequencies, and likelihoods

[insert text]

1.5.3.2 Potential ecosystem and species specific effects

[insert text]

1.5.3.3 Environment Risks

RQ: [insert RQ]

Risk Classification: [insert RQ risk class]

[insert text]

1.5.4 *Risk management recommendations*

[insert text]

1.5.5 *Uncertainties and data gaps*

1.5.5.1 Sensitivity Analyses

[insert text]

1.5.5.2 Uncertainty Analyses

[insert text]

1.5.5.3 Data gaps

Monitoring: [insert text]

Reporting: [insert text]

1.6 Risk communication and management

1.6.1 *Recommendations for risk mitigation: Classification and labelling*

Classification: [insert GHS classifications]

Labelling: [insert GHS labelling text]

Pictograms: [insert GHS pictograms]

Classification: [insert Proposed CoAG National Standard for Environmental Risk Management of Industrial Chemicals Schedules]

1.6.2 *Recommendations for risk mitigation: Safety and handling*

First Aid: [insert text]

Fire Fighting: [insert text]

Accidental Release: [insert text]

Storage and Handling: [insert text]

Exposure Controls – Engineering: [insert text]

Exposure Controls – Personal Protection: [insert text]

Exposure Controls – Administrative: [insert text]

Transportation: [insert text]

1.6.3 *Recommendations for risk mitigation: Disposal*

Disposal – chemical residues: [insert text]

Disposal – packaging and containers: [insert text]

Disposal – plant and equipment: [insert text]

1.6.4 *Recommendations for risk mitigation: Monitoring and reporting*

Monitoring: [insert text]

Reporting: [insert text]

1.7 References, abbreviations and acronyms

1.7.1 References

Reference (Australian Government Style Manual: limited punctuation). Accessed: DD Mmm YY [insert date accessed], via www [insert web address].

1.7.2 Abbreviations and acronyms

Table 18 Abbreviations, acronyms, symbols, units of measure

Abbreviation / Symbol	Meaning

DOSSIER ENDS.