Research Protocols for Narrative Review in support of the NHMRC Recreational Water Quality Guidelines: Chemical Hazards

Report Prepared for NHMRC

By Ecos Environmental Consulting Pty Ltd

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Executive Summary

The Office of the National Health and Medical Research Council (ONHMRC) has commissioned Ecos Environmental Consulting P/L to develop research protocols and conduct narrative reviews on two of four research topics that will be used to update the *Guidelines for Managing Risks from Recreational Water* (NHMRC, 2008).

The two research topics to be addressed by Ecos are Microbial Risks and Chemical Hazards (the other two topics Cyanobacteria and algae, and Free-living Organisms will be addressed elsewhere).

This document addresses Chemical Hazards and describes the definitions, research questions to be addressed, and the preliminary guidance provided by the NHMRC Recreational Water Quality Advisory Committee (RWQAC).

The document presents key details on the populations that will need to be reviewed to answer the research questions, including any susceptible populations or groups and justification for including them which are described in a Population, Exposure, Comparator, Outcome (PECO) table. The PECO table also lists all relevant exposure pathways, comparator populations and health outcomes to be considered.

Other major areas covered are:

- The process for extracting and presenting data
- A critical appraisal of evidence based on CASP (Critical Appraisal Skills Program)
- A risk of bias (quality) assessment also based on the CASP and augmented for certain study types by the OHAT Risk-of-Bias Tool produced by the US Office of Health Assessment and Translation. The Risk-of-Bias Tool assists in classifying risk of bias into 4 categories ranging through Definitely Low, Probably Low, Probably High and Definitely High risk of bias.
- The process for reporting the results of the narrative review.

This draft document will undergo revision based on feedback from the RWQAC before completion whereupon it will be used to guide the literature search, assessment and evaluation, and documentation required to carry out the narrative review for Chemical Hazards.

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1 Introduction

The Office of the National Health and Medical Research Council (ONHMRC) has commissioned Ecos Environmental Consulting P/L to develop research protocols and conduct narrative reviews on two of four research topics that will be used to update the *Guidelines for Managing Risks from Recreational Water* (NHMRC, 2008).

The two research topics to be addressed by Ecos are Microbial Risks and Chemical Hazards (the other two topics Cyanobacteria and algae, and Free-living Organisms will be addressed elsewhere). This document addresses Chemical Hazards.

A key requirement for the narrative reviews is the development of a research protocol to guide the review of the evidence. The research protocol sets out the methods to be used for the review including the research questions, population groups and health outcomes of interest. It also presents a structured search and evaluation strategy outlining the methods that will be used to locate, select and critically appraise relevant studies that will be used to answer the research questions. The research protocol forms the basis of the methods and results section of the Evidence Evaluation and Technical Reports which will document the findings of the review.

The research protocol specifies the key information needed for another reviewer to replicate the search and as much as possible outline how the evidence will be handled. The protocol is described in this document. A draft of this document will be provided to the ONHMRC and the Recreational Water Quality Advisory Committee (RWQAC) to agree on terms and processes before the review is started – this is to reduce risk of bias and to prevent 'scope creep'.

The research protocol for Chemical Hazards is described in the following sections.

2 Research Protocol – Chemical Hazards

2.1. Purpose and objectives of review

The purpose of the review is to inform the update to Chapter 9 of the *Guidelines for Managing Risks in Recreational Water* (NHMRC, 2008) and any relevant sections throughout the rest of the document with respect to the chemical hazards associated with the recreational use of water. Specifically, the review will provide NHMRC with an independent body of evidence to assure that the revision of the Guidelines is based on the most up-to-date and relevant scientific literature.

NHMRC has suggested reviewing publications from 2004 onwards for the Chemical Hazards reviews. Although the existing Guidelines were published in 2008, extending the date range back earlier should assist in locating any documents that may have been overlooked, or have become recognised as being of greater importance since that time, or missed the cut-off period during the preparation of the guidelines.

It is noted that the companion review of Microbial Risks lists 2003 as a starting date. For consistency, since we are also undertaking that review, we will also review the literature from 2003 onwards for Chemical Hazards.

A summary of the scope and application of the new guidelines is given **Appendix 1.**

2.2. Definitions

In this review, “Chemical Hazards” refers to risk associated with the contamination of recreational waters by chemical substances including organic compounds (e.g. PFAS, pesticides, hydrocarbons, surfactants, etc.), heavy metals, nanoparticles, endocrine disruptors and endotoxins. Cyanotoxins and algal toxins will be considered separately in another review.

Definitions of types, uses and users of recreational water is given in **Appendix 2**.

2.3. Research Question/s

The research questions that form the basis of this review were developed by the RWQAC. There is one primary question and three secondary questions.

2.3.1. Primary question

The primary question is: *Are exposures to the hazards outlined in the PECO Table below likely to give rise to any significant human health risks given that chemical concentrations in recreational waters are generally low?*

2.3.2. Secondary questions

The secondary questions are:

- *What chemicals (that potentially pose a risk to humans) are present at elevated concentrations in recreational waters and what are their sources?*

- *What chemicals are of most concern due to their physicochemical properties which may enhance their uptake via dermal, inhalation or ingestion exposure pathways? How can we adjust exposure assumptions for these chemicals?*
- *Should the focus be on "hot spots" i.e. site-specific rather than chemical specific, and/or include periodic toxicity screening of sites to complement chemical testing?*

2.3.3. Additional commentary and guidance from RWQAC

The RWQAC listed the following topics in relation to chemical hazards in recreational water that may assist in developing responses to the above questions:

- Substances of interest to include:
  - Key contaminants of concern in recreational waters;
  - Metals and metalloids, halogenated organic compounds and PAHs, nutrients, water soluble trace organic contaminants, PFAS;
  - Other high-risk chemicals and chemical hazards such as sunscreens and nanoparticles;
- Risk assessment methods (including exposure assessment calculations and assumptions);
- Consideration of short, medium- and long-term exposures; and
- Consider whether existing aquatic ecosystem health indicators can be used as surrogates for recreational water quality, noting that aquatic organisms are substantially more sensitive to toxicants than humans.

  The advantage of this is that there are already many monitoring programs, and data sets, for these indicators. A good example is the annual south east Queensland "Healthy Land & Water Report Card" where ecosystem health ratings (from A down to F) could be used to map onto general recreational water quality. Although this is debatable, in the absence of any other site specific data, sites ranked A to B- (15 sites) could be regarded as potentially suitable for swimming, while those ranked C+ to F (9 sites) would not be suitable.
- In addition to the last point, consideration of the use of indicator substances for chemical risk assessment and monitoring.

As noted earlier, the primary and secondary research requestions will be the focus of the review, however, in responding to those questions, it is understood that consideration of the additional commentary and guidance from RWQAC and associated questions, as listed above, will be required.

2.4. Population, Exposure, Comparator, Outcome (PECO) table

The key details on the populations that will need to be reviewed to answer the research questions, including any susceptible populations or groups and justification for including them are described in the PECO table (Table 2-1). The PECO table also lists all relevant exposure pathways, comparator populations and health outcomes to be considered.

Table 2-1. Population, Exposure (Comparator), Outcome (PE(C)O) table

<table>
<tr><th>Element</th><th>Criteria</th></tr>
<tr><td>Population</td><td>The general population will be considered, as is the usual case for all NHMRC water guidelines. Individuals with underlying medical conditions aside from general immune suppression are out of scope but the following subgroups will be considered as to whether they may require separate guidance in the guidelines.
Elderly
Infants and children
Pregnant women
Immunocompromised individuals
Indigenous Australians (Aboriginal and Torres Strait Islander peoples)
Any groups that might be exposed more frequently e.g. geographic location, socioeconomic status, lifestyle/occupational exposure.
Sub-groups with unusual exposure patterns making them more susceptible (e.g. athletes such as regular ocean swimmers and surfers, people or age-groups practicing energetic water-based activities) due to larger volumes of water ingested and/or inhaled, different frequency of exposure, etc.
The review will consider all studies that involve healthy human subjects of any age who have had recreational exposure to natural waters in any developed country, as listed on the OECD website:
(http:// http://www.oecd.org/about/members-and-partners/). External territories of member countries will be excluded.</td></tr>
<tr><td>Exposure (and comparator)</td><td>Hazards and sources:<table><tr><th>Hazard*</th><th>Sources</th></tr><tr><td>PFAS chemicals (not just regulated ones)</td><td>Military facilities, airports, fire stations and training grounds, STP effluent & sewer overflows</td></tr><tr><td>Pesticides</td><td>Rural and urban runoff</td></tr><tr><td>Other nanomaterials e.g. zinc oxide nanoparticles in sunscreens</td><td>Industrial discharges, STP effluent, sunscreens</td></tr><tr><td>Hydrocarbons (especially BTEX chemicals) and volatiles</td><td>Stormwater, fuel spills</td></tr><tr><td>Heavy metals (especially methylated)</td><td>Industrial discharges, stormwater, Mine discharges (incl. ‘legacy’ mines)</td></tr><tr><td>Endocrine disrupters</td><td>STP effluent and sewer overflows, animal production runoff</td></tr><tr><td>Surfactants, nonylphenols</td><td>STP discharges</td></tr><tr><td>Possible chemical interactions</td><td>Many. Synergistic interactions of most concern</td></tr><tr><td>Endotoxins</td><td>Lipopolysaccharide components of gram-negative bacteria cell walls</td></tr></table>Exposure settings – should include all exposures to recreational waters as per the definition in Appendix 2. Specific types of recreational water body, recreational activity are:
Recreational water bodies to be included are:
Marine:
beaches from the high tide waterline down
coastal waters in close proximity to land and thus influenced by land-based sources
estuaries, including tidally influenced estuarine beaches
Freshwater
Flowing waters (streams, creeks, canals, and rivers)
Wetlands, lakes and reservoirs
Beaches on rivers and lakes from the waterline down
Type of recreational activities to be covered by degree of contact as defined in the existing guidelines ((NHMRC, 2008).</td></tr>
</table>

Element	Criteria
	▪ *Whole-body contact (primary contact)* — activity in which the whole body or the face and trunk are frequently immersed or the face is frequently wet by spray, and where it is likely that some water will be swallowed or inhaled, or come into contact with ears, nasal passages, mucous membranes or cuts in the skin (e.g. swimming, bathing, diving, surfing, wave-boarding, body-boarding, wind-surfing, water parks or whitewater canoeing). ▪ *Incidental contact (secondary contact)* — activity in which only the limbs are regularly wet and in which greater contact (including swallowing water) is unusual (e.g. boating, wading, sailing, kayaking and fishing), and including occasional and inadvertent immersion through slipping or being swept into the water by a wave. ▪ *No contact (aesthetic uses)* — activity in which there is normally no contact with water (e.g. angling from shore), or where water is incidental to the activity (such as walking on a beach). ○ Most types of water-based recreational activities should fit under the above categories. Activities may include: ▪ Swimming ▪ Surfing ▪ Water skiing ▪ Jet skiing ▪ Diving, including snorkelling, scuba and activities such as spearfishing ▪ Kiteboarding, and kitesurfing ▪ Parasailing (from the beach or behind a boat) ▪ Sail boarding and wind surfing ▪ Kayaking and canoeing, including sea kayaking ▪ Rowing ▪ Fishing from a kayak or canoe ▪ Fishing from a shoreline or riverbank with wading ▪ Angling from the shore (no contact) ▪ Sunbathing (no contact) ▪ Other aesthetic uses, e.g. walking along the beach, etc. • Studies investigating illnesses acquired from treated recreational water (e.g. swimming pools, spas, hot tubs) will be excluded. • Health outcomes as a result of domestic exposure (e.g. drinking water or water used for washing) or occupational exposure to natural waters will also be excluded unless a study is clearly valuable in terms of protecting a subgroup. • Exposure pathways to be considered are oral ingestion of water, inhalation of aerosols and exposure via skin (dermis), eye (ocular) and ear (aural) pathways. It is expected that the literature with respect to chemical hazards in recreational waters will mainly deal with oral ingestion and dermal exposure with very little material being available on the other pathways. • Contaminant exposure pathways should not just focus on the water column but also consider surface films and sediments due to the partitioning behaviour of compounds in the environment. • The comparative populations are human populations with: ○ No contact with natural waters. ○ Different levels of recreational exposure (e.g. no head immersion).

Element	Criteria
	○ Recreational exposure to different grades of polluted water. ○ Note that papers that do not report rates of illness in a comparator group may be excluded as it would be impossible to calculate a risk metric for such studies.
Outcomes	Relevant health outcomes of interest are: • All relevant human health outcomes are of interest. The health outcomes may be: ○ Self-reported cases of illness (such as rash) following natural recreational water exposure ○ Confirmed diagnosis of toxic response following exposure.
Study Type	The review will consider: • Reviews of recreational water quality risk monitoring and management focussing on: ○ Identification and evaluation of existing methodologies for health risk assessment for chemical exposures; and ○ Site-specific case studies. • Existing recreational water quality guidelines/reports. A listing of reports supplied by the RWQAC is included in **Appendix 3**. • Grey literature, reports and guidelines from reputable international and national agencies (e.g. WHO, US EPA, State and Commonwealth Departments of Health, State EPAs, environmental agencies of OECD member countries where such documents are available in English, etc.) Where possible, the above studies will be categorised according to a selected list of Critical Appraisal Skills Programme (CASP) study types as follows: 1. Case control study 2. Cohort study 3. Diagnostic test study 4. Systematic review 5. Qualitative research 6. Randomised controlled trial (RCT) 7. Cross-sectional study (mix of case-control and cohort) Study categories will be used to guide a critical appraisal of study quality and selection for the review. See following sections. It is possible that the literature will contain very few if any case-control, cohort, diagnostic test, RCT or cross-sectional studies. However, there may be some systematic reviews and qualitative research studies to which the CASP method can be applied.

2.5. Search Strategy and Selection of Evidence

The specific steps that will be taken to find and select the evidence to be reviewed are outlined in Table 2-2.

Table 2-2. Summary of search strategy and selection of evidence

Item	Comment
Search terms	Keywords to be used to search for publications based upon the PECO elements and research questions – these will be used across all databases for consistency. **Key search terms** aboriginal, acid mine drainage, adverse effects, aerosols, allergic reaction/s, ambient water quality, analysis, anglers, angling, antibiotics, antimicrobial resistance, athletes, aural, bather acquired , bathing, bathing beaches, beach/es, benzene, bioaccumulative, boating, body-boarding, body-surfing,

Item	Comment
	BTEX, canoeing, case control study, chemicals, children, classification, coast, coastal, cohort study, colour, contaminant, control, cross-sectional study, dam, dermal, dermal irritation, dermatologic, diagnostic test study, diarrhea, diarrhoea, disability adjusted life year, disease, divers, diving, domestic animals, dose-response, effluent, elderly, endocrine, endocrine disruptors, estuaries, ethylene, exposure, eye irritation, fever, fishing, fishing canoe, fishing kayak, fishing riverbank, fishing shoreline, fishing wading, flu-like, freshwaters, fuel, gastroenteritis, gastrointestinal, hay fever-like, headache, health, health effects, health outcome/s, heavy metals, hepatotoxicity, hydrocarbons, illness, illness/es, immunocompromised, indicator, indigenous, induction of asthma, industrial discharges, ingestion, inhalation, inhalation-related symptoms, inorganic, jet skiing, jet-skiing, jurisdiction, kayakers, kayaking, kiteboarding, kitesurfing, lake, legislation, livestock, marine, methylated, methylated metals, microplastics, mine discharge, nanomaterials, nanoparticles, nausea, neurologic/al, neurotoxicity, non-point source pollution, nonylphenols, ocular, oil and grease, oral, organic, outbreaks, outfall, paddling, parasailing, pentathlon, perfluorinated, persistent, pesticides, PFAS, pharmaceuticals, pneumonia-like symptoms, point source pollution, potentiation, pregnant women, prevention, primary contact recreation, pruritis, qualitative research, quantitative risk assessment, randomised controlled trial, recreation, recreational, recreational exposure, recreational guidelines, recreational water quality, risk, river, rowing, runoff, sail boarding, sailing, saline waters, sand, scuba, sea kayaking, secondary contact recreation, sewage, sewage discharge, sewer overflows, shortness of breath exposure, skin irritation, skin rash/es, snorkelling, source tracking, source vulnerability, spearfishing, spills, standards, stormwater, sunbathing (no contact), sunscreen, surfactants, surfers, surfing, swimmer acquired , swimming, symptoms, synergism, systematic review, toluene, Torres Strait Islander, tourists, toxic, trace metals, triathlon, turbidity, , vomiting, wading, wakeboarding, wastewater, water contamination, water parks, water pollution, water quality, water skiing, water sports, wave-boarding, whitewater canoeing, wildlife, wind surfing, wind-surfing, xylene, zinc oxide Variations on terms that may appear with hyphens will also be considered (e.g. nanoparticle versus nano-particle). **Potential search strings** Potential search strings will be developed based on the above key words after familiarisation with the different search engines. It is possible that hierarchical searches will enable some compaction of the search terms, e.g. recreational water activities may be grouped under one search string.
Databases	The following databases will be searched: PubMed, Scopus, Google Scholar SpringerLink. Searches may also be made on Science Direct, Web of Science, Wily Online Library subject to further advice and liaison with RMIT University library services. Access to subscription databases will be via RMIT University library services.
Publication date	As noted earlier, NHMRC has suggested reviewing publications from 2003/4 onwards. Although the existing Guidelines were published in 2008, extending the date range back to 2003 should assist in locating any documents that may have been overlooked, or have become recognised as being of greater importance since that time, or missed the cut-off period during the preparation of the guidelines (believed to be 2004).
Language	Only English language documents will be reviewed. In the event that that RWQAC should decide that a non-English publication should be included, translation of this publication will be arranged by ONHMRC.

Item	Comment
Inclusion and exclusion criteria	Criteria for Inclusion/exclusion are: • Inclusion of all study types (local and international surveys; peer-reviewed publications or government reports/guidelines for indicators). • English language only. • Human health outcomes only (or well-conducted animal studies if human data is unavailable). • Publication date range from 2003 onwards. • Peer reviewed publications only with the exception of certain grey literature reports and guidelines from reputable international and national agencies (e.g. WHO, US EPA, State and Commonwealth Departments of Health, State EPAs, etc.). Most such documents would be peer-reviewed but determining if and how such peer review took place may not always be clear. • The list of existing recreational water guidelines/reports supplied by RWQAC (see **Appendix 3**). Importance (priority rating) of outcomes to be considered as part of the review using the CASP assessment protocols (see Section 2.7).
Validation methods	The search strategy will be validated to check that it works before undertaking a full search. This will be done by performing an initial search based upon the chosen search terms and evaluating the number of records retrieved. If very large numbers of records are retrieved, it will be taken as an indication that the search terms and strings need to be revised. Similarly, if very few records are retrieved where it is expected that many records would occur, this implies that the search strategy may need to be made less restrictive (e.g. by use of wildcard terms like "*" etc.). Search term efficiency can be improved by adding or modifying criteria and filters. For example, by combining "Fishing" and "Secondary Contact Recreation" papers addressing exposure via fishing are likely to be more efficiently retrieved and not swamped by papers addressing only fishing or other types of secondary contact recreation. It is expected that RMIT University's librarian will provide assistance here in constructing efficient search terms. Determining when too many search hits occur and when there are too few, is a somewhat subjective process. However the reality is that only several hundred documents at a maximum can be assessed within the resources of the project, that such lists can be confidently expected to contain the key references, and that lists of such length will contain a lot of duplication. Such considerations put an upper bound on the number documents to be considered. At the other end of the spectrum (i.e. too few documents retrieved), it would be expected that search terms and strings resulting in inadequate numbers of hits would be highlighted by the fact that many of the references supplied the RWQAC had been missed. Similarly, if all such documents are included, it would be a sign that the search strategy was effective enough. Another process that will assist in determining the effectiveness of the search terms and strings will be "forward and backward citation chasing". This involves searching backward in time by finding sources cited within a research article – often listed in a bibliography or references section – or forward in time by looking for sources that cite the article itself. If this process dredges up additional relevant documents that have been missed by the search terms and strings, it will be considered as an indication that the search efficiency needs to be improved as discussed above.
Screening methods	Search strings will initially be set to search key words, titles and abstracts, however, if thousands of publications are retrieved, search strings may be set to search just titles and key words. In addition, where high quality

Item	Comment
	review articles are identified, these may be used as the main evidence in response to the primary and secondary research questions or supporting questions posed by the RQWAC. Publications about which we are uncertain will be included in the first instance but noted as such and later evaluated for exclusion. The criteria for exclusion will be documented and advice may be sought from the RWQAC at that time. Presently it is difficult to propose specific criteria until the search has been undertaken. A summary of how documents were screened will be included consistent with the PRISMA method recommended by Moher, Liberati, et al., (2009). (see **Appendix 4**).
Quality check	See discussion under validation methods above
Grey literature	In addition to the grey literature list provided by RWQAC (**Appendix 3**) we will also search the websites of the following international organisations focussing on the first 40 titles of reports and documents retrieved in each case: • British Medical Research Council (MRC) • Centre for Disease Control and Prevention (CDC) • Environment Canada • European Centre for Disease Prevention and Control (ECDC) • European Environment Agency (EEA) • Health Canada • New Zealand Ministry of Health (NZ MoH) • Public Health England (PHE) • United Nations Environment Programme (UNEP) • United Nations Environment Programme Mediterranean Action Plan (UNEP MAP) • United States Environment Protection Agency (US EPA) • World Health Organization (WHO) It will not be possible to search the websites of the above organisations using the search terms and search strings described for the major database searches as these will be too long and complicated for the simple search engines associated with each website. Instead an abbreviated list of terms will be used – most likely such terms as recreation, water quality, primary and secondary contact etc. Lists of terms will be trialled, gauged for efficiency, and documented in the evaluation and technical reports to permit reproducibility of search results.
Documentation of search	Search results will be documented using the template shown in Table 2-3 which is based loosely on the PRISMA approach (Moher, Liberati, et al., 2009). Search results will record which publications have been found, which ones were excluded and the justification/criteria for exclusion. If there are many documents listed, this data may be supplied in an Excel Spreadsheet.
Retrieval of publications	The list of retrieved publications and any electronic copies will be stored in a bibliographic database using the Zotero bibliographic software (https://www.zotero.org/). We currently make extensive use of this software for our consulting work. Bibliographic data can be exported to other bibliographic software as required, e.g. Endnote. Papers will be held as electronic versions and reviewed in this format. Occasionally we may print off hard copies of high quality references where this assists in readability of the document. All search results and project files are held on a secure server at Ecos which is backed up to a secure cloud server via Ctera Networks subscription (https://www.ctera.com/). The cloud backups are time-based and lost files can be retrieved from previous backups going back several months. The system is also secure against ransomware attacks.

2.6. Process for extracting and presenting data

Information to be extracted from the publications identified in the searches will depend on the research questions, the PECO criteria, the evidence related to inclusion, the study methodology and evidence strength and limitations. A draft template for data extraction is set out in Table 2-3. The template includes bibliographic information (e.g. authors, year of publication), year(s) of study period, country of study, study characteristics etc.) and is cross-referenced with a classification of study quality and risk of bias (see section 16). Database tools in either Microsoft Excel or Microsoft Access will be used to construct an integrated report on each publication and to calculate summary statistics on the publication attributes. The decision on which software package to use will depend on the size of the search results. Tabulations of summary statistics will be presented in the Evaluation Reports and detailed tabulation of the results on key studies will be included in the Technical Reports.

Table 2-3. Draft template for data capture and presentation

Category	Item	Description
General information	Study ID	
	Date template completed	
	Authors Publication date Publication type Peer reviewed Country of origin Source of funding Possible conflicts of interest	
Study characteristics	Aim/objectives of study	
	Study type/design	
	Study duration	
	Type of water source/water body	
Population characteristics	Population/s studied	
	Selection criteria for population	
	Subgroups reported	
	Size of study	
Exposure and setting	Type of water source/water body Exposure scenario Exposure pathway Source of infection/contamination Causal chemical(s) Comparison group(s)	
Study methods	Water quality measurement used Method of chemical detection (if applicable) Water sampling methods (monitoring, surrogates). Was there sufficient replication in number of samples taken, what steps were taken to reduce contamination (especially for metals)? Limits of reporting for the chemical of concern Consideration of quality assurance such as field and lab blanks, reference sites, and reporting on related physico-chemical parameters	
Results (for each outcome)	Definition of outcome How outcome was assessed Method of measurement	

Category	Item	Description
	Number participants (exposed/non-exposed, missing/excluded) (if applicable)	
Statistics	Statistical methods used Details on statistical analysis (if any) Relative risk/odds ratio, confidence interval?	
CASP Category and OHAT Risk of Bias	Studies will be categorised according to a selected list of Critical Appraisal Skills Programme (CASP) or Cochrane/OHAT definitions of study types as follows: 1. Case control study 2. Cohort study 3. Diagnostic test study 4. Systematic review 5. Qualitative research 6. Randomised controlled trial 7. Cross-sectional study (mix of case-control and cohort) Study categories will be used to guide a critical appraisal of study quality and selection for the review. Excluding Systematic reviews and Qualitative Research, OHAT Risk of Bias Rating Tool classifications will be applied to each study type. Note that the OHAT classification steps differ for each study type, but that the final classification is consistent across study types (See Section 2.7)	
Author's conclusion	Interpretation of results Assessment of uncertainty (if any)	
Reviewer comments	Results included/excluded in review (if applicable) Notes on study quality e.g. gaps, methods	

2.7. Critical appraisal of evidence and risk of bias assessment

2.7.1. Critical appraisal of evidence

The quality of each study to be included will be assessed using the CASP (Critical Appraisal Skills Programme, Oxford CTVH, 2020)[1] quality assessment protocols for observational studies. The studies will be categorised according to a selected list of CASP study types as follows:

1. Systematic review
2. Qualitative research
3. Case control study
4. Cohort study
5. Diagnostic test study
6. Randomised controlled trial
7. Cross-sectional study (mix of case-control and cohort)

These study categories will be used to guide a critical appraisal of study quality and selection for the review.

The CASP protocol considers three broad issues in appraising a study:

(i) Are the results of the study valid?
(ii) What are the results?

[1] For further information on each CASP checklist see https://casp-uk.net/casp-tools-checklists/

(iii) Will the results help locally?

Depending on the type of study 10 to 13 questions are posed within the three categories above that are designed to assist the reviewer to consider the issues systematically. The first two to three questions are screening questions and can be answered quickly. If the answer to each is "yes", it is worth proceeding with the remaining questions. There is some degree of overlap between the questions and the reviewer is asked to record a "yes", "no" or "can't tell" to most of the questions. A number of supporting hints or prompts are listed for each question which are designed to remind the reviewer why the question is important. Answers and reasons to all questions are recorded in a table for each reviewed document (see **Appendix 5**). The response to the first few questions can be used as a filter to exclude studies that do not address a clearly focussed issue or use appropriate methodologies.

2.7.2. Risk of bias (quality) assessment

Risk of bias is also addressed to some extent by the questions listed in the CASP checklists, however, other more rigorous protocols can be applied to the following study types.

1. Case control study
2. Cohort study
3. Diagnostic test study
4. Randomised controlled trial
5. Cross-sectional study (mix of case control and cohort)

For these study types, we propose to apply the OHAT Risk-of-Bias Tool (OHAT = Office of Health Assessment and Translation of the US National Toxicology Program, OHAT, 2020). Note that each study will be cross-checked against CASP and Cochrane definitions (**Appendix 6)** to ensure correct classifications.

The methodological quality of individual studies will be assessed using an adaptation of the OHAT risk of bias tool (**Appendix 7**). Studies will be evaluated on applicable risk of bias questions based on study design. For each study, the OHAT Risk-of-Bias Tool poses 11 questions with specific questions applicable to each of the 6 different study design types. Since our PECOS table excludes experimental animal studies, this category is not included. It is also possible that Diagnostic Test Studies may be not be covered in the OHAT classification, however, this determination will be resolved once we have begun the literature review processes. The studies in the remaining categories will be classified according to the presence and extent of bias as follows:

++ ***Definitely Low*** *risk of bias*:

There is direct evidence of low risk-of-bias practices

(May include specific examples of relevant low risk-of-bias practices)

\+ ***Probably Low*** *risk of bias*:

There is indirect evidence of low risk-of-bias practices **OR** it is deemed that deviations from low risk-of-bias practices for these criteria during the study would not appreciably bias results, including consideration of direction and magnitude of bias.

– NR

***Probably High** risk of bias*:

There is indirect evidence of high risk-of-bias practices **OR** there is insufficient information (e.g., not reported or "NR") provided about relevant risk-of-bias practices

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***Definitely High** risk of bias*:

There is direct evidence of high risk-of-bias practices

(May include specific examples of relevant high risk-of-bias practices)

A conservative approach is taken wherein insufficient information to clearly judge the risk of bias for an individual question results in an answer rating of "Probably High" risk of bias.

Some of the key aspects that need to be examined include:

- The selection of the population studied
- How the exposure was defined/assessed
- Were the methods used valid?
- Whether any important confounders were identified and controlled for
- Whether any statistical analysis was undertaken
- Did the study show the linkage between cause and effect?

Data used to assess risk of bias will be extracted using existing approaches/templates such as those available in the OHAT Handbook, from the CASP website or the appendices of the US EPA (draft) methodological framework (US EPA, 2018) depending on study type. Study types that do not have an existing template (such as monitoring studies) can be assessed against the usual risk of bias domains using questions such as those outlined in the OHAT framework Table 5 where applicable.

Studies that are determined to have a high risk of bias or serious concerns with study quality can be excluded from the review. Their removal will be recorded with justification in the PRISMA flow diagram.

Conflicts of interest and funding data from the study characteristics tables will be considered when assessing whether these might have affected any of the risk of bias domains (e.g. selection of comparators, selective reporting of results). If there are serious overall concerns, these will be noted under 'Other sources of bias' in the risk of bias tool in Appendix 8.

The outcome of the risk of bias assessment will be presented in the Evidence Evaluation Report (described in Section 2.9.1), together with a discussion of the overall quality of each study. Full details of each assessment will be provided in the Technical Report (also described in Section 2.9.2).

Once a determination of risk of bias for each domain has been made, a visual summary of the risk of bias ratings for the included studies can be prepared and used in the next stage of the critical appraisal process to determine overall risk of bias across the body of evidence (see the OHAT Handbook Table 9 and **Appendix 8**).

2.8. Process for Assessing the Body of Evidence

The evidence collected and appraised for each research question will be grouped by study type and outcome if possible and summarised in an Evidence Summary table that will have an assignment of the certainty (or confidence) in that body of evidence.

2.8.1. Assessment of the body of evidence

A process based on the OHAT approach to using the GRADE system will be used to assess the certainty of a body of evidence. Evidence streams for each research question will be tabulated together by outcome if possible. An overall certainty rating will be assigned to each evidence stream after the domains used to assess certainty in the GRADE framework are applied to the body of evidence. These domains are:

- Overall risk of bias across studies;
- Unexplained inconsistency;
- Imprecision;
- Indirectness; and
- Publication bias.

Under the GRADE system, the overall quality of the evidence for an outcome is categorised as high, moderate, low or very low.

Each evidence stream will be assigned an initial certainty rating similar to that described in the OHAT Handbook Table 8. For example, evidence from randomised controlled trials is initially graded as high certainty and evidence from observational studies is initially graded as low certainty. If there are any study types that do not have an initial rating, an appropriate initial rating will be determined by the reviewer in a similar manner to the approach used in OHAT Handbook Table 8.

The certainty of the evidence can be downgraded or upgraded from the initial rating if any of the conditions in Figure 2-1 (elaborated in Table 2-4) are met. If none are met, the initial certainty rating is kept. These domains are explained in more detail in the OHAT Handbook. Conflicts of interest and funding sources will also be considered as a reason to downgrade if there are serious concerns that these have influenced the findings from the body of evidence.

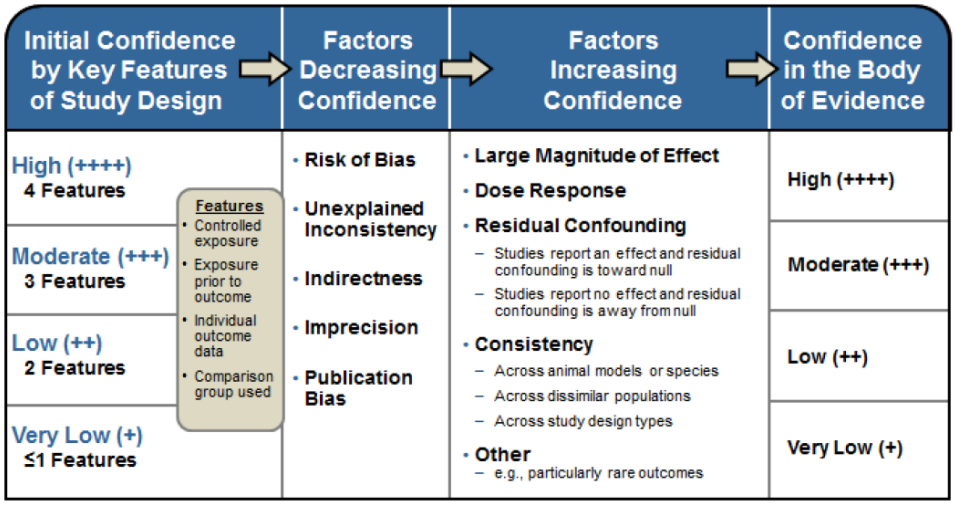

Figure 2-1. OHAT method for assessing confidence in the Body of Evidence (OHAT, 2019)

Table 2-4. OHAT reasons for down grading or upgrading certainty of evidence

Reasons to Downgrade	Reasons to Upgrade
• **Risk of bias** - Serious or very serious concerns about study quality across the body of evidence (reliability) (see **Appendix 9**) • **Unexplained inconsistency** - Important inconsistency of results across the included studies that can't be explained by study design • **Indirectness** - Some or major uncertainty about directness (relevance to the research question that is being answered) • **Imprecision** - Imprecise or sparse data • **Publication bias** - High probability of reporting bias (selective reporting of results across the body of evidence that might skew results)	• **Consistency** - Strong or very strong evidence of association based on consistent evidence from two or more observational studies, with no plausible confounders • **Magnitude of effect** - Very strong evidence of association based on direct evidence with no major threats to validity • **Dose-response** - Evidence of a dose-response gradient • **Residual confounding** - All plausible confounders would have reduced the effect • **Other reasons** – any topic-specific reasons as determined by experts in the field

The results of the certainty assessment process will be tabulated in a similar manner to that described in the OHAT framework (**Appendix 9**). Where a conclusion is unable to be made by the reviewer around any of the domains (e.g. inconsistency and imprecision may be difficult to ascertain with the kind of evidence that will be included in the review) this will be recorded as 'not applicable' or 'unknown'. Tables summarising the results for each outcome will be included in the Evidence Evaluation Report (see Section 2.9.1) and the full evidence profiles will be included in the Technical Report (Section 2.9.2).

2.9. Process for reporting of review findings

Following on from the production of this Research Protocol, two additional documents are to be produced to meet the needs of the Narrative Review, namely the Evidence Evaluation Report and the Technical Report. Report outlines for each document are presented in the following sections. As discussed earlier, we will use database tools to capture and generate report tables. Data synthesis for the Evidence Evaluation Report will be informed by meta-analyses where there is sufficient data to permit such an approach.

A summary of the methodology used to find and select the studies and the findings of the critical appraisal process will be included in the Evidence Evaluation Report. Full details will be provided in the Technical Report.

Outcome data presented in the included studies will be extracted and will be presented in an evidence summary table as appropriate, along with the overall certainty rating for those results. Draft evidence statements outlining how these results address the relevant research questions will be prepared. The evidence statements will take into account the extent and strength/limitations of the evidence. The evidence statements will be considered by RWQAC, who may provide advice on their revision.

2.9.1. Evidence Evaluation Report outline

The Evidence Evaluation report will consist of:

- Executive summary
- Introduction and Background: including definitions of key terms, outcome measures, abbreviations, rationale for review and objectives
- Methodology: brief overview only, with a reference to full details to be provided in the Technical Report
- Results: a summary of results for each research question, main findings, document characteristics
- Discussion: including strengths and limitations of the studies, comparison of existing literature, a discussion of gaps in the evidence (if identified during the evaluation of the evidence) and a suggestion of areas for further research
- Conclusions
- References
- Appendices
- References

2.9.2. Technical Report outline

The technical report will document detailed information about the methods used to undertake the literature reviews that would otherwise make the Evaluation Report difficult to read (e.g. lists of excluded studies, pages of search strings, individual study report tables). Similar to the Evidence Evaluation report, the Technical Report will describe the methodology used; however, this will be done in full detail, including:

- the research questions;
- the search strategy used to identify and retrieve studies;
- the process for selecting studies (i.e. inclusion/exclusion criteria);
- the methodology used to critically appraise the literature and the quality assessment of included studies;
- the methods used for data extraction;
- the methods used to critically appraise and synthesise the data of included studies;
- the methods used to analyse and summarise the results of included studies;
- the methods used for any calculations and explanatory text for any assumptions if used;
- documentation of the declared interest(s) of the author(s) of each paper;
- a description of how comments from the independent methodological review of the draft research protocol were addressed.

2.10. Process for Assessing Existing Guidance or Reviews

Due to the large volume of evidence that will be found undertaking some of the systematic literature search, several secondary research questions will be addressed instead using a review of existing guidance or reviews.

Recapping from Section 2.3.2, the secondary questions to the primary question[2] are:

(i). What chemicals (that potentially pose a risk to humans) are present at elevated concentrations in recreational waters and what are their sources?

(ii). What chemicals are of most concern due to their physicochemical properties which may enhance their uptake via dermal, inhalation or ingestion exposure pathways? How can we adjust exposure assumptions for these chemicals?

(iii). Should the focus be on "hot spots" i.e. site-specific rather than chemical specific, and/or include periodic toxicity screening of sites to complement chemical testing?

In addition, in Section 2.3.3 the RWQAC listed the following topics in relation to chemical hazards in recreational water that may assist in developing responses to the above questions (Table 2-5).

Table 2-5. Additional topics to consider in answering the secondary questions for this narrative review (reproduced from Section 2.3.2)

Additional Topics	Tasks required

• Substances of interest to include:
  ○ Key contaminants of concern in recreational waters;
  ○ Metals and metalloids, halogenated organic compounds and PAHs, nutrients, water soluble trace organic contaminants, PFAS;
  ○ Other high-risk chemicals and chemical hazards such as sunscreens and nanoparticles;
• Risk assessment methods (including exposure assessment calculations and assumptions);
• Consideration of short, medium- and long-term exposures; and
• Consider whether existing aquatic ecosystem health indicators can be used as surrogates for recreational water quality, noting that aquatic organisms are substantially more sensitive to toxicants than humans.
• In addition to the last point, consideration of the use of indicator substances for chemical risk assessment and monitoring.
	• Inclusion of extensive list of substances of interest in search terms
	• Data extraction template (Table 2-3) includes consideration of study methods including statistical methods plus CASP study classification and assessment
	• Assessment of aquatic ecosystem health indicators as surrogates for recreational water quality
	• Review whether substances common in contaminated waters (e.g. waters receiving effluent discharge) can be used as indicators for the presence of other toxicants.

These reviews may be best achieved by reviews of existing guidance or reviews.

Similar search strategies to those used to search and select primary studies will be used to identify existing guidance and reviews. In addition, grey literature such as jurisdictional reports and guidance will be provided by RWQAC members and assessed by reviewers.

[2] *Are exposures to the hazards outlined in the PECO Table below likely to give rise to any significant human health risks given that chemical concentrations in recreational waters are generally low?*

2.10.1. Critical appraisal of existing guidance and reviews

The methodological quality of the existing guidelines or reviews will be assessed using an adaptation of the tool provided in **Appendix 10**. The criteria listed in the tool are based on common domains that are evaluated in several existing tools for assessing guidelines and systematic reviews (e.g. AGREE tool). Criteria that are deemed appropriate/inappropriate for a research topic or evidence type (guideline process v reviews) will be removed or added as needed. One reviewer will be performing the assessment.

2.10.2. Presentation of the findings of the review

A summary of the methodology used to find and select existing guidance/reviews and the findings of the critical appraisal process of the included guidance/reviews will be included in the Evidence Evaluation Report. Full details will be provided in the Technical Report.

Outcome data presented in the guidelines/review will be extracted and will be presented in a results tables (evidence summary table) or figures as appropriate. Any important limitations of the existing guidance/reviews will be described. Draft evidence statements outlining how the existing guidance/reviews address the relevant research questions will be prepared. The evidence statements will take into account the extent and strength of the evidence. The evidence statements will be considered by RWQAC, who may provide advice on their revision.

2.11. Additional searches and process for making amendments to the protocol

2.11.1. Additional searches

It is acknowledged that feedback from the RWQAC and the project team may require further searches or information/reports sought. This feedback will be recorded for eventual inclusion in the evidence evaluation or technical report. Studies that are excluded after data extraction will also be recorded with justification.

2.11.2. Process for making amendments to the protocol

Where the nature of the available data dictates the need for changes to the research protocol, such changes will be documented in the Technical Report, and approval sought beforehand from NHMRC (e.g. the RWQAC) to make sure such changes are transparent.

2.12. Declaration of interests

The Authors of this Review have the following declared interests:

Interest Details	Summary
Dr Nick O'Connor	
Consultant in science and engineering to the Australian water industry. Recent major clients are listed below.	As principal consultant at Ecos Environmental Consulting, I am involved in many consulting projects for clients in the public and private sectors. However, the majority of my clients are regional and metropolitan water

	corporations for whom I provide consultancy advice in the areas of water-related human health and ecological risk assessment.
Consultant to Melbourne Water	I provide consultancy advice in the areas of water-related human health and ecological risk assessment.
Consultant to VicWater (Victorian Water Industry Association)	I provide consultancy advice about chemicals of concern in recycled water.
Member of Scientific Services Consultancy Panel for South East Water	I provide consultancy advice in the areas of water-related human health and ecological risk assessment.
Consultant to Victorian Department of Environment, Land, Water and Planning, Victorian Department of Health and Human Services and Victorian Environment Protection Authority.	I recently undertook a project in conjunction with Atura P/L and Water Futures P/L to develop the 2020 version of the Victorian Recycled Water Guidelines.
Dr Yufei Wang	
Researcher in chemical and environmental engineering, with a focus on industry-based water research. Recent projects summarised below:	As a researcher at RMIT University, I am involved in several water research projects, performing analysis and providing consultancy advice to our industrial partners.
Photolysis of emerging contaminants, R&D project for Melbourne Water	I perform research activities and report findings assessing the environmental impact on the attenuation of chemicals of concern and provide consultancy advice on their associated risks in recycled water.
Validation framework review and drinking water supply system performance assessment, R&D project for Water Source Australia	I provide consultancy advice about assessment of disinfection performance of a Point of Entry drinking water supply system.
Publication of journal articles	I report findings of my research on behaviour and risk assessment of chemicals of concern in recycled water

3 References

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NHMRC (2008) *Guidelines for managing risks in recreational water. National Health and Medical Research Council (Australia)*, Canberra, A.C.T., National Health and Medical Research Council. [online] http://www.nhmrc.gov.au/publications/synopses/_files/eh38.pdf (Accessed October 18, 2012).

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Oxford CTVH (2020) CASP - Critical Appraisal Skills Programme. Oxford Centre for Triple Value Healthcare Ltd. [online] https://casp-uk.net/ (Accessed June 13, 2020).

Rodrigues, A., Oliver, D. M., McCarron, A., and Quilliam, R. S. (2019) Colonisation of plastic pellets (nurdles) by E. coli at public bathing beaches. Marine Pollution Bulletin, **139**, 376–380. [online] http://www.sciencedirect.com/science/article/pii/S0025326X19300116 (Accessed June 22, 2020).

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Appendix 1 - Guideline Scope and Application

Unlike the *Guidelines for Managing Risks in Recreational Water* (2008), the updated Guidelines will cover the public health risks associated with recreational water quality *only*. This includes human health risks from biological and chemical hazards that affect the quality of recreational water that people might be exposed to. Other risks associated with recreational water use such as physical risks should be considered as part of the risk management planning process while applying the Framework; however, specific guidance on how to manage these risks will not be provided in the Guidelines. In addition, the Guidelines will not cover details on rescue, resuscitation or treatment associated with risks from recreational water quality.

The Guidelines should be applied within the broader context of protecting public health and as such are not intended to be prescriptive given the variety of recreational water settings and climates across Australia. The inclusion of the Framework is intended to allow for structured risk assessment and risk management planning across the wide variety of existing and emerging recreational water environments that Australian risk managers might encounter. This also includes any unique sites that are currently unregulated and may present risks to public health.

Included: Risks from microorganisms, cyanobacteria and algae, free-living microorganisms, chemical hazards.

Excluded:

- Risks from sun, heat and cold and other physical hazards associated with recreational water (e.g. drowning, animal attacks)
- Risks associated with exposure to foodstuffs collected from recreational water or its surroundings;
- Risks associated with ancillary facilities that are not part of the recreational water environment other than risks that may affect water quality (e.g. toilet facilities in adjacent areas are not considered unless these need to be managed to minimise contamination of the recreational water body);
- Adverse health effects that are not caused by recreational water quality (e.g. seasickness, the ‘bends’);
- Risks from sand/soil around recreational water bodies (unless disturbances of sand/soil affects water quality); however, the risk management framework should include assessment of these risks.

Appendix 2 - Definitions of Uses and Users of Recreational Water

Recreational water:

Included: Any natural or artificial water bodies without a chlorine disinfectant residual that might be used for recreating including coastal, estuarine and freshwater environments. Includes public, private, commercial and non-commercial recreational water sites. Includes unique unregulated sites such as wave pools, ocean- or river-fed swimming pools, artificial lagoons and water ski parks.

Excluded: Aquatic facilities using chemical disinfection including swimming pools, spas, splash parks, ornamental water sites.

Recreational water use:

Included: Any designated or undesignated activity relating to sport, pleasure and relaxation that involves whole body contact or incidental exposure (through any exposure route) to recreational water (e.g. swimming, diving, boating, fishing)

Excluded: Consuming the catch from fishing or foodstuffs collected from recreational water or its surroundings. Therapeutic uses of waters (e.g. hydrotherapy pools). Occupational exposure.

Recreational water users:

Recreators or users of recreational water bodies including:

- the general public including all relevant life stages, ages and states of health other than persons that are explicitly advised to avoid such activities (e.g. for specific medical conditions)
- tourists
- specialist sporting users (e.g. athletes, anglers, kayakers, divers, surfers)
- any groups that may have high exposures to recreational water.

Target audience of the Guidelines:

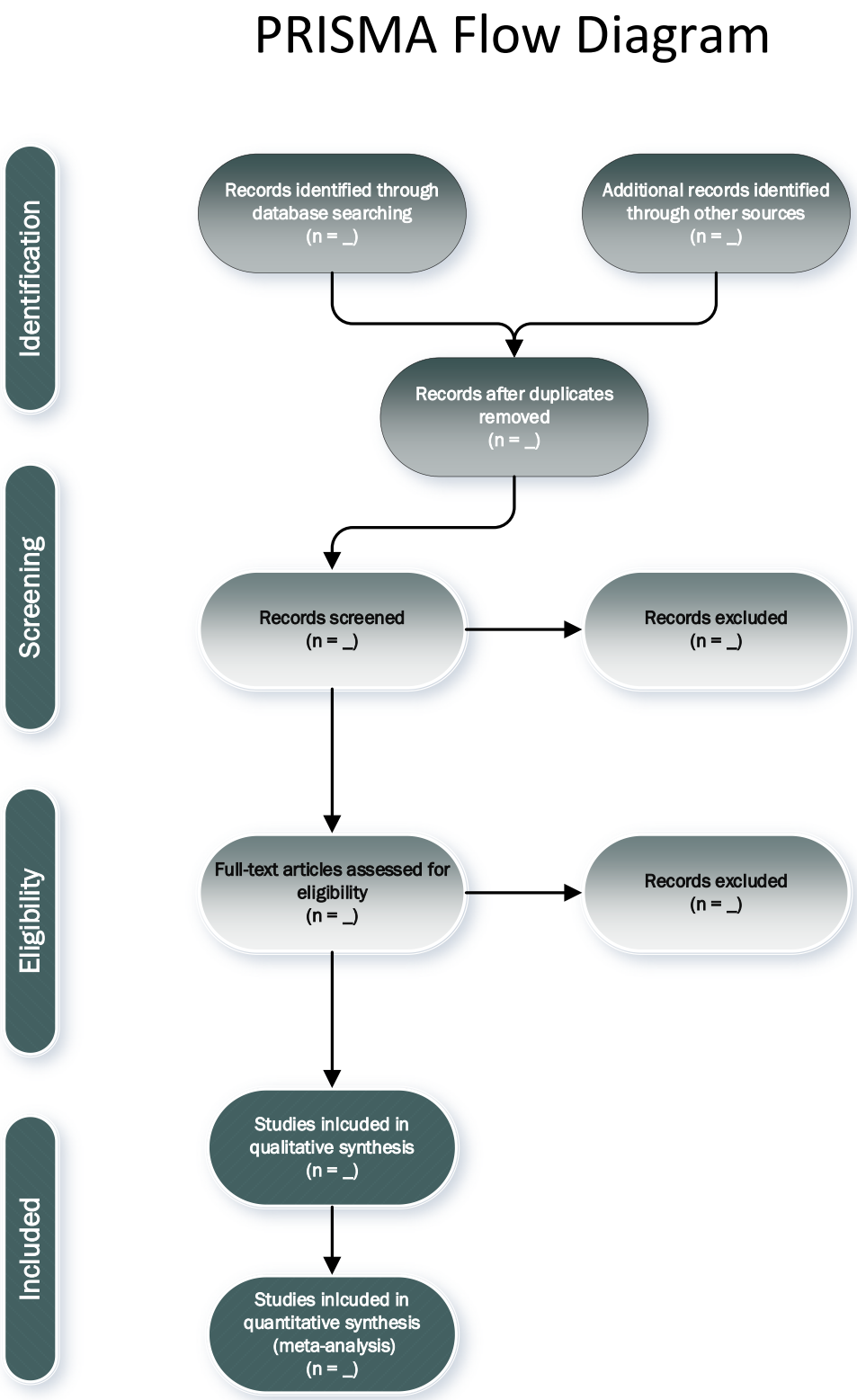
The Guidelines are intended for end users that will implement the Guidelines (government agencies, local councils, private recreational water managers); however, it is anticipated that there will also be significant public interest. It is anticipated that tailored guidance (e.g. plain English fact sheets or summaries) will be developed for specific groups where necessary.

Appendix 3 – List of existing recreational water quality guidelines/reports supplied by RWQAC

Existing recreational water guidelines /reports	Relevance	Adopt/adapt suggestions
NHMRC		Recreational guidelines 2008 Gaps regarding diffuse sources of faecal contamination (and animal sources)
MoE (NZ)	Y	MoE 2003. New Zealand guidelines 2003 https://www.mfe.govt.nz/publications/fresh-water/microbiological-water-quality-guidelines-marine-and-freshwater-0 Contains guidelines relevant to freshwater
	Y	MoE 2018. Regional information for setting draft targets for swimmable lakes and rivers A report on work underway to improve water quality in terms of effects on human health https://www.mfe.govt.nz/sites/default/files/media/Fresh%20water/Regional%20information%20for%20setting%20draft%20targets%20for%20swimmable%20lakes%20and%20rivers-final.pdf Catchment wide approach
OEH NSW 2011	Y	OEH NSW, 2011. Protocol for assessment and management of microbial risks in recreational waters. Office of Environment & Heritage, NSW, Sydney. Provides a simple template for sanitary inspections
EPA Victoria	Y	Pending publication related to QMRA study in Port Phillip Bay, Victoria Provides a simplified adaptation of sanitary inspection template from OEH NSW 2011 Provides key assumptions for a QMRA model (volume of ingestion, dose-response models, probability of getting ill when infected, etc.) Results will also be published in peer-reviewed articles (journals TBC)
US EPA	Y	U.S. EPA 2005. The EMPACT Beaches Project: results from a study on microbiological monitoring in recreational waters. National Exposure Research Laboratory, Office of Research and Development, United States Environmental Protection Agency, Cincinnati, Ohio. USEPA 2012. Recreational Water Quality Criteria. U.S. Environmental Protection Agency, Office of Water, Washington, DC. EPA 820-F-12-058 Available at: https://www.epa.gov/sites/production/files/2015-10/documents/rwqc2012.pdf U.S. EPA 2010. Quantitative Microbial Risk Assessment to Estimate Illness in Fresh water Impacted by Agricultural Animal Sources of Fecal Contamination. EPA 822-R-10-005. Available at: http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/P4-QMRA508.pdf US EPA, 2010. Comparison and Evaluation of Epidemiological Study Designs of Health Effects Associated with Recreational Water Use. US EPA, 2014. Microbial Risk Assessment (MRA) Tools, Methods and Approaches for Water Media. US EPA Office of Water, Washington DC. US EPA, 2016. 2016 Coliphage Experts Workshop: Discussion Topics and Findings No. EPA 823-F-16-001. Washington D.C. Review evidence of risks related to agriculture sources of faecal contamination and tools for monitoring and risk assessment
State of Hawaii	Y	State of Hawaii Water Quality Standards, 2014. Available at: https://health.hawaii.gov/cwb/files/2013/04/Clean_Water_Branch_HAR_11-54_20141115.pdf Catchment-wide approach to recreational water quality with water quality certification Beach report available at:

Existing recreational water guidelines /reports	Relevance	Adopt/adapt suggestions
		http://www.beachapedia.org/State_of_the_Beach/State_Reports/HI/Water_Quality#Identifying_Sources_of_Contamination_in_Nawiliwili_Bay_and_Hanalei_Bay Tiered approach to monitoring and identification of contamination sources
WHO	Y	WHO, 2003. Guidelines for Safe Recreational-water Environments, Coastal and Fresh-waters, vol. 1. World Health Organization, Geneva. Revision underway. WHO, 2016. Quantitative Microbial Risk Assessment: Application for Water Safety Management. World Health Organization, Geneva https://www.who.int/water_sanitation_health/publications/srwe1/en/ Describes tiered risk assessment approach to assess to water quality with examples in various settings
enHealth, 2012.	Y	Environmental health risk assessment: - Guidelines for assessing human health risks from environmental hazards. Commonwealth of Australia
NRMM 2006	Y	Australian Guidelines for water recycling: Managing health and environmental risks (Phase 1). Natural Resource Management Ministerial Council, Environment Protection and Heritage Council, Australian Health Minister's Conference, Canberra, Australia. Provide dose-response models and approach to risk assessment. Recent review should be finalised soon
Health Canada 2012	Y	Health Canada 2012. Guidelines for Canadian Recreational Water Quality, Third Edition. Water, Air and Climate Change Bureau, Healthy Environments and Consumer Safety Branch, Health Canada, Ottawa, Ontario. Provides good information on indicators and gaps in knowledge. Good descriptions of science based evidence to develop guidelines.

Appendix 4 - PRISMA 2009 Flow Diagram



Source: Moher, Liberati, *et al*., (2009)

Appendix 5 - CASP (Critical Appraisal Skills Program) Combined query table

		Choose appropriate query category for paper						Paper for appraisal and reference:			
Q.		**Case control study**	**Cohort study**	**Diagnostic test Study**	**Systematic review**	**Qualitative research**	**Randomised Controlled Trial**	*insert name of paper here*			
	Section A										
	Are the results of the trial valid?							**Yes**	**Can't Tell**	No	**Comments**
1		*Did the study address a clearly focused issue?*	*Did the study address a clearly focused issue?*	*Was there a clear questionfor the study to address?*	*Did the review address a clearly focused question?*	*Was there a clear statement of the aims of the research?*	*Did the study address a clearly focused issue?*				
2		*Did the authors use an appropriate method to answer their question?*	*Was the cohort recruited in an acceptable way?*	*Was there a comparison with an appropriate reference standard?*	*Did the authors look for the right type of papers?*	*Is a qualitative methodology appropriate?*	*Was the assignment of patients to treatments randomised?*				
3							*Were all of the patients who entered the trial properly accounted for at its conclusion?*				
	Is it worth continuing?							**Yes**	**Can't Tell**	No	**Comments**
3		*Were the cases recruited in an acceptable way?*	*Was the exposure accurately measured to minimise bias?*	*Did all patients get the diagnostic test and reference standard?*	*Do you think all the important, relevant studies were included?*	*Was the research design appropriate to address the aims of the research?*					
4		*Were the controls selected in an acceptable way?*	*Was the outcome accurately measured to minimise bias?*	*Could the results of the test have been influenced by the results of the reference standard?*	*Did the review's authors do enough to assess quality of the included studies?*	*Was the recruitment strategy appropriate to the aims of the research?*	*Were patients, health workers and study personnel 'blind' to treatment?*				
5		*Was the exposure accurately measured to minimise bias?*	*(a) Have the authors identified all important confounding factors?*	*Is the disease status of the tested population clearly described?*	*If the results of the review have been combined, was it reasonable to do so?*	*Was the data collected in a way that addressed the research issue?*	*Were the groups similar at the start of the trial*				
5			*(b) Have they taken account of the confounding factors in the design and/or analysis?*								
6		*(a) Aside from the experimental intervention, were the groups treated equally?*	*(a) Was the follow up of subjects complete enough?*	*Were the methods for performing the test described in sufficient detail?*		*Has the relationship between researcher and participants been adequately considered?*	*Aside from the experimental intervention, were the groups treated equally?*				
6		*(b) Have the authors taken account of the potential confounding factors in the design and/or in their analysis?*	*(b) Was the follow up of subjects long enough?*								

		Choose appropriate query category for paper						**Paper for appraisal and reference:**			
Q.		**Case control study**	**Cohort study**	**Diagnostic test Study**	**Systematic review**	**Qualitative research**	**Randomised Controlled Trial**	*insert name of paper here*			
	Section B										
	What are the results?							**Yes**	**Can't Tell**	No	**Comments**
6					*What are the overall results of the review?*						
7		*How large was the treatment effect?*	*What are the results of this study?*	*What are the results?*	*How precise are the results?*	*Have ethical issues been taken into consideration?*	*How large was the treatment effect?*				
8		*How precise was the estimate of the treatment effect?*	*How precise are the results?*	*How sure are we about the results? Consequences and cost of alternatives performed?*		*Was the data analysis sufficiently rigorous?*	*How precise was the estimate of the treatment effect?*				
9		*Do you believe the results?*	*Do you believe the results?*			*Is there a clear statement of findings?*					
	Section C:										
	Will the results help locally?							**Yes**	**Can't Tell**	No	**Comments**
8					*Can the results be applied to the local population?*						
9				*Can the results be applied to your patients/the population of interest?*	*Were all important outcomes considered?*		*Can the results be applied to the local population, or in your context?*				
10		*Can the results be applied to the local population?*	*Can the results be applied to the local population?*	*Can the test be applied to your patient or population of interest?*	*Are the benefits worth the harms and costs?*	*How valuable is the research?*	*Were all clinically important outcomes considered?*				
11		*Do the results of this study fit with other available evidence?*	*Do the results of this study fit with other available evidence?*	*Were all outcomes important to the individual or population considered?*			*Are the benefits worth the harms and costs?*				
12			*What are the implications of this study for practice?*	*What would be the impact of using this test on your patients/population?*							

Referencing: Critical Appraisal Skills Programme (2018). CASP (insert name of checklist i.e. Case Control Study) Checklist. [online] Available at: https://casp-uk.net/casp-tools-checklists/. Accessed: 16 June 2020.

Source: Oxford CTVH (2020)

Appendix 6 - Study type definitions

Study Type	CASP https://casp-uk.net/glossary/	Cochrane More study design definitions at https://community.cochrane.org/glossary
Case Control study	A case-control study is an epidemiological study that is used to identify risk factors for a medical condition. This type of study compares between two groups of patients, one with and one without the condition, and looks back in time to see how the characteristics of the two groups differ.	A study that compares people with a specific disease or **outcome** of interest (cases) to people from the same **population** without that disease or outcome (**controls**), and which seeks to find associations between the outcome and prior exposure to particular risk factors. This design is particularly useful where the outcome is rare and past exposure can be reliably measured. Case-control studies are usually **retrospective**, but not always.
Case study	A case study is in depth analysis and systematic description of one patient or group of similar patients to promote a detailed understanding of their circumstances.	A study reporting observations on a single individual.
Case series	-	A study reporting observations on a series of individuals, usually all receiving the same **intervention**, with no **control group**.
Cohort study	An observational study in which a group of people with a particular exposure (e.g. a putative risk factor or protective factor) and a group of people without this exposure are followed over time. The outcomes of the people in the exposed group are compared to the outcomes of the people in the unexposed group to see if the exposure is associated with particular outcomes (e.g. getting cancer or length of life).	An **observational study** in which a defined group of people (the cohort) is followed over time. The **outcomes** of people in subsets of this cohort are compared, to examine people who were exposed or not exposed (or exposed at different levels) to a particular **intervention** or other factor of interest. A **prospective** cohort study assembles **participants** and follows them into the future. A **retrospective** (or historical) cohort study identifies subjects from past records and follows them from the time of those records to the present. Because subjects are not allocated by the investigator to different interventions or other exposures, **adjusted analysis** is usually required to minimise the influence of other factors (**confounders**).
Cross-over study/trial	In a cross-over trial two (or more) treatments are tested one after another in the same group of patients. Generally, the order in which each patient receives the treatments is decided by chance.	A type of **clinical trial** comparing two or more **interventions** in which the participants, upon completion of the course of one treatment, are switched to another. For example, for a comparison of treatments A and B, the **participants** are randomly allocated to receive them in either the order A, B or the order B, A. Particularly appropriate for study of treatment options for relatively stable health problems. The time during which the firs **interventions** is taken is known as the first period, with the second intervention being taken during the second period.
Longitudinal study	A study of the same group of people at more than one point in time. (This type of study contrasts with a cross-sectional study, which observes a defined set of people at a single point in time.)	-
Observational study	In research about diseases or treatments, this refers to a study in which nature is allowed to take its course. Changes or differences in one characteristic (e.g. whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without the intervention of the investigator. There is a greater risk of selection bias than in experimental studies.	A study in which the investigators do not seek to intervene, and simply observe the course of events. Changes or differences in one characteristic (e.g. whether or not people received the **intervention** of interest) are studied in relation to changes or differences in other characteristic(s) (e.g. whether or not they died), without action by the investigator. There is a greater risk of **selection bias** than in **experimental studies**.

Study Type	CASP https://casp-uk.net/glossary/	Cochrane More study design definitions at https://community.cochrane.org/glossary
Prospective study	This is a measure of the proportion of people in a population who have a disease at a point in time, or over some period of time.	In evaluations of the effects of healthcare **interventions**, a study in which people are identified according to current **risk** status or exposure, and followed forwards through time to observe **outcome**. **Randomised controlled trials** are always prospective studies. **Cohort studies** are commonly either prospective or **retrospective**, whereas **case-control studies** are usually retrospective. In **Epidemiology**, 'prospective study' is sometimes misused as a synonym for cohort study.
Randomised Controlled Trial	Randomised controlled trial (RCT) is a trial in which participants are randomly assigned to one of two or more groups: the experimental group or groups receive the intervention or interventions being tested; the comparison group (control group) receive usual care or no treatment or a placebo. The groups are then followed up to see if there are any differences between the results. This helps in assessing the effectiveness of the intervention.	An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (for example, in a household) or interventions are assigned within individuals (for example, in different orders or to different parts of the body).

Appendix 7 - Risk of bias assessment tool for individual studies

Risk of bias assessment tool for individual studies (adapted from OHAT RoB tool – see Table 5 in OHAT Handbook for details on relevant questions for each study type)

Study ID: Study Type:	Yes/No Unknown N/A	Notes	Risk of bias rating (--/-/+/++)
Selection bias			
Was administered dose or exposure level adequately randomized?			
Was allocation to study groups adequately concealed?			
Did selection of study participants result in appropriate comparison groups?			
Cofounding bias			
Did the study design or analysis account for important confounding and modifying variables?*			
Performance Bias			
Were experimental conditions identical across study groups?			
Were the research personnel and human subjects blinded to the study group during the study?			
Attrition/Exclusion Bias			
Were outcome data complete without attrition or exclusion from analysis?			
Detection Bias			
Can we be confident in the exposure characterization? *			
Can we be confident in the outcome assessment? *			
Selective Reporting Bias			
Were all measured outcomes reported? *			
Other Sources of Bias			
Were there no other potential threats to internal validity (e.g., statistical methods were appropriate and researchers adhered to the study protocol)?*			

*Key questions for all study types (including any non-human or non-animal studies like monitoring or modelling data)

Risk of bias rating:

Definitely low risk of bias (--)	--	Probably low risk of bias (-)	-	Probably high risk of bias (+)	+	Definitely high risk of bias (++)	++

Appendix 8 - Overall risk of bias (body of evidence by study type)

Overall risk of bias (body of evidence by study type) (adapted from OHAT Handbook) (example)

Research Question: *e.g. What is the risk to human health from microbial sources in recreational water?* **Outcome:** *e.g. gastrointestinal illnesses*	Case report					Case-Control study						Cohort study						Other		
Risk of Bias Question	Study 1	Study 2	Study 3	Study 4	Study 5	Study 6	Study 7	Study 8	Study 9	Study 10	Study 11	Study 12	Study 13	Study 14	Study 15	Study 16	Study 17	Study 18	Study 19
Randomization																			
Allocation concealment																			
Confounding (design/analysis)	++	+	++	++	++	+	++	++	++	++	+	++	++	+	–	–	–	–	++
Unintended exposure	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Identical experimental conditions	++	++	+	+	++	++	++	++	++	+	++	+	++	++	++	++	++	++	++
Adhere to protocol	+	+	+	+	–	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Blinding of researchers during study																			
Missing outcome data	–	+	++	++	––	–	+	–	–	+	––	–	–	+	++	+	++	+	++
Assessment of confounding variables	+	+	++	++	++	–	+	+	++	++	+	+	+	++	++	–	+	+	++
Exposure characterization	++	–	+	+	–	–	+	+	–	–	–	+	+	+	+	+	+	–	+
Outcome assessment	+	+	+	+	+	+	++	+	+	–	++	+	+	+	+	+	+	+	+
Blinding of outcome assessors	+	+	+	+	++	+	+	+	+	+	+	+	––	+	++	+	+	+	+
Outcome reporting	+	+	+	++	––	+	+	+	+	–	+	+	––	+	+	+	++	–	+

Key:

Definitely low risk of bias	++
Probably low risk of bias	+
Probably high risk of bias	–
Definitely high risk of bias	––

Appendix 9 - Summary of findings – body of evidence

Summary of findings – body of evidence (adapted from OHAT Handbook)

Body of evidence	Risk of bias	Unexplained inconsistency	Indirectness	Imprecision	Publication bias	Magnitude of effect	Dose Response	Residual confounding	Consistency across species/model	Other reason to increase confidence?	Final certainty rating
Evidence stream or study type *(# studies)* *initial certainty rating*	*Serious, not serious, unknown* Describe trends, key questions, issues	*Serious, not serious, not applicable* Describe results in terms of consistency, explain apparent inconsistency (if it can be explained)	*Serious or not serious* Discuss use of upstream indicators or populations with less relevance, any time-related exposure considerations (see OHAT RoB tool)	*Serious, not serious, unknown* Discuss ability to distinguish treatment from control, describe confidence intervals (if available)	*Detected, undetected, unknown* Discuss factors that might indicate publication bias (e.g., funding, lag)	*Large, not large, unknown* Describe magnitude of response	*Yes, no, unknown* Outline evidence for or against dose response	*Yes, no, unknown* Address whether there is evidence that confounding would bias toward null	*Yes, no, not applicable (NA)* Describe cross-species, model, or population consistency	*Yes or no* Describe any other factors that increase confidence in the results	***High, moderate or low*** List reasons for downgrading or upgrading
Research question: *e.g. What are the risks to human health from microbial sources in recreational water exposure?*											
Outcome 1. *e.g gastrointestinal illness*											
e.g. human case control studies *(5 studies)* *Low to moderate certainty*											
Outcome 2:											

Appendix 10 - Administrative and technical criteria for assessing existing guidance or reviews

Administrative and technical criteria for assessing existing guidance or reviews

Criteria have been colour-coded to assess minimum requirements as follows: 'Must have', 'Should have' or 'May have'

	Criteria	Y/N/?/NA	Notes
	Overall guidance/advice development process		
	Are the key stages of the organisation's advice development processes compatible with Australian processes?		
	Are the administrative processes documented and publicly available?		
	Was the work overseen by an expert advisory committee? Are potential conflicts of interest of committee members declared, managed and/or reported?		
	Are funding sources declared?		
	Was there public consultation on this work? If so, provide details.		
	Is the advice peer reviewed? If so, is the peer review outcome documented and/or published?		
	Was the guidance/advice developed or updated recently? Provide details.		
	Evidence review parameters		
	Are decisions about scope, definitions and evidence review parameters documented and publicly available?		
	Is there a preference for data from studies that follow agreed international protocols or meet appropriate industry standards?		
	Does the organisation use or undertake systematic literature review methods to identify and select data underpinning the advice? Are the methods used documented clearly?		
	If proprietary/confidential studies or data are considered by the agency, are these appropriately described/recorded?		
	Are inclusion/exclusion criteria used to select or exclude certain studies from the review? If so, is justification provided?		
	Does the organisation use or adopt review findings or risk assessments from other organisations? What process was used to critically assess these external findings?		
	Can grey literature such as government reports and policy documents be included?		
	Is there documentation and justification on the selection of a toxicological endpoint for use as point of departure for health-based guideline derivation?		
	Evidence search		
	Are databases and other sources of evidence specified?		

	Criteria	Y/N/?/NA	Notes
	Overall guidance/advice development process		
	Does the literature search cover at least more than one scientific database as well as additional sources (which may include government reports and grey literature)?		
	Is it specified what date range the literature search covers? Is there a justification?		
	Are search terms and/or search strings specified?		
	Are there any other exclusion criteria for literature (e.g. publication language, publication dates)? If so, what are they and are they appropriate?		
	Critical appraisal methods and tools		
	Is risk of bias of individual studies taken into consideration to assess internal validity? If so, what tools are used? If not, was any method used to assess study quality?		
	Does the organisation use a systematic or some other methodological approach to synthesise the evidence (i.e. to assess and summarise the information provided in the studies)? If so, provide details.		
	Does the organisation assess the overall certainty of the evidence and reach recommendations? If so, provide details.		
	Derivation of health-based guideline values		
	Is there justification for the choice of uncertainty and safety factors?		
	Are the parameter value assumptions documented and explained?		
	Are the mathematical workings/algorithms clearly documented and explained?		
	Does the organisation take into consideration non-health related matters to account for feasibility of implementing the guideline values (e.g. measurement attainability)?		
	Is there documentation directing use of mechanistic, mode of action, or key events in adverse outcome pathways in deriving health-based guideline values?		
	What processes are used when expert judgement is required and applied? Is the process documented and published?		
	Is dose response modelling (e.g. BMDL) routinely used?		
	What is the organisation's policy for dealing with substances for which a non-threshold mode of action may be applicable in humans? Has the policy been articulated and recorded?		
	If applicable: For carcinogens, what is the level of cancer risk used by the organisation to set the health-based guideline value?		

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