EVIDENCE EVALUATIONS FOR AUSTRALIAN DRINKING WATER GUIDELINE CHEMICAL FACT SHEETS

Lead
Technical Report

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PREPARED BY

SLR Consulting Australia Pty Ltd
ABN 29 001 584 612
Level 11, 176 Wellington Parade
East Melbourne VIC 3002 Australia

T: +61 3 9249 9400
E: melbourne@slrconsulting.com www.slrconsulting.com

BASIS OF REPORT

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Abbreviations/Definitions

Acronym	Definition
APVMA	Australian Pesticides and Veterinary Medicines Authority
ATSDR	US Agency for Toxic Substances and Disease Registry
BMD_{01}	Dose Associated with a Benchmark Response (BMR) of 1 IQ-point.
BMDL	Lower one-sided 95% confidence limit of the BMD.
BPb	Blood lead
BW, bw	Body Weight
CDC	Centre for Disease Control (in United States)
DW	Drinking Water
DWG	Drinking Water Guideline
EFSA	European Food Safety Authority
FSANZ	Food Standards Australia New Zealand
IARC	International Agency for Research on Cancer
IEUBK	Integrated Exposure Uptake Biokinetic Model (for Pb)
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOAEL	Lowest Observed Adverse Effect Level
LOR	Limit of Reporting
MRL	Minimal Risk Level (ATSDR terminology)
NHMRC	National Health and Medical Research Council
NOAEL	No Observed Adverse Effect Level
OEHHA	Californian Office of Environmental Health and Hazard Assessment
Pb	Lead
PBPK	Physiologically Based Pharmacokinetic Model
PHG	Public Health Goal (in drinking water) (OEHHA terminology)
PPRTV	Provisional Peer-Reviewed Toxicity Value (US EPA terminology)
PTWI	Provisional Tolerable Weekly Intake (JECFA and EFSA terminology)
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RfD	Reference Dose (US EPA terminology)
The Guidelines	NHMRC and NRMMC (2011). Australian Drinking Water Guidelines 6 2011; Version 3.6 updated March 2021, National Health and Medical Research Council and Natural Resource Management Ministerial Council Commonwealth of Australia, Canberra.
US EPA	United States Environmental Protection Agency
WHO	World Health Organization
WQAC	Water Quality Advisory Committee

1 Introduction and Background

The National Health and Medical Research Council (NHMRC) have contracted SLR Consulting Australia Pty Ltd (SLR) to evaluate the existing guidance and evidence for 11 chemical factsheets in the 2011 *Australian Drinking Water Guidelines* (the Guidelines). The evidence reviews undertaken by SLR were governed by a newly designed methodological framework intended to increase transparency and quality control in the process of adopting or adapting existing guidelines. For each of the 11 chemicals, SLR was asked to:

- Customise and apply the 'Research Protocol' provided by NHMRC to answer research questions. The research questions varied slightly according to the chemical being evaluated.
- Produce a Technical Report and an Evaluation Report for each chemical factsheet.
  - The Technical Report is to capture the details and methods used to undertake each review.
  - The Evaluation Report is to interpret, synthesise and summarise the existing guidance and evidence pertaining to the research questions.

These tasks were performed in collaboration with the Water Quality Advisory Committee (WQAC) and NHMRC.

The report herein is the Technical Report for lead (Pb).

2 Research Questions

Research questions for this review were drafted by SLR and peer reviewed and agreed upon by the WQAC and NHMRC prior to conducting the search. They are provided in **Table 1**.

Table 1 Research Questions for Evidence Evaluation of Lead Factsheet Review

#	Research Questions
Health-based	
1	What is the critical human health endpoint for lead (if any)? Therefore, what are the key adverse health hazards from exposure to Lead in Australian drinking water?
2	What are the justifications for choosing this endpoint/health hazard?
3	What is the toxicological mode of action of lead for the critical human health endpoint?
4	Is lead an oral genotoxic carcinogen of relevance to humans?
5	What is the most appropriate dose metric for derivation of a drinking water guideline for lead?
6	What dose(s) (internal and/or external) are associated with the critical human health endpoint?
7	Is the proposed health-based guideline value relevant to the Australian context?
8	What is the guidance value?
9	Are there groups of people in the general population who may be more sensitive to lead exposure?
10	Is there a knowledge gap from the time at which existing guideline values were developed?
11	Does any recent literature change the guideline value? (e.g. demonstrating a new critical endpoint?)
Exposure-based	
12	What are the typical lead levels in Australian drinking water? Do they vary around the country or under certain conditions e.g. source of water, drought?

#	Research Questions
13	Do Australian levels differ considerably from elsewhere?
14	What are the principal routes of exposure to lead in the Australian general population?
15	What are the typical levels of Australian exposure? (e.g. 'background' lead levels)?
Risk-based	
16	What are the risks to human health from exposure to lead in Australian drinking water?
17	Is there evidence of any emerging risks that are not mentioned in the current factsheet that require review?
Supporting Information on Factsheet	
18	Is the general description current?
19	What are the indicators of the risks? How can we measure exposure? Is the information on measurement/analytical methods current?
20	Are there commercial analytical methods available that can measure at or below the guideline value?
21	Is the information for treatment options current in terms of current practices in Australia?
22	Can treatment technologies treat to the suggested level of the guideline value?
23	Is there any new information which should be added? Should anything be removed?

3 Evidence Evaluation Methods

3.1 Overview

This section summarises the methods followed to undertake the evidence evaluation review for Pb. The intention is to provide enough detail for a third party to reproduce the search.

It was evident that some flexibility was required in adapting the methodology recorded in the final Research Protocol for Pb to maximise efficiency in sourcing relevant information. Deviations from the final Research Protocol methodology have been recorded in this report. **Figure 1** shows an overview of the literature search process followed for Pb. This is presented as a PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram that describes the study selection process and numbers of records at each stage of screening (Moher et al. 2009).

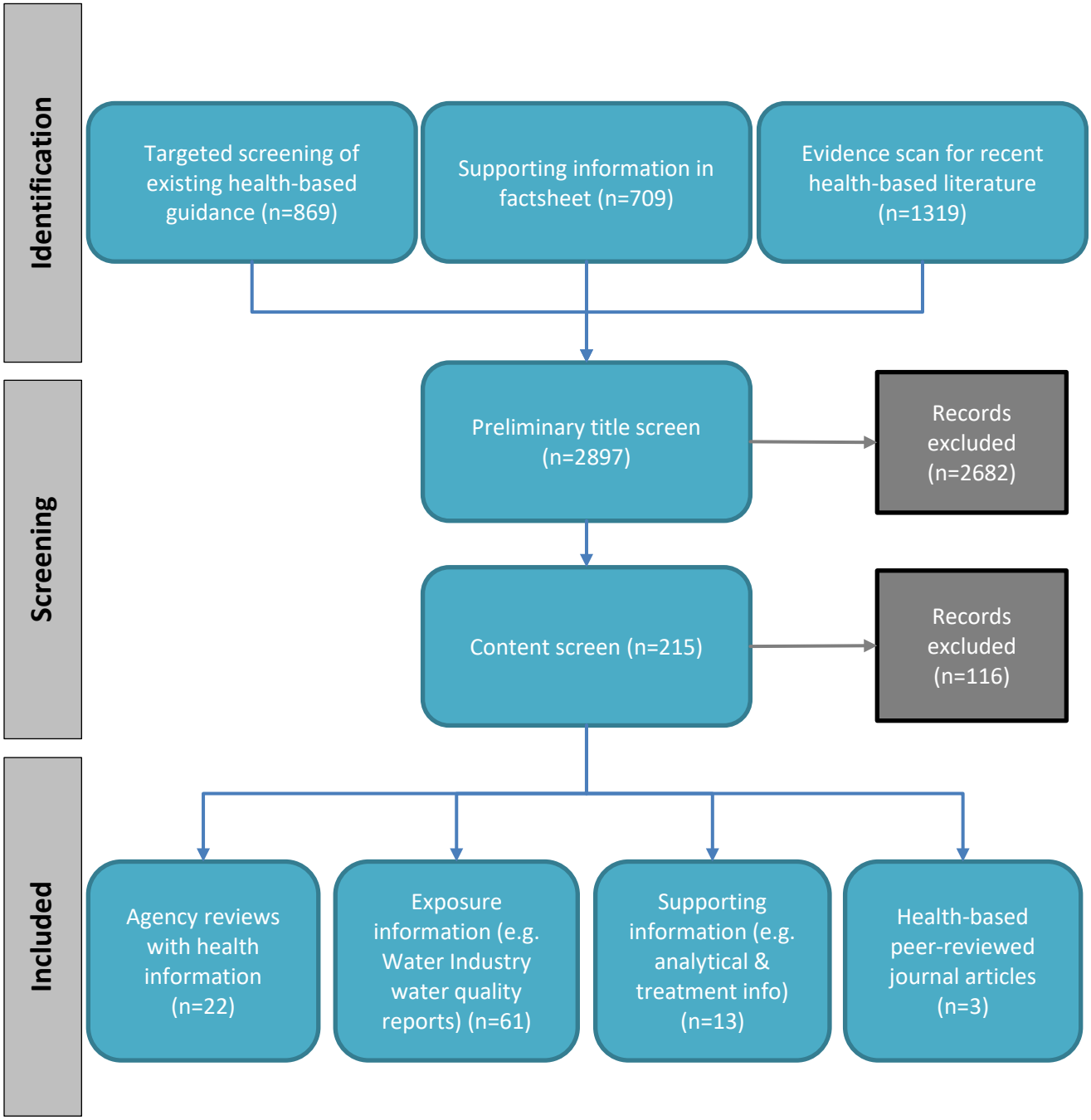

Figure 1 Overview of literature search process followed for Lead

3.2 Targeted screening of existing health-based guidance

Literature search strategy

The literature search strategy for existing health-based guidance documentation for Pb is summarised in **Table 2** below.

Table 2 Search strategy for Existing Guidance/Guidelines

Parameter	Comments
Search terms	After a few trial runs of various combinations of search terms, it became apparent that the search terms would need to remain relatively broad so as not to miss pivotal references/reviews. Consequently, the selected search term was: • (Lead)

Databases/Agency websites	The following sources were searched:
	• World Health Organization (WHO): https://www.who.int/ (in addition, 'Lead in drinking water' was searched in Google®) [2].
	• International Programme of Chemical Safety (IPCS Inchem): http://www.inchem.org/#/search
	• Joint FAO/WHO Expert Committee on Food Additives (JECFA): (Included in IPCS Inchem search)
	• European Food Safety Authority (EFSA): https://www.efsa.europa.eu/en
	• United States Environmental Protection Agency (US EPA), specifically [1]:
	  ○ Integrated Risk Information System (IRIS): https://www.epa.gov/iris
	  ○ Provisional Peer-reviewed Toxicity Values (PPRTV): https://www.epa.gov/pprtv
	• US Agency for Toxic Substances and Disease Registry (ATSDR): https://www.atsdr.cdc.gov/
	• Californian Office of Health and Hazard Assessment (OEHHA) Public Health Goals (in Drinking Water): https://oehha.ca.gov/water/public-health-goals-phgs
	• Food Standards Australia New Zealand (FSANZ), specifically [3]:
	  ○ Publications page: https://www.foodstandards.gov.au/publications/Pages/default.aspx
	  ○ Monitoring safety of food supply page: https://www.foodstandards.gov.au/science/surveillance/Pages/default.aspx
	  ○ Chemicals in food page: https://www.foodstandards.gov.au/consumer/chemicals/Pages/default.aspx
	• Australian Pesticides and Veterinary Medicines Authority (APVMA) Health Based Guidance Values: https://apvma.gov.au/node/26596
	The following additional sources were searched to provide exposure information in Australian drinking water supplies (to inform responses to Research Questions 12 and 15):
	• Melbourne Water: https://www.melbournewater.com.au/
	• Sydney Water: https://www.sydneywater.com.au/SW/index.htm
	• TasWater: https://www.taswater.com.au/
	• SA Water: https://www.sawater.com.au/
	• Water Corporation of Western Australia: https://www.watercorporation.com.au/
	• Power and Water Corporation Northern Territory Drinking Water Quality Reports: https://www.powerwater.com.au/about/what-we-do/water-supply/drinking-water-quality/past-drinking-water-quality-reports
	• Seqwater: https://www.seqwater.com.au/
	• Icon Water: https://www.iconwater.com.au/
	• Water Research Australia: https://www.waterra.com.au/

Publication Date	If databases/agency websites allowed for specification of date ranges, searches were constrained to the following date range to coincide with the year of the last Australian drinking water guideline fact sheet update for Pb: • 1 January 1996 to July 2021

Parameter	Comments
Language	English
Study Type	Publicly available agency/industry reports and reviews.

Inclusion and exclusion criteria	The following exclusion criteria were used to screen relevance of agency reports/reviews:
	• NR = Not Relevant. Information not directly relevant to answering research questions. Rationale for non-relevance was provided for transparency. E.g.
	  ○ Not HH related = Not human health related (e.g. criteria are for protection of aquatic life).
	  ○ Not a relevant exposure pathway = Since Pb is not volatile, guidelines for non-oral and non-dermal routes of exposure are not considered relevant (e.g. inhalation).
	  ○ Not relevant to chemical of interest.
	• NPA = Basis of guideline value or information underpinning review conclusions are Not Publicly Available, e.g. health-based guideline value has used unpublished proprietary information which could not be verified.
	• Language = Language other than English.

Validation methods used	Preliminary searches were undertaken with more specific search terms [(Lead) AND (toxicity or health); (Lead) AND (exposure) AND (Australia)]. Upon scanning preliminary search results, the reviewer found these search terms to be too specific, as a number of agency reports did not appear in the results. The search terms were consequently refined. In addition, from the preliminary search of the WHO website, it became evident that the latest background documentation for Pb (dated 2011) did not come up in the general search results when using the search term 'Lead'. Therefore, the WHO website search was supplemented by a Google® search to find the specific background document of interest.
Screening methods	Results were screened as follows: *Preliminary title screen* • Titles of results for each search were recorded in an Excel spreadsheet. Each website was on a separate tab of the spreadsheet. • The researcher scanned the titles. In a separate column a decision regarding relevance of the result was recorded as per the exclusion criteria. An additional column was included to provide commentary as (and if) required. • Where the researcher was uncertain as to the relevance of a particular result, the researcher discussed the matter with a subject expert prior to making a decision OR the result was considered potentially relevant and included. *Content screen* • The full text content of reports/reviews selected to be included from the preliminary title screen were reviewed by a subject expert to determine which reports/reviews to include in the data extraction step. Only reports/reviews which provided information relevant to answering the research questions were taken through to the data extraction step.
Documentation of search	Spreadsheets with full search results and screening outcomes (i.e. reasons for exclusion) are provided in **Appendix A.** Overall results presented in **Figure 1**, adapted from the PRISMA figure presented in Moher et al. (2009) and Figure 5 in NTP (2015).
Retrieval of publications	All relevant and potentially relevant results were recorded in an Endnote library and soft copies of files saved into a designated folder on the SLR server for review. The server is backed up on a daily basis.

Parameter	Comments
	1. Preliminary search trials with the US EPA general search engine (https://www.epa.gov/) resulted in over 122,671 hits, regardless of search term refinement. This number of hits was considered unmanageable to screen through with the resources available for this project. Consequently, the search was targeted to specific sections of the website considered most relevant to answering the research questions. 2. From the preliminary search of the WHO website, it became evident that the latest background documentation for Lead (dated 2011) did not come up in the general search results when using the search term 'Lead'. Therefore, the WHO website search was supplemented by a Google® search to find the specific background document of interest. 3. From the preliminary search of the FSANZ website, it became evident that the number of search results appeared infinite (there was no set number of hits provided, and no set pages of results; every time the final page of results was clicked on, additional pages appeared), regardless of search term refinement, with the vast majority of records being not relevant to the research questions. Consequently, specific sections of the website were consulted which were considered most relevant to answering the research questions.

Data Extraction and Quality Assessment

For each relevant result for which the full text was sourced:

- The full text was skimmed by a content expert.
- Where existing health-based guidance (in the form of drinking water guidelines or toxicity reference values, i.e. TRVs) was identified, relevant data on the guidance value in relation to the research questions were extracted using the format shown in **Table 3.** The individual data extraction tables are provided in **Appendix B**.
- For each health-based guidance review, quality of existing guidance/guidelines was assessed using the Assessment Tool (Appendix C in the Research Protocol). The individual completed Assessment tool tables for each guidance/guideline document are provided in **Appendix C**. Note this was only done for those agency reviews which derived a health-based guidance/guideline value.

Table 3 Example of data extraction table format for existing health-based guidance

Agency Report Reference: *Insert full bibliographical reference for report*		
General Information	Date of data extraction	
	Authors	
	Publication date	
	Literature search timeframe	
	Publication type	
	Peer reviewed?	
	Country of origin	
	Source of funding	
	Possible conflicts of interest	
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	
	Exposure timeframe	
	Critical human health endpoint	
	Justification provided by agency for critical endpoint	
	Critical study(ies) underpinning point of departure	
	Species for critical study(ies)	

Agency Report Reference: *Insert full bibliographical reference for report*		
	Point of departure type (e.g. NOAEL, LOAEL, $BMDL_{10}$, etc)	
	Point of departure value (include units)	
	Uncertainty factor(s) & rationale	
	Guideline value (include units)	
	Mode of action for critical health endpoint	
	Genotoxic carcinogen?	
	Identified sensitive sub-populations	
	Any non-health based considerations?	
Exposure considerations	Principal routes of exposure in general population	
	Levels in drinking water supplies (include location)	
	Any special considerations to exposure levels (e.g. higher in drought?)	
	Typical exposure in general population (include units for intakes & location)	
Risk Summary	Any risks to human health from drinking water identified in agency document?	
	Any emerging risks identified?	

Data summary/synthesis

In order to effectively compare data from different sources, the data has been presented side-by-side in tabular format for each individual research question.

Expert judgement was used to highlight areas of uncertainty or areas where an organisation's methods/interpretation differs from Australian science policy.

3.3 Evidence scan for recent studies

Literature search strategy

An evidence scan of recent literature was undertaken for research questions for which eligible guidance (for potential adoption or adaptation into the Guidelines) was identified in the targeted screening of existing health-based guidance (see **Section 3.2**). The aim of the evidence scan was to understand the availability of recent literature and to determine whether a formal systematic review to update the evidence underpinning available guidance is warranted.

The literature search strategy for undertaking the evidence scan for recent studies is summarised in **Table 4** below.

Table 4 Search strategy for evidence scan of recent health-based studies

Parameter	Comments
Search terms	The selected search terms were: • (Lead) AND (toxicity) AND (oral) • (Lead) AND (health) AND (oral) • (Lead) AND (toxicity) AND (drinking water) • (Lead) AND (health) AND (drinking water) • (Lead) AND (exposure) AND (Australia)
Databases	The following sources were searched: • MEDLINE/PubMed/TOXLINE
Publication Date	2015 – 2021, the bottom end of the range to coincide with the cutoff date in the literature search from the latest available health-based agency review found in the targeted screening step.
Language	English
Study Type	Peer-reviewed, published, in press, unpublished and ongoing studies were included. Due to the large number of obtained search results, study types were limited to existing systematic reviews, literature reviews and meta-analyses.
Inclusion and exclusion criteria	The following exclusion criteria were used to screen relevance of information: • NR = Not Relevant. Information not directly relevant to answering research questions. • Language = Language other than English. • UCC = Unlikely to Change Conclusions in Review.
Validation methods used	Preliminary test searches were undertaken to assist with selecting search terms. Refinements were made as considered appropriate to ensure adequate, but also specific coverage in the sources screened.
Screening methods	Results were screened as follows: *Preliminary title and abstract screen* • Titles of results for each search were recorded in an Excel spreadsheet. The results for each combination of search terms were exported into a separate tab of the spreadsheet. To readily eliminate duplicate records, results from all search term combinations were subsequently collated into one spreadsheet. • The researcher scanned the titles (and abstracts, if required). In a separate column a decision regarding relevance of the result was recorded as per the exclusion criteria. An additional column was included to provide commentary as (and if) required. • Where the researcher was uncertain as to the relevance of a particular result, the researcher discussed the matter with a subject expert prior to making a decision OR the result was considered potentially relevant and included. *Content screen* • The full text content of literature selected to be included from the preliminary title and abstract screen were reviewed by a subject expert to determine which articles to include in the data extraction step. Only articles/reviews which provided information considered to potentially affect the overall conclusions made by other jurisdictions were taken through to the data extraction step.

Parameter	Comments
Documentation of search	Spreadsheets with full search results and screening outcomes (i.e. reasons for exclusion) are provided in **Appendix A.** Overall results presented in **Figure 1**, adapted from the PRISMA figure presented in Moher et al. (2009) and Figure 5 in NTP (2015).
Retrieval of publications	All relevant and potentially relevant results were recorded in an Endnote library and soft copies of files saved into a designated folder on the SLR server for review. The server is backed up on a daily basis.

Data Extraction

For each relevant result for which the full text was sourced:

- Where deemed to be relevant to the research questions and potentially providing information that could alter the existing assessments (identified in the targeted screening of existing health-based guidance), relevant data were extracted using the example format shown in **Table 5.** The format was more applicable to epidemiological studies and was adapted slightly for animal studies and/or reviews. The individual data extraction tables are provided in **Appendix E**.

Table 5 Example of data extraction table format for evidence scan of recent health-based studies

Publication Reference: ***Insert full bibliographical reference for report***		
General Information	Date of data extraction	
	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 (if applicable)	
Population characteristics	Population/s studied	
	Selection criteria for population (if applicable)	
	Subgroups reported	
	Size of study	
Exposure and setting	Exposure pathway	
	Source of chemical/contamination	
	Exposure concentrations (if applicable)	
	Comparison group(s)	

Publication Reference: *Insert full bibliographical reference for report*		
Study methods	Water quality measurement used	
	Water sampling methods (monitoring, surrogates)	
Results (for each outcome)	Definition of outcome	
	How outcome was assessed	
	Method of measurement	
	Number of participants (exposed/non-exposed, missing/excluded) (if applicable)	
Statistics (if any)	Statistical method used	
	Details on statistical analysis	
	Relative risk/odds ratio, confidence interval?	
Author's conclusions	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	

Data summary/synthesis

Data summary/synthesis for the evidence scan was limited to those aspects identified which have the potential to influence the overall conclusions made by the jurisdictions who have derived existing health-based guidance/guidelines (i.e. the health-based research questions only). Relevant data were summarised in tabular format by research question.

3.4 Supporting information in factsheet

In the first instance, the existing guidance/guideline documents identified as per the methods outlined in **Section 3.2** were consulted for supporting information in the factsheet (i.e. general description, uses, measurement techniques and limits of reporting in drinking water, treatment options, etc).

The information was collated into data extraction tables such as the one in **Table 6**. The individual completed data extraction tables for supporting information are provided in **Appendix D**.

Table 6 Example of data extraction table format for supporting information in factsheet

Agency Report Reference: *Insert full bibliographical reference for report*		
General Description	Uses	
	Sources in drinking water	
	Other	
	Treatment technology	

Agency Report Reference: *Insert full bibliographical reference for report*		
Treatment of drinking water	Effectiveness	
	Any special conditions?	
	Other	
Measurement	Analytical method	
	Limit of determination/ Limit of Reporting (LOR)	
	Other	
Additional information	Any additional non-health related information considered important?	

In addition, an evidence scan of recent publicly available literature was undertaken as per the literature search methodology shown in **Table 7** below.

Table 7 Search strategy for evidence scan of supporting information in factsheet

Parameter	Comments
Search terms	The selected search terms for the Scopus database were: • (Lead) AND (treatment) AND (drinking water) [(1)] After a few trial runs of various combinations of search terms in the industry websites, it became apparent that the search capacities varied significantly between different webpages. Consequently, the selected search term (for industry websites) was kept relatively broad: • (Lead)
Databases/Other sources	The following source database was searched: • Scopus The following industry websites were searched: • Water Services Association of Australia: https://www.wsaa.asn.au/ • Standard Methods for the Examination of Water and Wastewater: https://www.standardmethods.org/ • US EPA Drinking Water Treatability Database: https://tdb.epa.gov/tdb/home The following Australian commercial laboratories were contacted directly via e-mail or website form for relevant information: • National Measurement Institute • SGS • ALS • Eurofins
Publication Date	Limited to last 5 years (2017-2021)
Language	English
Study Type	• Peer-reviewed, published, in press, unpublished and ongoing studies. • Australian laboratory information sheets or e-mail responses on measurement methods and limits of determination.

Parameter	Comments
Inclusion and exclusion criteria	The following exclusion criteria were used to screen relevance of information: • NR = Not Relevant. Information not directly relevant to answering research questions. • Research technique (analytical or treatment) = does not appear to be commercially applied. • Language = Language other than English. • NPA = Not publicly available. • NL = Chemical not listed under specific treatment process.
Validation methods used	Preliminary test searches were undertaken to assist with selecting search terms. Refinements were made as considered appropriate to ensure adequate, but also specific coverage in the sources screened.
Screening methods	Results were screened as follows: *Preliminary title and abstract screen* • Titles of results for each search were recorded in an Excel spreadsheet. Each source was on a separate tab of the spreadsheet. • The researcher scanned the titles (and abstracts, if required). In a separate column a decision regarding relevance of the result was recorded as per the exclusion criteria. An additional column was included to provide commentary as (and if) required. • Where the researcher was uncertain as to the relevance of a particular result, the researcher discussed the matter with a subject expert prior to making a decision OR the result was considered potentially relevant and included. *Content screen* • The full text content of literature selected to be included from the preliminary title and abstract screen were reviewed by a subject expert to determine which articles to include in the data extraction step. Only articles/reviews which provided information relevant to answering the research questions were taken through to the data extraction step.
Documentation of search	Spreadsheets with full search results and screening outcomes (i.e. reasons for exclusion) are provided in **Appendix A.** Overall results presented in **Figure 1**, adapted from the PRISMA figure presented in Moher et al. (2009) and Figure 5 in NTP (2015).
Retrieval of publications	All relevant and potentially relevant results were recorded in an Endnote library and soft copies of files saved into a designated folder on the SLR server for review. The server is backed up on a daily basis.
1. It became evident upon undertaking the initial searches using the following additional search term combinations ['(Lead) AND (analysis) AND (drinking water)' OR '(Lead) AND (testing) AND (drinking water)'] that these searches returned thousands of results that were not relevant to answering the research questions with respect to commercial analytical techniques used in Australia. Results obtained for analytical techniques in the peer-reviewed literature were research-based techniques for specific purposes and not currently commercially applied. It was considered more efficient and effective to contact Australian laboratories directly for information on their analytical techniques and commercial limits of reporting. Therefore, the search in the Scopus database was limited to information on treatment technologies.	

The following data were extracted from relevant publications and/or obtained from contacts with Australian laboratories:

- Citation information
- Name of treatment technology (as applicable)
- Name of analytical technique (as applicable)
- Associated Reporting Limit

The individual completed data extraction tables for supporting information are provided in **Appendix D**.

4 Results

A summary of the responses to the research questions for Pb is provided the tables below.

4.1 Health-based research question analysis

Table 8 Synthesis of extracted data for health-based research questions

#	Research Questions	Jurisdiction	Response to Research Questions
1	What is the critical human health endpoint for Lead (if any)? Therefore, what are the key adverse health hazards from exposure to Lead in Australian drinking water?	**ATSDR 2020**	Epidemiological studies have identified health effects of Pb in all organ systems at the lowest blood Pb evaluated (<5 µg/dL). However, exposure thresholds for effects have not been identified and it is not possible to determine from the epidemiological data which organ system are the most sensitive (i.e. primary) targets for Pb toxicity.
		EFSA 2010c	Only one endpoint was investigated in this targeted report, i.e. intellectual function or IQ score in children.
		EFSA 2012	The central nervous system is the main target organ for Pb toxicity. In adults, Pb-associated neurotoxicity was found to affect central information processing and short-term verbal memory, to cause psychiatric symptoms and to impair manual dexterity. There is considerable evidence demonstrating that the developing brain is more vulnerable to the neurotoxicity of lead than the mature brain.
		FSANZ 2019	High levels of Pb exposure have been associated with adverse cognitive effects (including reduced IQ) in children and cardiovascular effects (including increased blood pressure) in adults.
		IARC 2006	No critical health endpoints provided. However, there is a discussion of the toxic effects of inorganic Pb: • Weakness, irritability, asthenia, nausea, abdominal pain with constipation, and anaemia. • Renal toxicity. • Impairment in cognition, attention, and language function. • Cardiovascular effects with changes in endocrine and immune functions. • Spontaneous abortion risk is increased by maternal exposure to high concentrations of Pb.
		IPCS 2000	Neurobehavioural development of children.
		IPCS 2006a	The central nervous system is probably the most sensitive target of Pb, with both inorganic and organic Pb being neurotoxic but clinical patterns of injury being different. Effects include subtle effect on intellectual functioning and deficits in memory, attention, concentration, psychomotor performance and intelligence, as well as at higher exposure concentrations severe encephalopathy.

#	Research Questions	Jurisdiction	Response to Research Questions
		JECFA 2011a, b	The Committee concluded that the effects on neurodevelopment (for children) and systolic blood pressure (for adults) provided the appropriate bases for dose–response analyses (and therefore are considered to be the critical effects of Pb exposure).
		WHO 2011	WHO (2011) adopts JECFA (2011a, b) evaluation, therefore critical human health endpoints are the same (neurological in children, systolic blood pressure in adults).
		OEHHA 2009	Intelligence deficits in children
		US EPA 2004	Health effects associated with exposure to inorganic Pb and compounds include, but are not limited to, neurotoxicity, developmental delays, hypertension, impaired hearing acuity, impaired haemoglobin synthesis, and male reproductive impairment. Importantly, many of lead's health effects may occur without overt signs of toxicity. Pb has particularly significant effects in children, well before the usual term of chronic exposure can take place.
		NHMRC 2015a, b	Pb can affect many organs and bodily functions, with effects such as increased blood pressure, abnormally low haemoglobin, abnormal kidney function, long-term kidney damage and abnormal brain function having been observed at BPb levels between 10 and 60 µg/dL in adults and children. NHMRC's comprehensive review of the health effects of Pb found an association between reductions in Intelligence Quotient (IQ) and academic achievement in children at BPb levels less than 10 µg/dL. There is weaker evidence that BPb < 5 µg/dL are associated with reductions in IQ or academic achievement. For BPb between 5-10 µg/dL, an association was observed between higher occurrence of behavioural problems (poor attention, impulsivity and hyperactivity) in children, increased blood pressure in adults (including pregnant women) and a delay in sexual maturation or puberty onset in adolescent girls and boys.
		ATSDR 2004a,b; ATSDR 2006, ATSDR 2017b, ATSDR 2018, CDC 2009, 2013; EFSA 2010b	→ No relevant information
2	What are the justifications for choosing this endpoint/health hazard?	**ATSDR 2020**	Clinical significance of some of the organ system effects at low levels of exposure and blood Pb is more substantial than for others (e.g. neurological, renal, cardiovascular, haematological, immunological, reproductive, and developmental effects). This is not surprising because the mechanisms that induce toxicity are common to all cell types and because Pb is widely distributed throughout the body. Adverse health effects have been observed in these systems at BPb ≤10 µg/dL. Exposure thresholds for effects on specific organ systems have not been identified (i.e. no safe level has been identified). Cognitive deficits in children occurring at the lowest BPbs (≤5 µg/dL) are the best substantiated effects. However, data for some organ systems results are inconsistent, and insufficient data are available to provide information on dose-response relationships.
		EFSA 2010c	Not applicable (only one endpoint was subjected to BMD modelling in this targeted investigation).
		IPCS 2000	This is the basis of the previously established PTWI.
		IPCS 2006a	Central nervous system is probably most sensitive target to Pb.

#	Research Questions	Jurisdiction	Response to Research Questions
		JECFA 2011a,b	Exposure to Pb is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Impaired neurodevelopment in children is generally associated with lower BPb concentrations than the other effects, the weight of evidence is greater for neurodevelopmental effects than for other health effects and the results across studies are more consistent than those for other effects. For adults, the adverse effect associated with lowest BPb concentrations for which the weight of evidence is greatest and most consistent is a Pb-associated increase in systolic blood pressure.
		WHO 2011	As per JECFA (2011a, b).
		OEHHA 2009	The most significant health effects from the public health and regulatory point of view are the ones which occur at the lowest BPb levels, because these affect the greatest part of the population. For children these are the effects on intelligence and behaviour. For adults the most sensitive health effect is the increase in blood pressure and other cardiovascular effects. Both of these health effects are of concern below 10 µg/dL BPb. Since measurable neurobehavioural effects in children for Pb may occur with an increase in BPb of 1 µg/dL, this increase in Pb level may be considered a shift of concern for both children and adults. Other health effects such as kidney and gastrointestinal effects occur at higher BPb levels. The PHG was developed based on intelligence deficits in children, as this is the best-documented health endpoint that occurs at very low levels of exposure.
		NHMRC 2015a, b	See response to previous question. Evaluation was undertaken for weight of evidence of available dose-response relationships for the most well-studied health effects which occur at the lowest BPb levels.
		ATSDR 2004a,b; ATSDR 2006, ATSDR 2017b, ATSDR 2018, CDC 2009, 2013; EFSA 2010b, 2012; FSANZ 2019, IARC 2006, US EPA 2004 → No relevant information	
3	What is the toxicological mode of action of Lead for the critical human health endpoint?	**ATSDR 2020**	Critical health endpoint not identified. However, mechanisms of action associated with Pb-induced toxicity include perturbations of ion homeostasis and transport (e.g. displacing other metal ions such as iron, calcium, zinc, magnesium, selenium and manganese), protein binding, oxidative stress, and inflammation, which are common to all cell types.
		OEHHA 2009	The key mechanisms for neurological effects of Pb are postulated to be: • Mimicking of calcium action and/or disruption of Ca homeostasis (e.g. interactions with protein kinase C or calmodulin). • Substitution for zinc in some enzymes and zinc-finger domains found in enzymes, channels, and receptors. • Interference with specific neurotransmitter systems in the brain (i.e. glutamatergic, dopaminergic and cholinergic systems).

#	Research Questions	Jurisdiction	Response to Research Questions
		IARC 2006	Pb interferes with numerous physiological processes. In the haeme biosynthetic pathway, it inhibits δ-aminolevulinic acid dehydratase (also known as porphobilinogen synthase), probably through its high affinity for the zinc-binding site in the enzyme. Although Pb displaces zinc more readily in one of the alloenzymes of the protein, the relationship between δ-aminolevulinic acid dehydratase genotype and sensitivity to Pb at different BPb concentrations is at present unclear. Pb also causes an increase in zinc protoporphyrin, by a mechanism which is not fully established. Pb inhibits pyrimidine-5'-nucleotidase, resulting in accumulation of nucleotides, and subsequent haemolysis and anaemia.
		ATSDR 2004a,b; ATSDR 2006, ATSDR 2017b, ATSDR 2018, CDC 2009, 2013; EFSA 2010b, 2010c, 2012; FSANZ 2019, IPCS 2000, 2006a; JECFA 2011a, b; US EPA 2004, NHMRC 2015a, b →	No relevant information
4	Is Lead a genotoxic carcinogen of relevance to humans?	**ATSDR 2020**	Unclear. Numerous epidemiological studies have investigated associations between Pb exposure and cancer. Studies include exposure of workers and general populations, with many studies reporting PbB. In most studies, mean PbBs in these studies are <10 µg/dL. Although studies provide limited evidence of carcinogenicity of Pb in humans, results are inconsistent, and interpretation may be limited due to confounding factors. IARC has classified inorganic Pb compounds as probably carcinogenic to humans (Group 2A) based on sufficient evidence in animals and limited evidence in humans. Results of genotoxicity studies with Pb in humans are inconsistent. DNA damage has been observed in several *in vivo* exposure studies in rodents, where Pb was often administered by parenteral routes but negative in some oral studies. *In vitro* studies in human cell lines have yielded mixed results, whereas those in prokaryotic organisms have yielded mostly negative results.
		IARC 2006	There is little evidence that Pb interacts directly with DNA at normally encountered blood Pb concentrations. The genetic toxicity of Pb appears to be mediated in part by increases in, and modulation of, reactive oxygen species. In addition, Pb interacts with proteins, including those involved in DNA repair. This latter mechanism might be responsible for enhancing the genotoxicity of other agents. These properties could result in mutation, changes in gene expression and cell proliferation, all of which would contribute to a carcinogenic response if exposure is sustained. Inorganic Pb compounds are classified as probably carcinogenic in humans (Group 2A), due to limited evidence in humans but sufficient evidence in animals.
		IPCS 2000	There is evidence of carcinogenicity of Pb in experimental animal studies and also epidemiological studies of highly exposed populations. Genotoxicity of Pb is not discussed.
		JECFA 2011a, b	No. IARC has concluded there is sufficient evidence for the carcinogenicity of inorganic Pb compounds in experimental animals, causing renal and brain tumours, and that the evidence for the carcinogenicity of organic Pb compounds is inadequate. The results of genotoxicity studies and the inhibition of DNA repair suggest a non-DNA-reactive mode of action for the carcinogenicity of lead.

#	Research Questions	Jurisdiction	Response to Research Questions
		WHO 2011	Conflicting results in genotoxicity studies, but most suggest that some Pb salts are genotoxic. IARC considers that the overall evidence for carcinogenicity in humans is inadequate for Pb, but that inorganic Pb compounds are probably carcinogenic to humans based on experimental animal data.
		OEHHA 2009	Inconsistent findings for genotoxicity, but Pb is regarded by IARC and the US EPA as an animal carcinogen and probably human carcinogen.
		ATSDR 2004a,b; ATSDR 2006, ATSDR 2017b, ATSDR 2018, CDC 2009, 2013; EFSA 2010b, 2010c, 2012; FSANZ 2019, IPCS 2006a; US EPA 2004, NHMRC 2015a, b → No relevant information	
5	What is the most appropriate dose metric for derivation of a drinking water guideline for lead?	**ATSDR 2018, 2020; CDC 2009, 2013;**	No guidance value/guideline value derived but most frequently used biomarker for exposure is BPb.
		ATSDR 2017b	No guidance value/guideline value derived but Pb exposure is managed using a reference value for BPb.
		EFSA 2010c, 2012; JECFA 2011a, b; WHO 2011; NHMRC 2015a,b	No guidance value/guideline value derived but dose-response analysis of Pb was exclusively conducted using BPb to describe exposure, which was converted back to an intake using PBPK modelling.
		OEHHA 2009	BPb converted back to an intake using PBPK modelling.
		ATSDR 2004a,b; ATSDR 2006, EFSA 2010b, FSANZ 2019, IARC 2006, IPCS 2000, 2006a → No relevant information	
6	What dose(s) (internal and/or external) are associated with the critical human health endpoint?	**ATSDR 2020**	Cognitive deficits in children occurring at the lowest PbBs (≤5 µg/dL) are the best substantiated effects. Exposure thresholds not identified.
		ATSDR 2017b; CDC 2009, 2013	BPb 'level of concern' no longer recommended. Instead, childhood BPb reference value is recommended. In 2012, the 97.5th percentile of the population BPb in children ages 1-5 was 5µg/dL in the USA, and this became the official reference value. In 2016, the 97.5th percentile was revised to 3.5 µg/dL (but has not been adopted as official reference value).
		ATSDR 2018	Used a reference value of 5 µg/dL for childhood BPb when evaluating BPb results from testing program.
		EFSA 2010c	Multiple estimated depending on use of linear, piecewise linear or logarithmic model; and exposure measure selected. Logarithmic model generally had a better fit than the piecewise linear model and the linear model. Results for logarithmic model were (BMD_{01} and $BMDL_{01}$, respectively) [(1)] (µg/dL): • Concurrent Pb: 0.354, 0.26 • Peak Pb: 0.393, 0.273 • Life time Pb: 0.355, 0.25 • Childhood Pb: 0.558, 0.343

#	Research Questions	Jurisdiction	Response to Research Questions
		JECFA 2011a, b; WHO 2011	• Children: BPb associated with decrease in 1 IQ point was 8.5(0.7-27) µg/dL using the Hill model and 2.1(0.8-17) µg/dL using the bilinear model. • Adults: The median increase of 0.28 mmHg ± 0.15 mmHg per 1 µg/dL BPb (5^{th}-95^{th} percentiles 0.03-0.53 mmHg) was used for dose response analysis.
		OEHHA 2009	BPb level of concern: 1µg/dL is correlated with a decrease of 1 IQ point. Pb intake that would correspond to the level of concern (1µg/dL) is 2.86 µg/day (this is based on IEUBK modelling for 1-2 year old children, which indicated a BPb level increase of 0.35 µg/dL results from each increment in drinking water intake of 1 µg/day).
		NHMRC 2015a, b	• 10-60 µg/dL: Increased blood pressure, abnormally low haemoglobin, abnormal kidney function, long-term kidney damage and abnormal brain function in adults and children. • <10 µg/dL: Reductions in IQ and academic achievement in children. Evidence is weaker at BPb <5 µg/dL. • 5-10 µg/dL: Higher occurrence of behavioural problems (poor attention, impulsivity and hyperactivity) in children, increased blood pressure in adults (including pregnant women) and a delay in sexual maturation or puberty onset in adolescent girls and boys.
		ATSDR 2004a,b; ATSDR 2006, EFSA 2010b, 2012; FSANZ 2019, IARC 2006, IPCS 2000, 2006a; US EPA 2004 → No relevant information	
7	Is the proposed health-based guidance value relevant to the Australian context?	**OEHHA 2009**	Yes, for the most part, however it is noted OEHHA (2009) in their derivation of a PHG in drinking water have defined the BPb level of concern to be 1 µg/dL as this is correlated with a decrease of 1 IQ point. Australia has not determined what would be considered a BPb level of concern; current science policy in Australia is to reduce Pb exposure and to manage individual Pb exposures if BPb is >5µg/dL.
		NHMRC 2015a,b	No guidance value derived, as there was considered to be insufficient evidence to support a causal association between BPb levels <10 µg/dL and any of the health effects observed. Nevertheless, the Working Group concluded if a person has a BPb level >5 µg/dL, their exposure to Pb should be investigated and reduced. This BPb level is currently referenced by public health services and applied in risk assessments of Pb exposure undertaken in Australia. It therefore seems reasonable to use a similar and consistent approach for derivation of the Australian DWG.
		ATSDR 2004a,b; ATSDR 2006, 2017b, 2018, 2020; CDC 2009, 2013; EFSA 2010b, c; EFSA 2012; FSANZ 2019, IARC 2006, IPCS 2000, 2006a; JECFA 2011a, b; WHO 2011, US EPA 2004 → No health-based guidance/guideline value was derived by these agencies.	
8	What is the guidance/ guideline value?	**OEHHA 2009**	**0.95 µg/day** (includes 3x UF to account for uncertainty with regard to the degree of protection offered, considering the lack of a threshold for Pb and small sample size in main study). OEHHA (2009) converted this to a PHG in drinking water of **0.2 µg/L (rounded).**
		NHMRC 2015a,b	Target BPb **<5 µg/dL**

#	Research Questions	Jurisdiction	Response to Research Questions
		WHO 2011	**Provisional DWG: 10µg/L** (consistent with previous value based on PTWI which was withdrawn) but value was designated as provisional on the basis of treatment performance and analytical achievability.
		ATSDR 2004a,b; ATSDR 2006, 2017b, 2018, 2020; CDC 2009, 2013; EFSA 2010b, c; EFSA 2012; FSANZ 2019, IARC 2006, IPCS 2000, 2006a; JECFA 2011a, b; WHO 2011, USEPA 2004 → No health-based guidance/guideline value was derived by these agencies.	
9	Are there groups of people in the general population who may be more sensitive to Lead exposure?	**ATSDR 2020**	• Children and neonates are likely to have increased susceptibility to Pb due to brains still developing, higher absorption of Pb in children compared to adults, and behaviours that increase ingestion of Pb surface dusts. • Elderly are likely more susceptible because physiological functions decline with age and aging is associated with bone loss which may result in Pb being mobilised into blood, resulting in potential increases in BPb. • In women, pregnancy, lactation, and post-menopausal status may increase bone demineralisation, mobilising bone Pb into the blood and potentially redistributing Pb to other tissues. • Dietary Ca and nutritional status of Fe and Zn can affect absorption of Pb. • People with genetic polymorphisms may alter susceptibility to Pb through altered toxicokinetics or toxicodynamics (e.g. δ-ALAD and VDR).
		IARC 2006	Considerable body of evidence suggests children are more sensitive than adults to the neurotoxic properties of Pb.
		IPCS 2006a	Developing child has higher vulnerability to neurotoxic effects of Pb.
		JECFA 2011a, b; WHO 2011, OEHHA 2009; USEPA 2004, NHMRC 2015a,b	Children, infants and foetuses due to developing nervous system.
		ATSDR 2004a,b; ATSDR 2006, 2017b, 2018; CDC 2009, 2013; EFSA 2010b, 2010c, 2012; FSANZ 2019, IPCS 2000 → No relevant information	
10	Is there a knowledge gap from the time at which existing guideline values were developed?	**OEHHA 2009**	Potentially. Bibliography contained literature up to 2008.
		NHMRC 2015a,b	Potentially. Literature search timeframe cutoff was mid May 2013.
		WHO 2011	Potentially. Bibliography contained literature up to 2011.
		Other agencies → Therefore, an evidence scan was undertaken for 2015-2021.	Potentially. Latest available health-based review is ATSDR (2020) which included literature up to February 2015.

#	Research Questions	Jurisdiction	Response to Research Questions
11	Does any recent literature change the guideline value? (e.g. demonstrating a new critical endpoint?)		Evidence scan identified three relevant reviews: • Hemmativaghef (2020) in a review, identified the lowest BPb levels at which significant increases in hearing thresholds between the exposed population and controls (LOAELs) were identified was 2 µg/dL in one study up to 2.823–26.507 µg/dL in another study (with NOAELs identified around 2 µg/dL as well). Based on the NOAEL and LOAELs identified, a biological exposure index of 2 µg/dL was recommended by the authors for prevention of hearing impairment from Pb exposure. With the majority of studies finding a statistically significant association between BPb and hearing loss, the Hemmativaghef (2020) study is suggestive of a causal effect between the two parameters. However individual study bias and confounding was not evaluated by study authors. Therefore, this study is considered as supportive evidence to limit Pb exposure but is not recommended to underpin DWG derivation on its own. • Poropat et al. (2018) in a meta-analysis, found BPb concentrations in pregnant women to be a major risk factor for preeclampsia, with an increase of 1 µg/dL associated with a 1.6% increase in likelihood of preeclampsia. It is noted mean BPb in the majority of samples from women with preeclampsia was >5µg/dL. This paper does not provide evidence to indicate BPb <5µg/dL is associated with preeclampsia, which suggests this paper would not alter the conclusion to limit BPb to <5 µg/dL. • Wilson and Wilson (2016) provides an interesting perspective on the use (or inappropriate use) of statistical analysis methods in Pb epidemiological studies which may have affected interpretation of there not being a demonstrable threshold for Pb effect on child cognition. The paper examines why statistical tests and statistical models applied by previous researchers failed to identify confounding and concludes that effects of low Pb exposure (BPb <10 µg/dL) have been exaggerated. The relevant reviews identified in the evidence scan provide indirect support for not recommending the OEHHA (2009) guideline value for adoption/adaptation in Australia, and instead basing the recommended DWG for Pb on a reduction/ minimisation of Pb exposures, consistent with current Australian science policy.

1. The author used a benchmark response (BMR) of 1 IQ-point (BMR_{01}). The BMDL is defined as a lower one-sided 95% confidence limit of the BMD.

4.2 Exposure-related research question analysis

Table 9 Synthesis of extracted data for exposure-related research questions – Water Corporations

#	Research Questions	Jurisdiction	Response to Research Questions
12	What are the typical lead levels in Australian drinking water? Do they vary around the country or under certain conditions e.g. source of water, drought?	**ICON Water 2019, 2020 (ACT)**	• Mean: 0.0003 mg/L • Range: <0.0002 –0.0081 mg/L Main source of Pb in drinking water is household plumbing systems, therefore Australian Department of Health recommends flushing taps used for drinking and cooking for about 30 seconds first thing in the morning or after periods of absence. This will draw fresh water into the tap and reduce potential exposure to Pb.

#	Research Questions	Jurisdiction	Response to Research Questions
		Melbourne Water 2021, Yarra Valley 2010-2020, City West Water 2016 (VIC)	Range: <0.001 – 0.004 mg/L
		Tas Water 2014-2020 (Tasmania)	• Mean: 0.0002-0.002 mg/L • Range of minimums: <0.0001 –0.0008 mg/L • Range of maximums: 0.0002-0.0027 mg/L
		PWNT 2004-2020 (Northern Territory)	• Range of means: <0.001-0.02 mg/L Pb is not found in the source water used for public water supplies. Instead, Pb can enter tap water when plumbing materials containing Pb start to corrode. Pb was not detected from most of the water samples taken in the Northern Territory. However where the sample site plumbing has started to corrode Pb can be detected.
		Seqwater 2021 (QLD)	• Mean: <0.001 mg/L • Range: <0.001 – <0.001 mg/L
		Chapman et al. 2008 (various locations around Australia)	Rainwater tanks: Total detected: 53, Total tested: 69 • Mean: 0.0038 mg/L • Range: 0.0003 – 0.013 mg/L
		Rodrigo et al. 2009 (South Australia)	Stored rainwater used for drinking: • Median (soluble): 0.0006 mg/L • Median (total): 0.0008 mg/L • Maximum (soluble): 0.0224 mg/L • Maximum (total): 0.0301 mg/L Due to the soft and sometimes acidic nature of rainwater, when used in hot water systems, it leads to increases in Pb concentrations in the hot water.
13	Do Australian levels differ considerably from elsewhere?	Mean levels in drinking water appear to be lower than or similar to those in other developed countries (e.g. USA, Canada, Europe, Japan) (ATSDR 2020, EFSA 2012, IARC 2006). Lead contamination in drinking water came from corrosion by-products of Pb pipes and Pb-soldered joints in older houses. First-draw water contains highest Pb concentrations.	

Table 10 Synthesis of extracted data for other exposure-related research questions

#	Research Questions	Jurisdiction	Response to Research Questions
14	What are the principal routes of exposure to lead in the Australian general population?	**ATSDR 2020**	In the USA, soil and dust ingestion in children are the dominant exposure pathways at the upper percentiles, whereas at lower percentiles food and drinking water become more important.
		EFSA 2010b, 2012; FSANZ 2019	Diet and drinking water, although for children ingestion of soil and dust can also be an important contributor.
		IARC 2006	Ingestion (in crops, soil, water, food, dust) and inhalation (air).
		IPCS 2000	In adult non-smokers, it is food and water. In children, it is food, air, water, and dust or soil.
		JECFA 2011a,b	This depends on the region of the world and its socioeconomic status. Pb is a multimedia contaminant, with sources or pathways that include air, water, soil, dust, food, paint and consumer products. This can make source attribution challenging. The relative contribution of diet to total Pb exposure will vary depending on locale and contribution from non-dietary sources. Estimates from EFSA suggest at least half of children's exposure may be due to non-dietary sources with soil and dust being major contributors.
		WHO 2011	More than 80% of the daily intake of Pb is derived from ingestion of food, dirt and dust. Intake from drinking water (at 5 µg/L) forms a relatively small proportion of the total daily intake for children and adults, but a significant one for bottle-fed infants.
		OEHHA 2009	Primarily via oral route.
		NHMRC 2015a,b	Not stated. Most people in Australia live in places where there are very small amounts of Pb in food, drinking water, air, dust, soil and consumer products. However, peoples' exposure to Pb has substantially reduced in recent decades due to national initiatives which have restricted the addition of Pb to paint and petrol, and the use of Pb in consumer goods.
		ATSDR 2004a,b; ATSDR 2006, 2017b, 2018; CDC 2009, 2013; EFSA 2010c, IPCS 2006a, USEPA 2004 → No relevant information	
15	What are the typical levels of Australian exposure (e.g. 'background' lead levels)?	**ATSDR 2020**	In USA, estimated average dietary intake of Pb was 10 µg/day in 1995-1997. Geometric mean BPb levels in US population for years 2015-2016 were: • 0.82 µg/dL for whole population. • 0.758 µg/dL in 1-5 year olds. • 0.571 µg/dL in 6-11 year olds. • 0.467 µg/dL in 12-19 year olds. • 0.92 µg/dL in ≥20 year olds.
		ATSDR 2017b	In US population, the 97.5th percentile BPb for children aged 1-5 years (in 2011-2014) was 3.5 µg/dL.
		ATSDR 2018	In Philadelphia USA, among the 104 children tested for BPb in their household, their geometric mean BPb was 2.0 µg/dL [95% CI, 1.7–2.3 µg/dL]).

#	Research Questions	Jurisdiction	Response to Research Questions
		CDC 2009, 2013	In USA, geometric means and 90th percentiles (µg/dL) for the following age groups (for latest data, listed as 2003-2004): • Overall: 1.43, 3.2 • 1-5 yrs: 1.77, 3.9 • 6-11 yrs: 1.25, 2.6 • 12-19 yrs: 0.946, 1.9 • ≥ 20 yrs: 1.52, 3.3 In 2012, the 97.5th percentile BPb in children 1-5 yrs of age was 5µg/dL.

		EFSA 2010b	In Europe, dietary Pb intakes were estimated to be:
			• Lower bound exposure:
			  ○ 0.4-1.7 µg/kg bw/day (median consumer)
			  ○ 0.7-7.9 µg/kg bw/day (99.9th percentile consumer)
			• Upper bound exposures: An average of 1.8x higher.

		EFSA 2012	Mean lifetime dietary exposure to Pb was estimated to be: • 0.68 µg/kg bw/d in overall European population based on middle bound mean Pb occurrence. • 1.32 and 1.03 µg/kg bw/d for toddlers and other children, respectively. • 0.83-0.91 µg/kg/day for infants. • 0.5 µg/kg/d for adults. Highest individual contributor to dietary Pb exposure was tap water at 6.1%.

		FSANZ 2019	• Mean and 90th percentile (respectively) estimated dietary exposures to Pb (µg/kg bw/d):
			  ○ Lower bound: 0.016-0.048 and 0.032-0.1
			  ○ Upper bound: 0.16-0.38 and 0.23-0.56
			  ○ Highest in 2-5 yr old children: 0.048-0.38 and 0.1-0.56.

		IARC 2006, IPCS 2000	Estimates of Pb intakes from the diet provided for various countries, primarily data from the 80's and 90's. Detail not extracted here, as the information is relatively outdated.
		JECFA 2011a, b	Dietary exposure estimates provided for a number of different countries (µg/kg bw/day): • In Australia (2 yrs): 0.03-0.93 (other countries not listed here).
		WHO 2011	Estimated exposures: • Air: 0.5 µg/day (infant) to 4 µg/day (adult), assuming a concentration of 0.2 µg/m^3 in air. • Water: 3.8 µg/day (infant) to 10 µg/day (adult), assuming a concentration of 5 µg/L in drinking water. • Food (most countries): 23-66 µg/day (2 year old). • Soil and house dust: Levels highly variable so intakes also vary considerably.

#	Research Questions	Jurisdiction	Response to Research Questions
		ATSDR 2004a, b; ATSDR 2006, EFSA 2010c, IPCS 2006a, OEHHA 2009, USEPA 2004, NHMRC 2015a,b → No relevant information	

4.3 Risk-based research question analysis

Table 11 Synthesis of extracted data for risk-associated research questions

#	Research Questions	Jurisdiction	Response to Research Questions
16	What are the risks to human health from exposure to lead in Australian drinking water?	**EFSA 2012**	None identified for drinking water *per se*. However, in 2010, EFSA concluded that the PTWI of 25 µg/kg bw set by JECFA in 1986 was no longer appropriate and that, as there was no evidence of a threshold for a number of critical endpoints including developmental neurotoxicity and adult nephrotoxicity, it would not be appropriate to derive a PTWI. The conclusion was confirmed by JECFA in 2010, while also expressing a concern that there was potential at current levels of exposure for Pb to affect neurodevelopment in infants, children and the foetus of pregnant women. Using an alternative measure, the 2010 EFSA opinion identified a 95th percentile lower confidence limit of the benchmark dose of 1 % extra risk ($BMDL_{01}$) of 0.50 µg/kg bw/ day for developmental neurotoxicity in young children. It also lists cardiovascular effects and nephrotoxicity in adults as potential critical adverse health effects of Pb with respective $BMDL_{01}$ and $BMDL_{10}$ of 1.50 and 0.63 µg/kg bw/d.
		JECFA 2011a, b	No, not drinking water *per se*. However, the risk assessment undertaken by the Committee (which is for total Pb exposure) estimated that the previously established PTWI of 25 µg/kg bw is associated with a decrease of at least 3 IQ points in children and an increase in systolic blood pressure of approximately 3mmHg in adults. These changes are important when viewed as a shift in the distribution of IQ or blood pressure within a population. The Committee therefore concluded that the PTWI could no longer be considered health protective, and it was withdrawn. Because the dose-response analyses do not provide any indication of a threshold for the key effects of Pb, the Committee concluded that it was not possible to establish a new PTWI that would be considered health protective.
		ATSDR 2004a, b; ATSDR 2006, 2017b, 2018, 2020; CDC 2009, 2013; EFSA 2010b, 2010c; IPCS 2000, IPCS 2006a, OEHHA 2009, USEPA 2004, NHMRC 2015a,b; FSANZ 2019, IARC 2006, WHO 2011, OEHHA 2009, → None identified or No information provided	

#	Research Questions	Jurisdiction	Response to Research Questions
17	Is there evidence of any emerging risks that are not mentioned in the current factsheet that require review?	**EFSA 2012**	See response to previous question.
		JECFA 2011a, b	The Committee concluded that, in populations with prolonged dietary exposures to Pb that are at the higher end of the ranges identified (~9 µg/kg bw/day), measures should be taken to identify major contributing sources and foods and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.
		Hemmativaghef 2020	This literature review found no significant increases in hearing thresholds (i.e. ototoxicity) between the exposed groups and controls (NOAELs) at BPb from 1–1.99 µg/dL up to 2.148–2.822 µg/dL. On the other hand, the lowest BPb levels at which significant increases in hearing thresholds between the exposed population and controls (LOAELs) were identified was 2 µg/dL up to 2.823–26.507 µg/dL. Based on the NOAEL and LOAELs identified, the authors recommend a biological exposure index of 2 µg/dL for prevention of hearing impairment from Pb exposure. It is noted that this study, on its own, would not be sufficient for derivation of a DWG however may provide supporting information on the critical health effects of Pb.
		Poropat et al. 2018	BPb concentrations in pregnant women are a major risk factor for preeclampsia, with an increase of 1 µg/dL associated with a 1.6% increase in likelihood of preeclampsia, which appears to be the strongest risk factor for preeclampsia yet reported. Women with concentrations higher than 5 µg/dL should be actively monitored for preeclampsia and be advised to take prophylactic calcium supplementation. All pregnant women should be advised to actively avoid Pb exposure.
		ATSDR 2004a, b; ATSDR 2006, 2017b, 2018, 2020; CDC 2009, 2013; EFSA 2010b, 2010c; IPCS 2000, IPCS 2006a, OEHHA 2009, USEPA 2004, NHMRC 2015a,b; FSANZ 2019, IARC 2006, WHO 2011, OEHHA 2009, → None identified or No information provided	

4.4 Supporting factsheet information research question analysis

The supporting information in the fact sheet for Pb consists of the following (NHMRC and NRMMC 2011):

- **General Description:** "*Lead can be present in drinking water as a result of dissolution from natural sources, or from household plumbing systems containing lead. These may include lead in pipes, or in solder used to seal joints. The amount of lead dissolved will depend on a number of factors including pH, water hardness and the standing time of the water. Lead is the most common of the heavy metals and is mined widely throughout the world. It is used in the production of lead acid batteries, solder, alloys, cable sheathing, paint pigments, rust inhibitors, ammunition, glazes and plastic stabilisers. The organo-lead compounds tetramethyl and tetraethyl lead are used extensively as anti-knock and lubricating compounds in gasoline. Drinking water concentrations of lead reported overseas are usually less than 0.002 mg/L, but concentrations of 0.1 mg/L have been reported in Scotland where lead pipes and soft, acidic water are contributing factors. Approximately 80% of the daily intake of lead is from the ingestion of food, dirt and dust. Food contains small but significant quantities of lead, which can increase when acidic food is stored in lead-glazed ceramic pottery or lead-soldered cans. The use of lead-free solders is becoming more widespread in the food processing industry. The average Australian adult dietary intake of lead is approximately 0.1 mg per day.*
- **Typical values in Australian drinking water: "***In major Australian reticulated supplies, total lead concentrations range up to 0.01 mg/L, with typical concentrations less than 0.005 mg/L*."
- **Treatment of drinking water: "***Lead concentrations in drinking water can be reduced by conventional methods of water treatment using coagulants or lime softening*".
- **Measurement: "***The concentration of lead in drinking water can be determined by graphite furnace atomic absorption spectroscopy (APHA Method 3500-Pb Part B 1992). The limit of determination is 0.005 mg/L*".

Table 12 Synthesis of extracted data for research questions relevant to supporting factsheet information – Agency reviews

#	Research Questions		Jurisdiction	Response to Research Questions
18	Is the general description current?	Uses	**ATSDR 2020, EFSA 2012, IARC 2006, IPCS 2000, JECFA 2011a, b; NHMRC 2015a, b; OEHHA 2009, WHO 2011** → Yes, based on the uses provided in these documents, the general description on uses in the current Australian fact sheet for Pb appears to still be appropriate.	
		Sources in DW	**ATSDR 2020, EFSA 2012, IARC 2006, IPCS 2000, NHMRC 2015a, b; OEHHA 2009, WHO 2011, PWNT 2020** → Yes, based on the sources in drinking water provided in these documents, the general description in the current Australian fact sheet for Pb appears to still be appropriate. The source of Pb in drinking water is stated to be mainly corrosion of Pb pipes or Pb-soldered joints, or source water contamination.	
19			**ATSDR 2020**	Drinking water: • EPA 2003 Method 200.5 (ICP-AES) (LOR 1.1 µg/L) • EPA 1994f Method 200.8 (ICP-MS) (LOR 0.02 µg/L)
			FSANZ 2019	For analysis of food and drinking water: ICP acid digest preparation (LOR 0.005 mg/kg in food, 0.0001 mg/L in drinking water).

#	Research Questions	Jurisdiction	Response to Research Questions
	What are the indicators of the risks? How can we measure exposure? Is the information on measurement/analytical methods current?	**IARC 2006**	Water: • ICP-AES Method D1976 (LOD 42 µg/L) • ICP-MS Method D5673 (LOD 0.08 µg/L) • XRF Method D6502 (LOD 1 µg/L) • AAS Method 239.1 (LOD 100 µg/L)
		WHO 2011	Atomic absorption spectrometry and anodic stripping voltammetry are the methods most frequently used for determining the levels of Pb in environmental and biological materials. Detection limits of less than 1 µg/L can be achieved by means of atomic absorption spectrometry.
DW = Drinking Water.			

Table 13 Synthesis of extracted data for research questions relevant to supporting factsheet information – Other sources

#	Research Questions	Jurisdiction	Response to Research Questions
19	What are the indicators of the risks? How can we measure exposure? Is the information on measurement/analytical methods current?	**Correspondence with Australian Commercial Laboratories**	Method reference: US EPA 6010, 6020, APHA 3010 and 3030 Description: Filtered (0.45µm) and acidified in the field prior to analysis. Analysis by ICP-MS. (Eurofins in-house method LTM-MET-3040). Reference methods include USEPA Method 6020B, USEPA Method 3010A and USEPA Method 3015A
		Water Corporations (Nadebaum et.al 2004, Chapman et al. 2008, Rodrigo et al. 2009; Icon Water 2019, PWNT 2020)	Icon Water (2019) lists method US EPA 200.8 (LOD 0.0002 mg/L). Others list LOD's of 0.001 mg/L or 0.002 mg/L but do not provide the analytical method detail.
20	Are there commercial analytical methods available that can measure at or below guideline value?	**Correspondence with Australian Commercial Laboratories**	The standard LOR ranges from 0.0002 to 0.05 mg/L (i.e. 0.2 to 50 µg/L), with trace LORs ranging from 0.0002 to 0.002 mg/L (i.e. 0.2 to 2 µg/L), depending on the laboratory.
		Water Corporations (Nadebaum et.al 2004, Chapman et al. 2008, Rodrigo et al. 2009; Icon Water 2019, PWNT 2020)	LOR 0.0002 to 0.002 mg/L (i.e. 0.2 to 2 µg/L).
21		**Correspondence with Australian Commercial Laboratories**	-

#	Research Questions	Jurisdiction	Response to Research Questions
	Is the information for treatment options current in terms of current practices in Australia?	**WHO 2011**	Pb is exceptional in that most Pb in drinking-water arises from plumbing in buildings, and the remedy consists principally of removing plumbing and fittings containing it, which requires both time and money. In the interim, all practical measures to reduce total exposure to Pb, including corrosion control, should be implemented. It is extremely difficult to achieve a concentration below 10 µg/L by central conditioning, such as phosphate dosing.
		Peer-reviewed literature	A total of 22 potentially relevant papers on lead treatment in drinking water were identified in a Scopus literature search (see **Appendix D**). These studies described mostly commercially used water treatment techniques with small adjustments in order to improve Pb removal efficiency. Approaches described include: Metal organic framework (MOF), Polymerisation in MOF pore structure, Aggregation of Pb phosphate particles, Stabilised FeS nanoparticles, Oxidised Fe_3O_4 membranes, Gravitation filtration using granular activated carbon, Adsorption (sawdust, magnetic adsorption, silicates, cellulose metallothionein), Iron oxide modified clay activated carbon beds, Sand filtration and GAC and non-woven geotextile, Zeolite based nano-composite, Blended phosphate treatment, and Fabricated magnetic filters with mesh structure. The majority of studies demonstrated Pb removal efficiency in a range between 93-100%, meeting the WHO Drinking Water Guideline of 0.01 mg/L.
22	Can treatment technologies treat to the suggested level of the guideline value?	**Correspondence with Australian Commercial Laboratories**	-
		Water Corporations (Icon Water 2019, 2020; Tas Water 2014-2020, PWNT 2004-2020, Seqwater 2021, Chapman et al. 2008, Rodrigo et al. 2009)	Conventional treatment technology appears to be able to reduce mean lead concentrations of source water to 0.0002 to 0.002 mg/L (i.e. 0.2 to 2 µg/L) most of the time. However occasional instances of higher concentrations (e.g. 20 µg/L) such as in the Northern Territory have been recorded. Mean concentrations in rainwater tanks appear to be similar (e.g. 0.8 to 3.8 µg/L). However, the concentrations in water exiting the tap may be higher in older buildings if Pb-soldered pipes are present. According to WHO (2011), it is extremely difficult to achieve a concentration below 10 µg/L in such buildings by central conditioning, such as phosphate dosing.
23	Is there any new information which should be added? Should anything be removed?		Update LOR in measurement section, treatment section can be expanded to include reference to difficulties in treating Pb concentrations in older houses without replacement of Pb-soldered plumbing, and typical values in Australian drinking water can be updated.

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APPENDIX A

Literature search screening outcome spreadsheets

Appendix A contents here

APPENDIX B

Data extraction tables – Health-based guidance/guidelines

Existing Health-Based Guidance for Lead

ATSDR 2020

Agency Report Reference: ***ATSDR (2020). Toxicological Profile for Lead. US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. August 2020.***		
General Information	Date of data extraction	08/11/2021
	Authors	Abadin H, Taylor J, Buser M, Scinicariello F, Przybyla J, Klotzbach JM, Diamond GL, Citra M, Chappell LL, Mcllroy LA
	Publication date	August 2020
	Literature search timeframe	February 2015-September 2019 (update to draft profile, which included literature up to February 2015)
	Publication type	Agency Review
	Peer reviewed?	Yes
	Country of origin	USA
	Source of funding	Not stated, but likely US government
	Possible conflicts of interest	No. Expert contributors are screened for conflict of interest prior to their involvement/contribution.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	Not applicable. No guidance value (i.e. Minimal Risk Level) was derived by ATSDR, because clear thresholds for effects have not been identified.
	Exposure timeframe	Not applicable (no guidance/guideline value derived)
	Critical health endpoint(s) – oral exposure	Epidemiological studies have identified health effects of Pb in all organ systems at the lowest blood Pb evaluated (<5 µg/dL). However, exposure thresholds for effects have not been identified and it is not possible to determine from the epidemiological data which organ system are the most sensitive (i.e. primary) targets for Pb toxicity.
	Justification provided by agency for critical endpoint	Clinical significance of some of the organ system effects at low levels of exposure and blood Pb is more substantial than for others (e.g. neurological, renal, cardiovascular, haematological, immunological, reproductive, and developmental effects). This is not surprising because the mechanisms that induce toxicity are common to all cell types and because Pb is widely distributed throughout the body. Adverse health effects have been observed in these systems at blood Pb (PbB) ≤10 µg/dL. Exposure thresholds for effects on specific organ systems have not been identified (i.e. no safe level has been identified). Cognitive deficits in children occurring at the lowest PbBs (≤5 µg/dL) are the best substantiated effects. However, data for some organ systems results are inconsistent, and insufficient data are available to provide information on dose-response relationships.
	Critical study(ies) underpinning point of departure	Not applicable (no guidance value derived).
	Species for critical study(ies)	Not applicable (no guidance value derived).
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	Not applicable (no guidance value derived).

Agency Report Reference: ***ATSDR (2020). Toxicological Profile for Lead. US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. August 2020.***		
	Point of departure value (include units)	Not applicable (no guidance value derived).
	Uncertainty factor(s) & rationale	Not applicable (no guidance value derived).
	The derivation:	Not applicable (no guidance value derived).
	Guideline value (include units)	Not applicable (no guidance value derived).
	Mode of action for critical health endpoint	Critical health endpoint not identified. However, mechanisms of action associated with Pb-induced toxicity include perturbations of ion homeostasis and transport (e.g. displacing other metal ions such as iron, calcium, zinc, magnesium, selenium and manganese), protein binding, oxidative stress, and inflammation, which are common to all cell types.
	Genotoxic oral carcinogen?	Unclear. Numerous epidemiological studies have investigated associations between Pb exposure and cancer. Studies include exposure of workers and general populations, with many studies reporting PbB. In most studies, mean PbBs in these studies are <10 µg/dL. Although studies provide limited evidence of carcinogenicity of Pb in humans, results are inconsistent, and interpretation may be limited due to confounding factors. IARC has classified inorganic Pb compounds as probably carcinogenic to humans (Group 2A) based on sufficient evidence in animals and limited evidence in humans. Results of genotoxicity studies with Pb in humans are inconsistent. Numerous epidemiological studies with PbB ≥10 µg/dL report associations for exposure to Pb and genotoxic endpoints (gene mutation, DNA damage, SCE, MN formation, and DNA methylation), although some inverse associations have been reported. Few epidemiology studies have evaluated genotoxicity at PbB ≤10 µg/dL, with some endpoints only evaluated in a single study which makes it difficult to draw conclusions. DNA damage has been observed in several *in vivo* exposure studies in rodents, where Pb was often administered by parenteral routes but negative in some oral studies. *In vitro* studies in human cell lines have yielded mixed results, whereas those in prokaryotic organisms have yielded mostly negative results.

Agency Report Reference: ***ATSDR (2020). Toxicological Profile for Lead. US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. August 2020.***		
	Identified sensitive sub-populations	• Children and neonates are likely to have increased susceptibility to Pb due to brains still developing, higher absorption of Pb in children compared to adults, and behaviours that increase ingestion of Pb surface dusts. • Elderly are likely more susceptible because physiological functions decline with age and aging is associated with bone loss which may result in Pb being mobilised into blood, resulting in potential increases in BPb. • In women, pregnancy, lactation, and post-menopausal status may increase bone demineralisation, mobilising bone Pb into the blood and potentially redistributing Pb to other tissues. • Dietary Ca and nutritional status of Fe and Zn can affect absorption of Pb. • People with genetic polymorphisms may alter susceptibility to Pb through altered toxicokinetics or toxicodynamics (e.g. δ-ALAD and VDR).
	Any non-health-based considerations?	US public health policy has changed to focus on eliminating Pb poisoning as a public health problem. The US Centre for Disease Control (CDC) considers BPb to be elevated in children when it exceeds a reference value defined as the 97.5th percentile for the US population. The current CDC reference value, based on data from the NHANES 2007–2008 and 2009–2010, is 5 µg/dL.
Exposure considerations	Principal routes of exposure in general population	The general population may be exposed to Pb in ambient air, foods, drinking water, soil and dust (and some consumer products). Based on a multimedia Pb exposure modelling analysis for children 1–5 years old at upper percentiles of BPb levels in the US population, soil and dust ingestion are dominant exposure pathways, but for lower percentiles, other age groups (e.g. younger children), or specific local US locations, the main other exposure sources/pathways could be important, such as drinking water and food.
	Levels in drinking water supplies (include location)	Data only provided for specific locations with Pb-based solder problems, e.g. in 2003, <2% of US public water systems serving >3,300 people exceeded 15 µg/L.
	Any special considerations to exposure levels (e.g. higher in drought?)	Pb in drinking water can derive from source water contamination, but the more common source of Pb in drinking water is from internal corrosion of water distribution system piping and plumbing. Internal corrosion of Pb service lines, Pb-based pipe solder, brass meters and plumbing fixtures, and dissolution of existing protective scales contribute directly to Pb levels in drinking water.

Agency Report Reference: ***ATSDR (2020). Toxicological Profile for Lead. US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. August 2020.***		
	Typical exposure in general population (include units for intakes & location)	In the United States: • Diet: Estimated average dietary intake of Pb was 10 µg/day in 1995-1997, and US EPA estimated mean dietary Pb intakes in children aged 6-84 months to be ~2 µg/day. • Intakes for other routes of exposure not provided. However, BPb is measured as part of the NHANES survey. Geometric mean BPb levels in US population for years 2015-2016 were: • 0.82 µg/dL for whole population. • 0.758 µg/dL in 1-5 year olds. • 0.571 µg/dL in 6-11 year olds. • 0.467 µg/dL in 12-19 year olds. • 0.92 µg/dL in ≥20 year olds.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No, elevated BPb in children is most likely a result of ingesting Pb-contaminated soil, and most likely source is Pb-based paint that has deteriorated into paint chips and Pb dust.
	Any emerging risks identified?	No.

ATSDR 2004a, b, ATSDR 2006

Agency Report Reference: ***ATSDR (2004a). Interaction Profile for: Lead, Manganese, Zinc, and Copper. Agency for Toxic Substances and Disease Registry. May 2004.*** ***ATSDR (2004b). Interaction Profile for: Arsenic, Cadmium, Chromium, and Lead. Agency for Toxic Substances and Disease Registry. May 2004.*** ***ATSDR (2006). Interaction Profile for: Chlorpyrifos, Lead, Mercury, and Methylmercury. Agency for Toxic Substances and Disease Registry. August 2006.***		
General Information	Date of data extraction	08/11/2021
	Authors	ATSDR (2004a): Roney N and Colman J ATSDR (2004b): Roney N, Colman J, Ingerman L, Diamond G ATSDR (2006): Pohl H and Colman J
	Publication date	May 2004, August 2006
	Literature search timeframe	2004a,b: Up until January 2000 2006: Not stated, but bibliography contains literature up to 2005.
	Publication type	Agency reviews (Interaction profiles)
	Peer reviewed?	Yes
	Country of origin	USA
	Source of funding	Not stated, but likely US government
	Possible conflicts of interest	Not stated.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	Not applicable (no guidance/guideline value derived), but these reviews contain potentially relevant information regarding toxicological interactions between Pb and other substances. Hence this table has been amended to allow capturing the relevant information.

Agency Report Reference: *ATSDR (2004a). Interaction Profile for: Lead, Manganese, Zinc, and Copper. Agency for Toxic Substances and Disease Registry. May 2004.* *ATSDR (2004b). Interaction Profile for: Arsenic, Cadmium, Chromium, and Lead. Agency for Toxic Substances and Disease Registry. May 2004.* *ATSDR (2006). Interaction Profile for: Chlorpyrifos, Lead, Mercury, and Methylmercury. Agency for Toxic Substances and Disease Registry. August 2006.*		
	Exposure timeframe	Not applicable (no guidance/guideline value derived).
	Critical health endpoint(s) – oral exposure	
	Justification provided by agency for critical endpoint	
	Critical study(ies) underpinning point of departure	
	Species for critical study(ies)	
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	
	Point of departure value (include units)	
	Uncertainty factor(s) & rationale	
	The derivation:	
	Guideline value (include units)	
	Mode of action for critical health endpoint	
	Genotoxic oral carcinogen?	Not discussed with respect to lead alone.
	Identified interactions with Pb?	• Predicted directions of interaction of binary mixtures (lead-zinc, lead-copper) were less than additive or additive, but for lead-manganese it was greater than additive (both exert neurological effects). • Data for lead-cadmium and lead-arsenic mixtures indicated the direction of interaction may not be consistent across endpoints. For example, for Cd and Pb, the predicted direction is greater than additive for the neurological effects and testicular effects (a less sensitive effect), less than additive for renal and haematological effects, and additive for cardiovascular effects. • Interaction information for Pb, chlorpyrifos and mercury/ methylmercury indicates joint toxic action is primarily less than additive or additive and, therefore does not increase the concern for potential health hazard above that indicated by a hazard index approach.

ATSDR 2017b

Agency Report Reference: ***ATSDR (2017b). Final Report LPPRV work group report 01-13-2017. Consensus Recommendations on Revision of the Blood Lead Reference Value. Agency for Toxic Substances and Disease Registry.***		
General Information	Date of data extraction	08/11/2021
	Authors	Kosnett MJ, Cheng P-Y, Cory-Slechta D, Jones R, Lowry JA, Parsons PJ, Strickland MJ
	Publication date	January 13, 2017
	Publication type	Agency memorandum/recommendation
	Description	In 2010, the CDC Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) convened a work group to evaluate new approaches, terminology, and strategies for defining elevated BPb among children. On January 4, 2012, building on the work group's recommendations, ACCLPP approved a report entitled "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention." The findings of the report included recommendations that CDC abandon the term "level of concern" with respect to childhood BPb, and instead use a childhood BPb reference value based on the 97.5th percentile of the population BPB in children ages 1-5 (currently 5 µg/dL) to identify children and environments associated with lead-exposure hazards. The reference value should be updated by CDC every four years based on the most recent population based BPb surveys among children. In 2016, CDC reported the results of the US NHANES Survey for 2011-2014. The 97.5th percentile BPb for children aged 1- 5 years was 3.5 µg/dL. CDC wish to understand the implications of establishing a new blood lead reference value that is lower than 5 µg/dL.

	Findings	The Working group concluded that a reasonable course of action is the following:
		• BPb reference value should be revised to 3.5 µg/dL.
		• However, whether the BPb measurement of a child should trigger the child-specific response actions recommended in a previous document for a BPB equal to or greater than the reference value should depend on the nature and magnitude of the BPb measurement.
		  ○ If the average of the initial and confirmatory venous BPb measurements by any methodology is ≥5 µg/dL, there will be 97.5% confidence that the child's true BPb exceeds the BPb reference value of 3.5 µg/dL and the response actions should be initiated.
		  ○ Pending the availability of additional information regarding estimated clinical laboratory precision at BPb values of 3.5 µg/dL, if the average of the initial and confirmatory BPb measurement is ≥ 3.5 µg/dL but < 5 µg/dL, child-specific response actions should be deferred. For public health surveillance, all BPb equal to or greater than 3.5 µg/dL should be reported to the appropriate local, state, and federal agencies and programs together with identification of the type of analytical method used to perform each measurement.

ATSDR 2018

Agency Report Reference: *ATSDR (2018). Assessment of Child Blood Lead Levels in a Philadelphia Community, 2014. February 2018. National Center for Environmental Health, Agency for Toxic Substances and Disease Registry.*		
General Information	Date of data extraction	08/11/2021
	Authors	Not stated (ATSDR)
	Publication date	February 2018
	Publication type	Agency report
	Description	During July 2014, the CDC, ATSDR, and City of Philadelphia Department of Public Health (PDPH) conducted a study in Philadelphia. The community areas have been subject to various environmental and public health investigations since the 1970s. However, previous investigations were limited by their use of convenience samples. The study was conducted to quantify the risk of elevated BPb among children using a representative population-based survey design. The study provides insight into BPb in a random sample of children living in Philadelphia neighbourhoods with a history of Pb-related industry.
	Findings	Among the 104 children tested for BPb in their household, their geometric mean BPb was 2.0 µg/dL [95% CI, 1.7–2.3 µg/dL]) and 13 (12.5%) had BPb ≥5 µg/dL (2 who had BPb ≥10 µg/dL). Ninety-one (87.5%) of these 104 children had a previous BPb test on average 30.6 months prior to the study BPb test. Among the 42 children who did not have a venous BPb sample collected as part of this study but whose BPb results were abstracted from historical surveillance data, none had BPb ≥5 µg/dL. Their mean age was 3.6 years (range 10 to 82 months) and the average time to their prior blood lead test was 2.1 years. The study found a higher proportion of children with BPb ≥5 µg/dL compared to Philadelphia child surveillance data in the same study ZIP codes and compared with the most recent published US estimates: six times the percent of children with BPb ≥5 µg/dL and modestly higher geometric mean BPb. The study identified three factors that were associated with higher geometric mean BPb among children: leaded dust at the front door entryway; residence built prior to 1900; and a child currently or ever receiving Medicaid. Additionally, they found households with two or more elevated environmental Pb samples significantly predicted child BPb ≥5 µg/dL compared to those with no or only 1 elevated environmental Pb result.

CDC 2009, 2013

Agency Report Reference: *CDC (2009). Fourth National Report on Human Exposure to Environmental Chemicals. Department of Health and Human Services. Centers for Disease Control and Prevention. US.* *CDC (2013) Blood Lead Levels in Children – Fact Sheet. Department of Health and Human Services. Centers for Disease Control and Prevention. US.*		
	Date of data extraction	08/11/2021

Agency Report Reference: *CDC (2009). Fourth National Report on Human Exposure to Environmental Chemicals. Department of Health and Human Services. Centers for Disease Control and Prevention. US.* *CDC (2013) Blood Lead Levels in Children – Fact Sheet. Department of Health and Human Services. Centers for Disease Control and Prevention. US.*		
General Information	Authors	2009: Not stated (CDC report) 2013: Not stated (CDC fast sheet)
	Publication date	2009 and 2013
	Publication type	Agency report and agency fact sheet
	Description	CDC (2009) provides geometric mean BPb levels and selected percentiles for the US population from the National Health and Nutrition Examination Survey.
	Findings	Geometric means and 90th percentiles (µg/dL) for the following age groups (for latest data, listed as 2003-2004): • Overall: 1.43, 3.2 • 1-5 yrs: 1.77, 3.9 • 6-11 yrs: 1.25, 2.6 • 12-19 yrs: 0.946, 1.9 • ≥ 20 yrs: 1.52, 3.3 In 2012, the 97.5th percentile BPb in children 1-5 yrs of age was 5µg/dL.

EFSA 2010b

Agency Report Reference: *EFSA (2010b). Scientific Report: Long-term dietary exposure to lead in young children living in different European countries. European Food Safety Authority (EFSA). EFSA-Q-2009-00837. OJ L 364 ,* 20.12.2006, p. 5-24.		
General Information	Date of data extraction	08/11/2021
	Authors	Boon PE, Sioen I, von der Voet H, Huybrechts I, De Neve M, Amiano P, Azpiri M, Busk L, Christensen T, Hilbig A, Hirvonen T, Koulouridaki S, Lafay L, Liukkonen K-H, Moschandreas J, Papoutsou S, Ribas-Barba L, Ruprich J, Serra-Majem L, Tornaritis M, Turrini A, Urtizberea M, Verger E, Westerlund A, Mathilde K, De Henauw S, van Klaveren JD
	Publication date	5 May 2010
	Publication type	Scientific report submitted to EFSA
	Description	No guidance value derived in this document *per se* but contains relevant information potentially important to decision making by WQAC. Long-term dietary exposure to lead in children aged 1 up to 14 years living in 12 different European countries was estimated using daily food consumption patterns and mean lead concentrations in various food commodities.

Agency Report Reference: *EFSA (2010b). Scientific Report: Long-term dietary exposure to lead in young children living in different European countries. European Food Safety Authority (EFSA). EFSA-Q-2009-00837. OJ L 364 , 20.12.2006, p. 5-24.*		
	Findings	• Lower bound exposure: ○ 0.4-1.7 µg/kg bw/day (median consumer) ○ 0.7-7.9 µg/kg bw/day (99.9th percentile consumer) • Upper bound exposures: ○ An average of 1.8x higher.

EFSA 2010c

Agency Report Reference: *EFSA (2010c). Scientific/Technical Report: An international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children (Question No. EFSA-Q-2009-01078). European Food Safety Authority (EFSA). CT/EFSA/CONTAM/2009/03. 28 January 2010.*		
General Information	Date of data extraction	08/11/2021
	Authors	Jørgensen E B
	Publication date	28 January 2010
	Literature search timeframe	Not stated.
	Publication type	Agency document.
	Peer reviewed?	Not stated.
	Country of origin	Denmark
	Source of funding	European Union
	Possible conflicts of interest	Not stated.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	No guidance value derived. However, this report is potentially relevant since it presents the results of benchmark dose (BMD) modelling using the raw data from seven individual cohort studies summarised by Lanphear et al. (2005) on the effect of Pb on intellectual function in children.
	Exposure timeframe	Four exposure variables were available: • Concurrent Pb • Peak Pb • Life time Pb • Early childhood Pb
	Critical health endpoint(s) – oral exposure	Only one endpoint was investigated in this targeted report, i.e. intellectual function or IQ score. The author used a benchmark response (BMR) of 1 IQ-point (BMR_{01}). The BMDL is defined as a lower one-sided 95% confidence limit of the BMD.
	Justification provided by agency for critical endpoint	Not applicable (only one endpoint was subjected to BMD modelling in this targeted investigation).
	Critical study(ies) underpinning point of departure	Lanphear et al. (2005)
	Species for critical study(ies)	Humans (children)
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	BMD_{01} and $BMDL_{01}$

Agency Report Reference: *EFSA (2010c). Scientific/Technical Report: An international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children (Question No. EFSA-Q-2009-01078). European Food Safety Authority (EFSA). CT/EFSA/CONTAM/2009/03. 28 January 2010.*		
	Point of departure value (include units)	Multiple estimated depending on use of linear, piecewise linear or logarithmic model; and exposure measure selected. Logarithmic model generally had a better fit than the piecewise linear model and the linear model. Results for logarithmic model were (BMD_{01} and $BMDL_{01}$, respectively) (µg/dL): • Concurrent Pb: 0.354, 0.26 • Peak Pb: 0.393, 0.273 • Life time Pb: 0.355, 0.25 • Childhood Pb: 0.558, 0.343
	Uncertainty factor(s) & rationale	Not applicable (no guidance value was derived).
	The derivation:	Not applicable (no guidance value was derived).
	Guideline value (include units)	Not applicable (no guidance value was derived).
	Mode of action for critical health endpoint	No information provided.
	Genotoxic oral carcinogen?	No information provided.
	Identified sensitive sub-populations	No information provided.
	Any non-health-based considerations?	No information provided.
Exposure considerations	Principal routes of exposure in general population	No information provided.
	Levels in drinking water supplies (include location)	No information provided.
	Any special considerations to exposure levels (e.g. higher in drought?)	No information provided.
	Typical exposure in general population (include units for intakes & location)	No information provided.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No information provided.
	Any emerging risks identified?	No information provided.

References:

Lanphear BP, Hornung R, Khoury J, Yolton K, Baghurst P, Bellinger D, Canfield RL, Dietrich KN, Bornschein R, Greene T, Rothenberg SJ, Needleman HL, Schnaas L, Wasserman G, Graziano J and Roberts R (2005). Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives, 113, 894-899.

EFSA 2012

Agency Report Reference: *EFSA (2012). Lead dietary exposure in the European population. European Food Safety Authority (EFSA). EFSA Journal 2012;10(7):2831.*		
General Information	Date of data extraction	08/11/2021
	Authors	Fabiansson S, Arcella D, Cappe S
	Publication date	4 July 2012
	Literature search timeframe	Not stated, but bibliography contains literature up to 2011.
	Publication type	Agency report on dietary Pb exposure in Europe.
	Peer reviewed?	Yes.
	Country of origin	Europe
	Source of funding	Not stated, but likely EU
	Possible conflicts of interest	Not stated
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	No guidance value derived. Report stated there is no recommended tolerable intake level as there is no evidence of thresholds for a number of critical health effects. Legislative measures have been gradually introduced to reduce exposure by removing Pb from paint, food cans, water pipes and petrol.
	Exposure timeframe	Not applicable (no guidance value derived).
	Critical health endpoint(s) – oral exposure	The central nervous system is the main target organ for Pb toxicity. In adults, Pb-associated neurotoxicity was found to affect central information processing and short-term verbal memory, to cause psychiatric symptoms and to impair manual dexterity. There is considerable evidence demonstrating that the developing brain is more vulnerable to the neurotoxicity of lead than the mature brain.
	Justification provided by agency for critical endpoint	See above.
	Critical study(ies) underpinning point of departure	Not applicable (no guidance value was derived).
	Species for critical study(ies)	Not applicable (no guidance value was derived).
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	Not applicable (no guidance value was derived).
	Point of departure value (include units)	Not applicable (no guidance value was derived).
	Uncertainty factor(s) & rationale	Not applicable (no guidance value was derived).
	The derivation:	Not applicable (no guidance value was derived).
	Guideline value (include units)	Not applicable (no guidance value was derived).
	Mode of action for critical health endpoint	Not stated.
	Genotoxic oral carcinogen?	The International Agency for Research on Cancer (IARC) classified inorganic lead as probably carcinogenic to humans (Group 2A) in 2006. No mention of genotoxicity in this report.
	Identified sensitive sub-populations	Not stated.
	Any non-health-based considerations?	Not applicable (no guidance value was derived).

Agency Report Reference: *EFSA (2012). Lead dietary exposure in the European population. European Food Safety Authority (EFSA). EFSA Journal 2012;10(7):2831.*		
Exposure considerations	Principal routes of exposure in general population	Food is the major source of exposure to Pb in the general population, although for children ingestion of soil and dust can also be an important contributor.
	Levels in drinking water supplies (include location)	Mean Pb concentrations in Europe varied between 0.5 (carbonated mineral water) to 6 µg/L (in tap water).
	Any special considerations to exposure levels (e.g. higher in drought?)	There are seemingly decreasing Pb level in foods.
	Typical exposure in general population (include units for intakes & location)	Mean lifetime dietary exposure to Pb was estimated to be: • 0.68 µg/kg bw/d in overall European population based on middle bound mean Pb occurrence. • 1.32 and 1.03 µg/kg bw/d for toddlers and other children, respectively. • 0.83-0.91 µg/kg/day for infants. • 0.5 µg/kg/d for adults. Highest individual contributor to dietary Pb exposure was tap water at 6.1%.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No.
	Any emerging risks identified?	In 2010, EFSA concluded that the provisional tolerable weekly intake (PTWI) of 25 µg/kg bw set by JECFA in 1986 was no longer appropriate and that, as there was no evidence of a threshold for a number of critical endpoints including developmental neurotoxicity and adult nephrotoxicity, it would not be appropriate to derive a PTWI. The conclusion was confirmed by JECFA in 2010, while also expressing a concern that there was potential at current levels of exposure for Pb to affect neurodevelopment in infants, children and the foetus of pregnant women. Using an alternative measure, the 2010 EFSA opinion identified a 95th percentile lower confidence limit of the benchmark dose of 1 % extra risk ($BMDL_{01}$) of 0.50 µg/kg bw/ day for developmental neurotoxicity in young children. It also lists cardiovascular effects and nephrotoxicity in adults as potential critical adverse health effects of Pb with respective $BMDL_{01}$ and $BMDL_{10}$ of 1.50 and 0.63 µg/kg bw/d.

FSANZ 2019

Agency Report Reference: *FSANZ (2019) 25th Australian Total Diet Study. June 2019. Food Standards Australia New Zealand.*		
General Information	Date of data extraction	08/11/2021
	Authors	Not stated (FSANZ report)
	Publication date	June 2019
	Publication type	Agency report

Agency Report Reference: *FSANZ (2019) 25th Australian Total Diet Study. June 2019. Food Standards Australia New Zealand.*		
	Description	Provides estimated dietary exposures of various chemicals (including Pb) for the general Australian population.

	Findings	• Concentrations of Pb and estimated dietary exposure for the Australian population were consistent with those reported in the international scientific literature.
		• There is no health-based guidance value for Pb as international assessments have been unable to establish a safe level of human exposure. High levels of lead exposure have been associated with adverse cognitive effects (including reduced IQ) in children and cardiovascular effects (including increased blood pressure) in adults.
		• Major dietary contributors to lead exposure are wide ranging and include water, sweetened soft drinks, baked goods, some dried and tinned fruits, pork, some deli meats, honey, chocolates and fudge.
		• Since the restriction of Pb use in fuels, human exposure to Pb mainly occurs through contaminated food, dust and dirt.
		• Mean and 90th percentile (respectively) estimated dietary exposures to Pb (µg/kg bw/d):
		  ○ Lower bound: 0.016-0.048 and 0.032-0.1
		  ○ Upper bound: 0.16-0.38 and 0.23-0.56
		  ○ Highest in 2-5 yr old children: 0.048-0.38 and 0.1-0.56.

IARC 2006

Agency Report Reference: *IARC (2006) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 87 - Inorganic and Organic Lead Compounds. World Health Organization (WHO)/International Agency for Research on Cancer (IARC) 10–17 February 2004, Lyon, France.*		
General Information	Date of data extraction	08/11/2021
	Authors	List of Participants: Anttila A, Apostoli P, Bond JA, Gerhardsson L, Gulson BL, Hartwig A, Hoet P, Ikeda M, Jaffe EK, Landrigan PJ, Levy L, Needleman HL, O'Flaherty EJ, Olin S, Olsen JH, Rossman TG, Sakai T, Shen X, Sorahan T, Steenland K, Sunderman FW, Tavares TM, Tripathi R, Waalkes MP and Junghans T (invited specialist)
	Publication date	Published 2006, from views and expert opinions of an IARC Working Group which met in Lyon on 10-17 February 2004
	Literature search timeframe	Not stated, but bibliography contains literature up to 2004.
	Publication type	Agency review
	Peer reviewed?	Review represents views of numerous experts on a Working Group. Additional peer review does not appear to be undertaken.
	Country of origin	International (World Health Organization)
	Source of funding	World Health Organization
	Possible conflicts of interest	Not stated, but all individual affiliations are listed. Those from industry with potential vested interest appear to be observers but not contributors to the monograph.

Agency Report Reference: *IARC (2006) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 87 - Inorganic and Organic Lead Compounds. World Health Organization (WHO)/International Agency for Research on Cancer (IARC) 10–17 February 2004, Lyon, France.*		
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	No guidance value derived. Review considers carcinogenicity data and classification for inorganic Pb compounds.
	Exposure timeframe	Not applicable (no guidance value derived).
	Critical health endpoint(s) – oral exposure	No critical health endpoints provided. However, there is a discussion of the toxic effects of inorganic Pb: • Typical clinical manifestations of Pb poisoning include weakness, irritability, asthenia, nausea, abdominal pain with constipation, and anaemia. • Renal manifestation of acute Pb poisoning include glycosuria, aminoaciduria and phosphaturia. Chronic exposure to low concentrations of Pb is associated with increased urinary excretion of low-molecular weight proteins and lysosomal enzymes; interstitial fibrosis, glomerular sclerosis, tubular dysfunction, tubular dysfunction and ultimately chronic renal failure. • Impairment in cognition, attention, and language function. • Cardiovascular effects with changes in endocrine and immune functions. • Spontaneous abortion risk is increased by maternal exposure to high concentrations of Pb.
	Justification provided by agency for critical endpoint	See above.
	Critical study(ies) underpinning point of departure	Not applicable (no guidance value derived)
	Species for critical study(ies)	Not applicable (no guidance value derived)
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	Not applicable (no guidance value derived)
	Point of departure value (include units)	Not applicable (no guidance value derived)
	Uncertainty factor(s) & rationale	Not applicable (no guidance value derived)
	The derivation:	Not applicable (no guidance value derived)
	Guideline value (include units)	Not applicable (no guidance value derived)
	Mode of action for critical health endpoint	Lead interferes with numerous physiological processes. In the haeme biosynthetic pathway, it inhibits δ-aminolevulinic acid dehydratase (also known as porphobilinogen synthase), probably through its high affinity for the zinc-binding site in the enzyme. Although Pb displaces zinc more readily in one of the alloenzymes of the protein, the relationship between δ-aminolevulinic acid dehydratase genotype and sensitivity to Pb at different BPb concentrations is at present unclear. Pb also causes an increase in zinc protoporphyrin, by a mechanism which is not fully established. Pb inhibits pyrimidine-5'-nucleotidase, resulting in accumulation of nucleotides, and subsequent haemolysis and anaemia.

Agency Report Reference: *IARC (2006) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 87 - Inorganic and Organic Lead Compounds. World Health Organization (WHO)/International Agency for Research on Cancer (IARC) 10–17 February 2004, Lyon, France.*		
	Genotoxic oral carcinogen?	There is little evidence that Pb interacts directly with DNA at normally encountered blood Pb concentrations. The genetic toxicity of Pb appears to be mediated in part by increases in, and modulation of, reactive oxygen species. In addition, Pb interacts with proteins, including those involved in DNA repair. This latter mechanism might be responsible for enhancing the genotoxicity of other agents. These properties could result in mutation, changes in gene expression and cell proliferation, all of which would contribute to a carcinogenic response if exposure is sustained. Inorganic Pb compounds are classified as probably carcinogenic in humans (Group 2A), due to limited evidence in humans but sufficient evidence in animals.
	Identified sensitive sub-populations	Considerable body of evidence suggests children are more sensitive than adults to the neurotoxic properties of Pb.
	Any non-health-based considerations?	No
Exposure considerations	Principal routes of exposure in general population	Ingestion (in crops, soil, water, food, dust) and inhalation (air).
	Levels in drinking water supplies (include location)	• Mexico 1983: 2 ± 1 µg/L • Mumbai 1984: 12 ± 3 µg/L • Karachi 2002: 3.1-4.3 µg/L • Japan 2001: 98% <5 µg/L • Canada & USA 1986: 2-8 µg/L
	Any special considerations to exposure levels (e.g. higher in drought?)	Lead contamination in drinking water previously came from corrosion by-products of Pb pipes and Pb-soldered joints in older houses. First-draw water contains highest Pb concentrations.
	Typical exposure in general population (include units for intakes & location)	Estimates of Pb intakes from the diet provided for various countries, primarily data from the 80's and 90's. Detail not extracted here, as the information is relatively outdated.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No
	Any emerging risks identified?	No

IPCS 2000

Agency Report Reference: *IPCS (2000). WHO Food Additives Series :44 – Lead. The Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization (WHO)/International Programme on Chemical Safety (IPCS). Geneva 2000.*		
General Information	Date of data extraction	08/11/2021
	Authors	Not stated. Prepared by the 53rd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
	Publication date	2000

Agency Report Reference: *IPCS (2000). WHO Food Additives Series :44 – Lead. The Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization (WHO)/International Programme on Chemical Safety (IPCS). Geneva 2000.*		
	Literature search timeframe	Not stated, but bibliography contains literature up to 1999.
	Publication type	Agency review
	Peer reviewed?	Not stated
	Country of origin	International (World Health Organization)
	Source of funding	WHO
	Possible conflicts of interest	Not stated.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	Provisional Tolerable Weekly Intake (PTWI), however it is noted this PTWI was established by a prior JECFA meeting (30th meeting) and has since been withdrawn (in 2010). It is noted the derivation of the previous PTWI is not provided in this particular report (it is provided in an earlier report which was not included within the cutoff dates of the literature review undertaken).
	Exposure timeframe	Chronic exposure (presumably lifetime)
	Critical health endpoint(s) – oral exposure	Neurobehavioural development of children.
	Justification provided by agency for critical endpoint	This is the basis of the previously established PTWI.
	Critical study(ies) underpinning point of departure	Not applicable (PTWI derivation not discussed).
	Species for critical study(ies)	Not applicable (PTWI derivation not discussed).
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	Not applicable (PTWI derivation not discussed).
	Point of departure value (include units)	Not applicable (PTWI derivation not discussed).
	Uncertainty factor(s) & rationale	Not applicable (PTWI derivation not discussed).
	The derivation:	Not applicable (PTWI derivation not discussed).
	Guideline value (include units)	Not applicable (PTWI derivation not discussed).
	Mode of action for critical health endpoint	Not stated.
	Genotoxic oral carcinogen?	There is evidence of carcinogenicity of Pb in experimental animal studies and also epidemiological studies of highly exposed populations. Genotoxicity of Pb is not discussed.
	Identified sensitive sub-populations	Not stated.
	Any non-health-based considerations?	No.
Exposure considerations	Principal routes of exposure in general population	In adult non-smokers, it is food and water. In children, it is food, air, water, and dust or soil.
	Levels in drinking water supplies (include location)	Not stated

Agency Report Reference: *IPCS (2000). WHO Food Additives Series :44 – Lead. The Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization (WHO)/International Programme on Chemical Safety (IPCS). Geneva 2000.*		
	Any special considerations to exposure levels (e.g. higher in drought?)	Not stated
	Typical exposure in general population (include units for intakes & location)	Estimates of Pb intakes from the diet provided for various countries however the data is quite dated and more recent data is available from other publications. Detail not extracted here, as the information is relatively outdated.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No
	Any emerging risks identified?	No

IPCS 2006a

Agency Report Reference: *IPCS (2006a) Environmental Health Criteria 234: Elemental Speciation in Human Health Risk Assessment. International Programme on Chemical Safety (IPCS).*		
General Information	Date of data extraction	09/11/2021
	Authors	Apostoli P, Cornelis R, Duffus J, Hoet P, Lison D, Templeton D
	Publication date	2006
	Literature search timeframe	Not stated, but bibliography contains literature up to 2006.
	Publication type	Agency review
	Peer reviewed?	Yes
	Country of origin	International
	Source of funding	Joint sponsorship of the United Nations Environment Programme, the International Labour Organization and the World Health Organization, and produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals.
	Possible conflicts of interest	All individuals who as authors, consultants, or advisers participate in the preparation of the EHC monograph must, in addition to serving in their personal capacity as scientists, inform the responsible officer if at any time a conflict of interest, whether actual or potential, could be perceived in their work. They are required to sign a conflict-of-interest statement. Such a procedure ensures the transparency and probity of the process.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	No guidance value derived in this document. However, the document provides important summary information on the health effects of Pb (and other chemicals).
	Exposure timeframe	Not applicable (no guidance value derived in this report).

Agency Report Reference: *IPCS (2006a) Environmental Health Criteria 234: Elemental Speciation in Human Health Risk Assessment. International Programme on Chemical Safety (IPCS).*		
	Critical health endpoint(s) – oral exposure	The central nervous system is probably the most sensitive target of Pb, with both inorganic and organic Pb being neurotoxic but clinical patterns of injury being different. Effects include subtle effect on intellectual functioning and deficits in memory, attention, concentration, psychomotor performance and intelligence, as well as at higher exposure concentrations severe encephalopathy.
	Justification provided by agency for critical endpoint	See above.
	Critical study(ies) underpinning point of departure	Not applicable (no guidance value derived in this report).
	Species for critical study(ies)	Not applicable (no guidance value derived in this report).
	Point of departure type (e.g. NOAEL, LOAEL, BMDL10, etc)	Not applicable (no guidance value derived in this report).
	Point of departure value (include units)	Not applicable (no guidance value derived in this report).
	Uncertainty factor(s) & rationale	Not applicable (no guidance value derived in this report).
	The derivation:	Not applicable (no guidance value derived in this report).
	Guideline value (include units)	Not applicable (no guidance value derived in this report).
	Mode of action for critical health endpoint	Not discussed for Pb.
	Genotoxic oral carcinogen?	Not discussed for Pb.
	Identified sensitive sub-populations	Developing child has higher vulnerability to neurotoxic effects of Pb.
	Any non-health-based considerations?	No.
Exposure considerations	Principal routes of exposure in general population	Not discussed in this document.
	Levels in drinking water supplies (include location)	Not discussed in this document.
	Any special considerations to exposure levels (e.g. higher in drought?)	Not discussed in this document.
	Typical exposure in general population (include units for intakes & location)	Not discussed in this document.
Risk Summary	Any risks to human health from drinking water identified in agency document?	Not discussed in this document.
	Any emerging risks identified?	Not discussed in this document.

JECFA 2011a, 2011b

Agency Report Reference: ***JECFA (2011a). Safety evaluations of groups of related flavouring agents. Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series 64. World Health Organization.*** ***JECFA (2011b).*** **Evaluation of certain food additives and contaminants.** ***Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*****. WHO** ***Technical Report Series 960. World Health Organization.***		
General Information	Date of data extraction	09/11/2021
	Authors	Benford DJ, Bellinger D, Bolger M, Carrington C, Hailemariam K, Petersen B, Rath S, Zang Y
	Publication date	2011
	Literature search timeframe	Not stated, but bibliography contains literature up to 2010.
	Publication type	Agency review
	Peer reviewed?	Although not stated, document is a result of the seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and thus has considered the views of a large number of experts. JECFA serves as a scientific advisory body to FAO, WHO, their member states and the Codex Alimentarius Commission.
	Country of origin	International (JECFA)
	Source of funding	Not stated (but presumed to be WHO and FAO)
	Possible conflicts of interest	Not stated.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	No guidance value derived in this document, however the toxicological and epidemiological information for Pb was reviewed which resulted in recommending the withdrawal of the previously derived provisional tolerable weekly intake (PTWI) for Pb.
	Exposure timeframe	Not applicable (no guidance value derived).
	Critical human health endpoint(s)	The Committee concluded that the effects on neurodevelopment (for children) and systolic blood pressure (for adults) provided the appropriate bases for dose–response analyses.
	Justification provided by agency for critical endpoint	Exposure to Pb is associated with a wide range of effects, including various neurodevelopmental effects, mortality (mainly due to cardiovascular diseases), impaired renal function, hypertension, impaired fertility and adverse pregnancy outcomes. Impaired neurodevelopment in children is generally associated with lower BPb concentrations than the other effects, the weight of evidence is greater for neurodevelopmental effects than for other health effects and the results across studies are more consistent than those for other effects. For adults, the adverse effect associated with lowest BPb concentrations for which the weight of evidence is greatest and most consistent is a Pb-associated increase in systolic blood pressure.
	Critical study(ies) underpinning point of departure	Children (BPb & IQ): Lanphear et al. (2005) pooled analysis Adults (BPb & systolic blood pressure): Four different studies (Glenn et al. 2003, 2006; Vupputuri et al. 2003, Nash et al. 2003)
	Species for critical study(ies)	Humans

Agency Report Reference: *JECFA (2011a). Safety evaluations of groups of related flavouring agents. Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series 64. World Health Organization.* *JECFA (2011b).* Evaluation of certain food additives and contaminants. *Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).* WHO *Technical Report Series 960. World Health Organization.*		
	Point of departure type (e.g. NOAEL, LOAEL, $BMDL_{10}$, etc)	Not applicable (no guidance value derived in this document).
	Point of departure value (include units)	Not applicable (no guidance value derived in this document).
	Uncertainty factor(s) & rationale	Not applicable (no guidance value derived in this document).
	Guidance value (include units)	Not applicable (no guidance value derived in this document). However, to conduct the dose-response analysis in this report which led to withdrawal of the previous PTWI, the following dose response information was applied: • Children: BPb associated with decrease in 1 IQ point was 8.5(0.7-27) µg/dL using the Hill model and 2.1(0.8-17) µg/dL using the bilinear model. • Adults: The median increase of 0.28 mmHg ± 0.15 mmHg per 1 µg/dL BPb (5^{th}-95^{th} percentiles 0.03-0.53 mmHg) was used for dose response analysis.
	Mode of action for critical health endpoint	Not discussed in this document.
	Genotoxic oral carcinogen?	No. IARC has concluded there is sufficient evidence for the carcinogenicity of inorganic Pb compounds in experimental animals, causing renal and brain tumours, and that the evidence for the carcinogenicity of organic Pb compounds is inadequate. The results of genotoxicity studies and the inhibition of DNA repair suggest a non-DNA-reactive mode of action for the carcinogenicity of lead.
	Identified sensitive sub-populations	Children, infants and foetuses due to developing nervous system.
	Any non-health based considerations?	No.
Exposure considerations	Principal routes of exposure in general population	This depends on the region of the world and its socioeconomic status. Pb is a multimedia contaminant, with sources or pathways that include air, water, soil, dust, food, paint and consumer products. This can make source attribution challenging. The relative contribution of diet to total Pb exposure will vary depending on locale and contribution from non-dietary sources. Estimates from EFSA suggest at least half of children's exposure may be due to non-dietary sources with soil and dust being major contributors.
	Levels in drinking water supplies (include location)	Not discussed in this document.
	Any special considerations to exposure levels (e.g. higher in drought?)	Not discussed in this document.

Agency Report Reference: ***JECFA (2011a). Safety evaluations of groups of related flavouring agents. Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series 64. World Health Organization.*** ***JECFA (2011b).*** **Evaluation of certain food additives and contaminants.** ***Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).*** **WHO** ***Technical Report Series 960. World Health Organization.***		
	Typical exposure in general population (include units for intakes & location)	Dietary exposure estimates provided for a number of different countries (µg/kg bw/day): • Australia (2 yrs): 0.03-0.93 • Canada (2-3 yrs): 0.26 • Chile (children): 6-9 • China (2-7 yrs): 3.1 • Europe (1-3 yrs): 1.1-3.1 • India (children): 0.9-1.3 • New Zealand (1-3 yrs): 0.31 • USA (2 yrs): 0.11
Risk Summary	Any risks to human health from drinking water identified in agency document?	No, not drinking water *per se*. However, the risk assessment undertaken by the Committee (which is for total Pb exposure) estimated that the previously established PTWI of 25 µg/kg bw is associated with a decrease of at least 3 IQ points in children and an increase in systolic blood pressure of approximately 3mmHg in adults. These changes are importance when viewed as a shift in the distribution of IQ or blood pressure within a population. The Committee therefore concluded that the PTWI could no longer be considered health protective, and it was withdrawn. Because the dose-response analyses do not provide any indication of a threshold for the key effects of Pb, the Committee concluded that it was not possible to establish a new PTWI that would be considered health protective.
	Any emerging risks identified?	The Committee concluded that, in populations with prolonged dietary exposures to Pb that are at the higher end of the ranges identified (~9 µg/kg bw/day), measures should be taken to identify major contributing sources and foods and, if appropriate, to identify methods of reducing dietary exposure that are commensurate with the level of risk reduction.

References:

Glenn BS, Stewart WF, Links JM, Todd AC, Schwartz BS (2003). The longitudinal association of lead with blood pressure. Epidemiology. 14:30–36.

Glenn BS, Bandeen-Roche K, Lee B-K, Weaver VM, Todd AC, Schwartz BS (2006). Changes in systolic blood pressure associated with lead in blood and bone. Epidemiology. 17(5):538–544.

Lanphear BP, Hornung R, Khoury J, Yolton K, Baghurst P, Bellinger DC, Canfield RL, Dietrich KN, Bornschein R, Greene T, Rothenberg SJ, Needleman HL, Schnaas L, Wasserman G, Graziano J, Roberts R (2005). Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives. 113:894–899.

Nash D, Magder L, Lustberg M (2003). Blood lead, blood pressure, and hypertension in perimenopausal and postmenopausal women. JAMA: the journal of the American Medical Association. 289:1523–1532.

WHO 2011

Agency Report Reference: *WHO (2011). Lead in Drinking Water. Background document for development of WHO Guidelines for Drinking-water Quality. World Health Organization.*		
General Information	Date of data extraction	09/11/2021
	Authors	Revision of background document undertaken by Cotruvo J, Fawell JK, Giddings M, Jackson P, Magara Y, Ngowi F, Ohanian E
	Publication date	2011
	Literature search timeframe	Not stated, but bibliography contains literature up to 2011.
	Publication type	Agency review
	Peer reviewed?	Yes.
	Country of origin	Not specified (World Health Organization - concerted effort).
	Source of funding	Not specified; likely WHO
	Possible conflicts of interest	Individual experts are invited to serve as members of the Drinking Water Quality Committee (DWQC). Members are selected primarily on the basis of excellence, independence, relevance of their expertise and willingness to support the work of the DWQC (WHO 2009). All members sign a Declaration of Interest as a pre-requisite to participation. Members refrain from participating in decision-making processes related to their particular area of conflicting interest (if applicable) (WHO 2009, JECFA 2017a).
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	Provisional drinking water guideline (not health-based but based on treatment performance and analytical achievability).
	Exposure timeframe	Not stated but presumed to be long-term (guideline value is not health-based).
	Critical human health endpoint	Not applicable (guideline value is not health-based). WHO (2011) adopts JECFA (2011a, b) evaluation, therefore critical human health endpoints are the same (neurological in children, systolic blood pressure in adults).
	Justification provided by agency for critical endpoint	As per JECFA (2011a, b).
	Guideline value (include units)	No health-based guideline value derived (due to withdrawal of JECFA PTWI). Provisional drinking water guideline value of **10 µg/L** (consistent with previous value based on PTWI which was withdrawn) retained, but was designated as provisional on the basis of treatment performance and analytical achievability.
	Mode of action for critical health endpoint	Not discussed in this document.
	Genotoxic carcinogen?	Conflicting results in genotoxicity studies, but most suggest that some Pb salts are genotoxic. IARC considers that the overall evidence for carcinogenicity in humans is inadequate for Pb, but that inorganic Pb compounds are probably carcinogenic to humans based on experimental animal data.

Agency Report Reference: *WHO (2011). Lead in Drinking Water. Background document for development of WHO Guidelines for Drinking-water Quality. World Health Organization.*		
	Identified sensitive sub-populations	As per JECFA (2011a, b): Foetuses, infants and children are the most sensitive to Pb.
	Any non-health based considerations?	Yes, it is extremely difficult to achieve a Pb concentration lower than 10 µg/L by central conditioning, such as phosphate dosing, therefore the previous guideline value of 10 µg/L was maintained but designated as provisional on the basis of treatment performance and analytical achievability.
Exposure considerations	Principal routes of exposure in general population	More than 80% of the daily intake of Pb is derived from ingestion of food, dirt and dust. Intake from drinking water (at 5 µg/L) forms a relatively small proportion of the total daily intake for children and adults, but a significant one for bottle-fed infants.
	Levels in drinking water supplies (include location)	Geometric mean/median level of Pb in drinking water in USA and Canada ~2-4.8 µg/L.
	Any special considerations to exposure levels (e.g. higher in drought?)	Pb is present in tap water to some extent as a result of dissolution from natural sources, but primarily from household plumbing systems in which pipes, solder, fittings or services connections to homes contain Pb. The amount of Pb dissolved from the plumbing system depends on several factors, including the presence of chloride and dissolved oxygen, pH, temperature, water softness and standing time of the water, soft, acidic water being the most plumbosolvent. Although Pb can be leached from Pb piping indefinitely, it appears that the leaching of Pb from soldered joints and brass taps decreases with time. The level of Pb in drinking-water may be reduced by corrosion control measures such as the addition of lime and the adjustment of the pH in the distribution system from <7 to 8–9.
	Typical exposure in general population (include units for intakes & location)	Estimated exposures: • Air: 0.5 µg/day (infant) to 4 µg/day (adult), assuming a concentration of 0.2 µg/m^3 in air. • Water: 3.8 µg/day (infant) to 10 µg/day (adult), assuming a concentration of 5 µg/L in drinking water. • Food (most countries): 23-66 µg/day (2 year old). • Soil and house dust: Levels highly variable so intakes also vary considerably.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No.
	Any emerging risks identified?	No.

References:

JECFA (2017a). Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Working Procedures. Joint FAO/WHO Expert Committee on Food Additives. Geneva, February 2017. https://www.who.int/foodsafety/chem/jecfa/JECFA-WP-REV2017.pdf?ua=1.

WHO (2009). WHO Guidelines for Drinking-water quality: Policies and procedures used in updating the WHO Guidelines for Drinking-water Quality. World Health Organization.

OEHHA 2009

Agency Report Reference: OEHHA *(2009). Public Health Goal for Lead in Drinking Water. Pesticide and Environmental Toxicology Branch. Office of Environmental Health Hazard Assessment. April 2009.*		
General Information	Date of data extraction	09/11/2021
	Authors	Avalos J (Additional contributors also listed).
	Publication date	April 2009
	Literature search timeframe	Not stated *per se*. However, bibliography contains cited references up to the year 2008.
	Publication type	Agency review
	Peer reviewed?	Yes Primary reviewers: Miller M and Carlisle J Final reviewers: Fan A, Alexeeff G, and Howd R
	Country of origin	United States (California)
	Source of funding	Not stated, however appears to be the Government of California.
	Possible conflicts of interest	Not stated in this document.
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	Drinking water guideline (i.e. Public Health Goal)
	Exposure timeframe	Chronic duration (i.e. approximately lifetime).
	Critical human health endpoint(s)	Intelligence deficits in children
	Justification provided by agency for critical endpoint	The most significant health effects from the public health and regulatory point of view are the ones which occur at the lowest BPb levels, because these affect the greatest part of the population. For children these are the effects on intelligence and behaviour. For adults the most sensitive health effect is the increase in blood pressure and other cardiovascular effects. Both of these health effects are of concern below 10 µg/dL BPb. Since measurable neurobehavioural effects in children for Pb may occur with an increase of in BPb of 1 µg/dL, this increase in Pb level may be considered a shift of concern for both children and adults. Other health effects such as kidney and gastrointestinal effects occur at higher BPb levels. The PHG was developed based on intelligence deficits in children, as this is the best-documented health endpoint that occurs at very low levels of exposure.
	Critical study(ies) underpinning point of departure	Carlisle and Dowling (2006) analysis of Lanphear et al. (2005)
	Species for critical study(ies)	Humans
	Point of departure type (e.g. NOAEL, LOAEL, $BMDL_{10}$, etc)	BPb level of concern: 1µg/dL is correlated with a decrease of 1 IQ point. Pb intake that would correspond to the level of concern (1µg/dL) is 2.86 µg/day (this is based on IEUBK modelling for 1-2 year old children, which indicated a BPb level increase of 0.35 µg/dL results from each increment in drinking water intake of 1 µg/day).

Agency Report Reference: OEHHA *(2009). Public Health Goal for Lead in Drinking Water. Pesticide and Environmental Toxicology Branch. Office of Environmental Health Hazard Assessment. April 2009.*		
	Point of departure value (include units)	2.86 µg/day
	Uncertainty factor(s) & rationale	3x to account for uncertainty with regard to the degree of protection offered, considering the lack of a threshold for Pb. The UF also accounts for extrapolation from the small sample size used in the main study of Lanphear et al. (2005) to the large, diverse population of children in California.
	Guidance value (include units)	**0.95 µg/day**
	Other assumptions in derivation of drinking water guideline value	• Water ingestion amount of 1 L/day for a child • Relative source contribution (RSC) of 20% (to account for exposures in children living in areas where high environmental concentrations of Pb still persist).
	Guideline value (include units and derivation)	Guideline value (µg/L) = [0.95 µg/day x 0.2] ÷ 1 L/day = 0.19 µg/L or **0.2 µg/L (rounded)**.
	Mode of action for critical health endpoint	The key mechanisms for neurological effects of Pb are postulated to be: • Mimicking of calcium action and/or disruption of Ca homeostasis (e.g. interactions with protein kinase C or calmodulin). • Substitution for zinc in some enzymes and zinc-finger domains found in enzymes, channels, and receptors. • Interference with specific neurotransmitter systems in the brain (i.e. glutamatergic, dopaminergic and cholinergic systems).
	Genotoxic oral carcinogen?	Inconsistent findings for genotoxicity, but Pb is regarded by IARC and the US EPA as an animal carcinogen and probably human carcinogen.
	Identified sensitive sub-populations	Children and neonates.
	Any non-health based considerations?	No
Exposure considerations	Principal routes of exposure in general population	Primarily via oral route
	Levels in drinking water supplies (include location)	US EPA (1988) estimated that 99% of the US population using public water supplies were exposed to drinking water with levels of Pb below 5 µg/L and that about 2 million people are served by drinking water with levels of Pb above 5 µg/L. In California, analysis of over 15,000 drinking water and 1000 surface water sources found no sources with reportable levels of Pb (greater than 5 µg/L) between 1994 and 2004.
	Any special considerations to exposure levels (e.g. higher in drought?)	The concentration of Pb is dependent upon sources of pollution, Pb content of sediments, and characteristics of the system (pH, temperature). In drinking water, the major source of Pb is leaching from the plumbing and solder. Pb enters drinking water from Pb in pipes and fixtures and from Pb solder used to join pipes. This is particularly troublesome in older homes.

Agency Report Reference: OEHHA *(2009). Public Health Goal for Lead in Drinking Water. Pesticide and Environmental Toxicology Branch. Office of Environmental Health Hazard Assessment. April 2009.*		
	Typical exposure in general population (include units for intakes & location)	Not provided in this document.
Risk Summary	Any risks to human health from drinking water identified in agency document?	Not discussed.
	Any emerging risks identified?	No

References:

Carlisle JC, Dowling K (2006). Child–specific health guidance for lead. Presented at Annual Meeting of the Society of Toxicology, March, 2006. The Toxicologist, Abstr. 2185, p. 448. As cited in OEHHA (2009).

Lanphear BP, Hornung R, Khoury J, Yolton K, Baghurst P, Bellinger DC, Canfield RL, Dietrich KN, Bornschein R, Greene T, Rothenberg SJ, Needleman HL, Schnaas L, Wasserman G, Graziano J, Roberts R (2005). Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. Environmental Health Perspectives. 113:894–899.

US EPA (1988). Hazardous Waste Identification Regulations. U.S. Environmental Protection Agency. Code of Federal Regulations 40 CFR 261. As cited in OEHHA (2009).

USEPA 2004

Agency Report Reference: US EPA (2004). Lead and compounds (inorganic); CASRN 7439-92-1. Integrated Risk Information System (IRIS). U.S. Environmental Protection Agency.		
General Information	Date of data extraction	09/11/2021
	Authors	Not stated.
	Publication date	2004
	Publication type	Agency evaluation
	Description	No guidance value (i.e. Reference dose) was derived in this document. Only a qualitative discussion is presented.

Agency Report Reference: US EPA (2004). Lead and compounds (inorganic); CASRN 7439-92-1. Integrated Risk Information System (IRIS). U.S. Environmental Protection Agency.		
	Findings/Qualitative discussion	Health effects associated with exposure to inorganic Pb and compounds include, but are not limited to, neurotoxicity, developmental delays, hypertension, impaired hearing acuity, impaired haemoglobin synthesis, and male reproductive impairment. Importantly, many of lead's health effects may occur without overt signs of toxicity. Pb has particularly significant effects in children, well before the usual term of chronic exposure can take place. Children under 6 years old have a high risk of exposure because of their more frequent hand-to-mouth behaviour. It appears that some of these effects, particularly changes in the levels of certain blood enzymes and in aspects of children's neurobehavioral development, may occur at BPb levels so low as to be essentially without a threshold. The Agency's RfD Work Group discussed inorganic Pb (and Pb compounds) at two meetings (07/08/1985 and 07/22/1985) and considered it inappropriate to develop an RfD for inorganic Pb. In 2004, it was still considered inappropriate to derive an RfD for Pb.

NHMRC 2015a, b

Agency Report Reference: NHMRC (2015a) NHMRC Information Paper: Evidence on the Effects of Lead on Human Health. Publication reference: EH58A. National Health and Medical Research Council, Australia. *NHMRC (2015b) NHMRC Statement: Evidence on the Effects of Lead on Human Health. NHMRC ref #: EH58. National Health and Medical Research Council, Australia.*		
General Information	Date of data extraction	09/11/2021
	Authors	Lead Working Committee: Dwyer S, Baghurst P, Gulson B, Harrison R, Lynch V, Matisons M, Newell S, Simon D, Kan SS, Smith W, Wigg N, Moore M
	Publication date	May 2015
	Literature search timeframe	January 2004-mid May 2013
	Publication type	Agency review
	Peer reviewed?	Yes
	Country of origin	Australia
	Source of funding	NHMRC
	Possible conflicts of interest	The methodological review team completed a declaration of interest process before being appointed by NHMRC and no conflicts of interest were identified.

Agency Report Reference: NHMRC (2015a) NHMRC Information Paper: Evidence on the Effects of Lead on Human Health. Publication reference: EH58A. National Health and Medical Research Council, Australia. *NHMRC (2015b) NHMRC Statement: Evidence on the Effects of Lead on Human Health. NHMRC ref #: EH58. National Health and Medical Research Council, Australia.*		
Health considerations	Guideline value type (e.g. oral TRV, drinking water guideline)	No guidance value derived, as there was considered to be insufficient evidence to support a causal association between BPb levels <10 µg/dL and any of the health effects observed. Nevertheless, the Working Group concluded if a person has a BPb level >5 µg/dL, their exposure to Pb should be investigated and reduced.
	Exposure timeframe	Not applicable (no guidance value derived).
	Critical human health endpoint(s)	Pb can affect many organs and bodily functions, with effects such as increased blood pressure, abnormally low haemoglobin, abnormal kidney function, long-term kidney damage and abnormal brain function having been observed at BPb levels between 10 and 60 µg/dL in adults and children. NHMRC's comprehensive review of the health effects of Pb found an association between reductions in Intelligence Quotient (IQ) and academic achievement in children at BPb levels less than 10 µg/dL. There is weaker evidence that BPb < 5 µg/dL are associated with reductions in IQ or academic achievement. For BPb between 5-10 µg/dL, an association was observed between higher occurrence of behavioural problems (poor attention, impulsivity and hyperactivity) in children, increased blood pressure in adults (including pregnant women) and a delay in sexual maturation or puberty onset in adolescent girls and boys.
	Justification provided by agency for critical endpoint	See above.
	Critical study(ies) underpinning point of departure	Not applicable (no guidance value derived).
	Species for critical study(ies)	Not applicable (no guidance value derived).
	Point of departure type (e.g. NOAEL, LOAEL, $BMDL_{10}$, etc)	Not applicable (no guidance value derived).
	Point of departure value (include units)	Not applicable (no guidance value derived).
	Uncertainty factor(s) & rationale	Not applicable (no guidance value derived).
	Guidance value (include units)	Not applicable (no guidance value derived). However, NHMRC concluded that if a person has a BPb >5 µg/dL, their exposure to Pb should be investigated and reduced.
	Other assumptions in derivation of drinking water guideline value	Not applicable (no guidance value derived).
	Guideline value (include units and derivation)	Not applicable (no guidance value derived).
	Mode of action for critical health endpoint	Not discussed in these documents.

Agency Report Reference: NHMRC (2015a) NHMRC Information Paper: Evidence on the Effects of Lead on Human Health. Publication reference: EH58A. National Health and Medical Research Council, Australia. *NHMRC (2015b) NHMRC Statement: Evidence on the Effects of Lead on Human Health. NHMRC ref #: EH58. National Health and Medical Research Council, Australia.*		
	Genotoxic oral carcinogen?	Not discussed in these documents.
	Identified sensitive sub-populations	Unborn babies, infants and young children due to the developing brain and nervous system.
	Any non-health based considerations?	Reduction of exposure.
Exposure considerations	Principal routes of exposure in general population	Not stated. Most people in Australia live in places where there are very small amounts of Pb in food, drinking water, air, dust, soil and consumer products. However, peoples' exposure to Pb has substantially reduced in recent decades due to national initiatives which have restricted the addition of Pb to paint and petrol, and the use of Pb in consumer goods.
	Levels in drinking water supplies (include location)	Not provided in these documents.
	Any special considerations to exposure levels (e.g. higher in drought?)	Drinking water may contain small amounts of Pb due to the existence of Pb in the solder and fittings of older pipes.
	Typical exposure in general population (include units for intakes & location)	Not provided in these documents.
Risk Summary	Any risks to human health from drinking water identified in agency document?	No.
	Any emerging risks identified?	No.

Exposure-Related Information for Lead

ICON WATER 2019, 2020

Agency Report Reference: *ICON Water (2019). Drinking Water Quality Report 2018-19. ICON Water. Canberra. ICON Water (2020). Drinking Water Quality Report 2019-20. ICON Water. Canberra.*		
General Information	Date of data extraction	29/10/2021
	Authors	Not stated.
	Publication date	2019-2020

Agency Report Reference: *ICON Water (2019). Drinking Water Quality Report 2018-19. ICON Water. Canberra. ICON Water (2020). Drinking Water Quality Report 2019-20. ICON Water. Canberra.*		
	Publication type	Drinking Water Corporation report.
	Description	No guidance value derived in this document *per se* but contains relevant information on Pb exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings[1]	Australian Drinking Water Guideline (Health): 0.01 mg/L Min: <0.0002 mg/L Max: 0.0081 mg/L Mean: 0.0003 mg/L
[1]Summary data for all drinking water quality zones in the supply system		

Melbourne Water (2021), Yarra Valley Water (2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020) and City West Water (2016)

Agency Report Reference: *See bibliography.*		
General Information	Date of data extraction	29/10/2021
	Authors	Not stated.
	Publication date	2010-2021
	Publication type	Drinking Water Corporation report.
	Description	No guidance value derived in this document *per se* but contains relevant information on Lead exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings[1]	Australian Drinking Water Guideline (health): 0.01 mg/L Min: <0.001 mg/L Max: 0.004 mg/L
[1]Summary data for all drinking water quality zones in the supply system		

Tas Water 2014, 2015a, 2016a, 2016b, 2016c, 2016d, 2017a, 2017b, 2017c, 2017d, 2018a, 2018b, 2018c, 2019a, 2019b, 2020

Agency Report Reference: *See bibliography*		
General Information	Date of data extraction	05/11/2021
	Authors	Jes Temby, Luc Richard, Frances Smith, Ailsa Sypkes, Michael Brewster
	Publication date	2014-2020
	Publication type	Drinking Water Corporation reports.

Agency Report Reference: *See bibliography*		
	Description	No guidance value derived in this document *per se* but contains relevant information on Lead exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings[1]	Australian Drinking Water Guideline (Health): 0.01 mg/L Mean: 0.0002 - 0.002 mg/L Minimum: <0.0001 - 0.0008 mg/L Maximum: 0.0002 - 0.0027 mg/L

[1]Summary data for all drinking water quality zones in the supply system

Incidents:

1. 11/11/2014 High lead levels detected in quarterly sample from Shannon Drive in Port Sorell. Lead 36.2 µg/L against the limit of 10 µg/L.
2. 12/05/2014 High lead levels detected at Shannon Drive, Port Sorell, exceeding the ADWG. Lead 41.1 µg/L against the limit of 10 µg/L.
3. 09/07/2014 Lead 10.2 µg/L against the limit of 10 µg/L.
4. 13/08/2014 Total lead detection 57.5 µg/L.
5. 03/09/2014 Total lead detection 20.4 µg/L.
6. 16/12/2014 Total lead detection 59.2 µg/L.
7. 06/03/2015 Total lead detection 16.2 µg/L.
8. 04/05/2015 Total lead detection 107 µg/L.
9. 04/05/2015 Total lead detection 12 µg/L.
10. 05/05/2015 Total lead detection 11 µg/L.

Exceedances have been reported throughout 2015. Investigations into extent and source of Pb contamination resulted in 28 non-conformances (results exceeding 10 µg/L). Sources were to be determined.

PWNT 2004, 2005, 2006, 2007a, 2008a, 2009a, 2009b, 2010a, 2010b, 2011a, 2011b, 2012, 2014, 2015, 2016a, 2016b, 2017, 2018, 2019, 2020

Agency Report Reference: *See bibliography*		
General Information	Date of data extraction	05/11/2021
	Authors	Not stated.
	Publication date	2014-2020
	Publication type	Drinking Water Corporation report.
	Description	No guidance value derived in this document *per se* but contains relevant information on Lead exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings[1]	Australian Drinking Water Guideline (Health): 0.01 mg/L Mean Range: <0.001 – 0.02 mg/L [2]

1. Summary data for all drinking water quality zones in the supply system.
2. PWNT recorded a Pb concentration of 0.02 mg/L on one occasion in 2020 at Wilora.

Seqwater 2021a, 2021b, 2021c, 2021d, 2021e, 2021f, 2021g, 2021h

Agency Report Reference: *See bibliography*		
General Information	Date of data extraction	05/11/2021
	Authors	Not stated.
	Publication date	April 2021
	Publication type	Drinking Water Corporation report.
	Description	No guidance value derived in this document *per se* but contains relevant information on Lead exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings[1]	Australian Drinking Water Guideline (Health): 0.01 mg/L Mean: <0.001mg/L Minimum: <0.001 mg/L Maximum: <0.001 mg/L
[1]Summary data for all drinking water quality zones in the supply system		

Chapman et al. 2008

Agency Report Reference: ***Chapman H, Cartwright T, Huston R, and O'Toole (2008). Water quality and health risks from urban rainwater tanks. Research Report 42. Cooperative Research Centre for Water Quality and Treatment. CRC for Water Quality and Treatment 2008.***		
General Information	Date of data extraction	05/11/2021
	Authors	Heather Chapman, Tony Cartwright, Rob Huston, and Joanne O'Toole
	Publication date	2008
	Publication type	Research report No 42.
	Description	No guidance value derived in this document *per se* but contains relevant information on Lead exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings	Total detected:53 Total tested: 69 Mean: 0.0038 mg/L Minimum: 0.0003 mg/L Maximum: 0.013 mg/L[1] ADWG Limit: 0.01 mg/L
1. Exceedance of ADWG		

Rodrigo et al. 2009

Agency Report Reference: ***Rodrigo S., Sinclair M. I., and Leder K. S., (2009). Quality of stored rainwater used for drinking in metropolitan South Australia. Research Report No 84. Cooperative Research Centre for Water Quality and Treatment, Australia.***		
General Information	Date of data extraction	05/11/2021
	Authors	Rodrigo S, Leder K, Sinclar M
	Publication date	2009
	Publication type	Research report No 84.
	Description	No guidance value derived in this document *per se* but contains relevant information on Lead exposure levels in Australian drinking water supply system (may or may not be relevant for context).
	Findings	Median (soluble): 0.0006 mg/L Median (total): 0.0008 mg/L Maximum (soluble): 0.0224 mg/L[1] Maximum (total): 0.0301 mg/L[1] ADWG Limit: 0.01 mg/L
[1] Exceedance of ADWG		

APPENDIX C

Existing guideline/guidance assessment tables

Criteria for assessing existing guidance or guidelines

Administrative and technical criteria for assessing existing guidance or guidelines

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

*Note only OEHHA (2009) has recommended a health-based guidance/guideline value for Pb, however WHO (2011) and NHMRC (2015a, b) have also been included in this section as they provide important health-related information to assist in deriving a health-based guideline *de novo*.

OEHHA 2009

Agency Report Reference: OEHHA *(2009). Public Health Goal for Lead in Drinking Water. Pesticide and Environmental Toxicology Branch. Office of Environmental Health Hazard Assessment. April 2009.*

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?	Y	-
	Are the administrative processes documented and publicly available?	Y	Yes. The process is described in a risk assessment technical support document which is posted on OEHHA's website once finalised.
	Was the work overseen by an expert advisory committee? Are potential conflicts of interest of committee members declared, managed and/or reported?	?	Not clearly stated in the OEHHA (2009) document.
	Are funding sources declared?	Y	Although funding sources are not declared in the document, it is likely Californian government-funded.
	Was there public consultation on this work? If so, provide details.	Y	Not clearly stated in the document, but the document did undergo public consultation (OEHHA 2009b). The first draft was posted on OEHHA website on July 24, 2008 and a one-day public workshop was held on September 11, 2008 to discuss it. A second draft was posted on OEHHA website on February 6, 2009 for a 30-day public review and comment period. No comments were received after posting.
	Is the advice peer reviewed? If so, is the peer review outcome documented and/or published?	?	Not stated in document.
	Was the guidance/advice developed or updated recently? Provide details.	NA	-
	Evidence review parameters		
	Are decisions about scope, definitions and evidence review parameters documented and publicly available?	Y	Scope of review is provided and publicly available.

Criteria		Y/N/?/NA	Notes
	Is there a preference for data from studies that follow agreed international protocols or meet appropriate industry standards?	NA	All valid studies appear to be considered. Validity appears to be determined via expert judgement.
	Does the organisation use or undertake systematic literature review methods to identify and select data underpinning the advice? Are the methods used documented clearly?	N	For this review, the literature searches undertaken are not detailed so they do not appear to have been undertaken systematically. Although a literature search has clearly been done, it is unclear whether this was done in a systematic manner as the details are not documented.
	If proprietary/confidential studies or data are considered by the agency, are these appropriately described/recorded?	Y	Yes. PHG technical support documents provide summaries of studies but not raw data. Nonetheless, companies and other entities are informed that any information submitted to OEHHA will become public information.
	Are inclusion/exclusion criteria used to select or exclude certain studies from the review? If so, is justification provided?	N	Not detailed in document.
	Does the organisation use or adopt review findings or risk assessments from other organisations? What process was used to critically assess these external findings?	NA	OEHHA appears to have undertaken its own review.
	Can grey literature such as government reports and policy documents be included?	Y	-
	Is there documentation and justification on the selection of a toxicological endpoint for use as point of departure for health-based guideline derivation?	Y	-
	Evidence search		
	Are databases and other sources of evidence specified?	Y (1/2)	Databases not specified, but all references also cited in bibliography.
	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)?	?	Not stated.
	Is it specified what date range the literature search covers? Is there a justification?	N	However, the bibliography lists references up to the year 2008.
	Are search terms and/or search strings specified?	N	-
	Are there any other exclusion criteria for literature (e.g. publication language, publication dates)? If so, what are they and are they appropriate?	NA	Inclusion/exclusion criteria not provided.
	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?	N	No information given regarding whether risk of bias assessment was undertaken for individual studies.

Criteria		Y/N/?/NA	Notes
	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.	N	Doesn't appear to have been done for this document. However, recently, OEHHA has been collaborating with US EPA's Integrated Risk Information System (IRIS) Program on evidence mapping using DistillerSR software and the Health Assessment Workspace Collaborative (HAWC) web application.
	Does the organisation assess the overall certainty of the evidence and reach recommendations? If so, provide details.	N	Yes, typically done in newer reports where a systematic review was undertaken. However, this has not been done for the Pb public health goal document.
	Derivation of health-based guideline values		
	Is there justification for the choice of uncertainty and safety factors?	Y	Justification provided.
	Are the parameter value assumptions documented and explained?	Y	-
	Are the mathematical workings/algorithms clearly documented and explained?	Y	-
	Does the organisation take into consideration non-health related matters to account for feasibility of implementing the guideline values (e.g. measurement attainability)?	NA	No. OEHHA are statutorily prohibited from doing so. This step is the responsibility of a sister agency, the State Water Resources Control Board when establishing regulatory Maximum Contaminant Levels for chemicals in drinking water.
	Is there documentation directing use of mechanistic, mode of action, or key events in adverse outcome pathways in deriving health-based guideline values?	Y	Guidance documentation is not cited, however OEHHA considers mechanistic, mode of action, and other relevant information in PHG derivation (and relies on expert judgement of author and reviewers).
	What processes are used when expert judgement is required and applied? Is the process documented and published?	Y	When expert judgment is used, the rationale is provided in the technical support document.
	Is dose response modelling (e.g. BMDL) routinely used?	Y	Yes.
	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?	Y	Yes, OEHHA has guidance documents that are publicly available (https://oehha.ca.gov/air/air-toxics-hot-spots). For carcinogens that do not have a slope factor, an additional uncertainty factor of 10 is applied to the guideline derivation.
	If applicable: For carcinogens, what is the level of cancer risk used by the organisation to set the health-based guideline value?	NA	The level of cancer risk used in developing PHGs for carcinogens is one in one million (1×10^{-6}). However, for Pb, since the non-carcinogen PHG was lower than the one for carcinogens, the latter was recommended as the final PHG.

Summary:

Total # of 'Must-Have' criteria met (or not applicable): 13.5/20 = 67.5%

Total # of 'Should-Have' criteria met (or not applicable): 6/10 = 60%

Total # of 'May-Have' criteria met (or not applicable): 2/2 = 100%

Criteria	Y/N/?/NA	Notes
References: OEHHA (2009b). Public Health Goals for Lead, Oxamyl and Pentachloropgenol. April 24, 2009. [Accessed 10/11/2021]. https://oehha.ca.gov/water/public-health-goal/public-health-goals-lead-oxamyl-and-pentachlorophenol		

WHO 2011

WHO (2011). Lead in Drinking Water. Background document for development of WHO Guidelines for Drinking-water Quality. World Health Organization.

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?	Y	
	Are the administrative processes documented and publicly available?	Y	
	Was the work overseen by an expert advisory committee? Are potential conflicts of interest of committee members declared, managed and/or reported?	Y	
	Are funding sources declared?	Y	Although funding sources are not declared in the document, it is likely funded by the WHO.
	Was there public consultation on this work? If so, provide details.	Y	The front matter of the text indicates the draft documents were released to the public domain for comment and submitted for final evaluation by expert meetings.
	Is the advice peer reviewed? If so, is the peer review outcome documented and/or published?	Y	
	Was the guidance/advice developed or updated recently? Provide details.	NA	
	Evidence review parameters		
	Are decisions about scope, definitions and evidence review parameters documented and publicly available?	Y	
	Is there a preference for data from studies that follow agreed international protocols or meet appropriate industry standards?	N	Not specified.

Criteria		Y/N/?/NA	Notes
	Does the organisation use or undertake systematic literature review methods to identify and select data underpinning the advice? Are the methods used documented clearly?	N	Unclear in this document.
	If proprietary/confidential studies or data are considered by the agency, are these appropriately described/recorded?	Y	Unpublished proprietary data are referenced as such in reference lists, and where they form pivotal information they are described in detail.
	Are inclusion/exclusion criteria used to select or exclude certain studies from the review? If so, is justification provided?	N	
	Does the organisation use or adopt review findings or risk assessments from other organisations? What process was used to critically assess these external findings?	Y	WHO use JECFA evaluations in a number of instances as the basis of the health-based evidence used to discuss the drinking water guideline (although the guideline was not derived on health-based considerations). JECFA is a sub-committee of the WHO (and FAO) and follows similar procedures for their reviews.
	Can grey literature such as government reports and policy documents be included?	Y	
	Is there documentation and justification on the selection of a toxicological endpoint for use as point of departure for health-based guideline derivation?	NA	There is discussion on the health evidence which leads to the conclusion that a health-based guideline is not derived, but the guideline was derived on non-health based considerations.
	Evidence search		
	Are databases and other sources of evidence specified?	N	Although the bibliography provides references for all literature consulted, the databases consulted for the literature review are not listed in the agency review.
	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)?	NA	Unable to be ascertained from the information in the document.
	Is it specified what date range the literature search covers? Is there a justification?	Y (½)	Literature search details are not specified, however the dates of publications in the bibliography suggest a literature search cutoff date of 2011.
	Are search terms and/or search strings specified?	N	Literature search details are not specified.
	Are there any other exclusion criteria for literature (e.g. publication language, publication dates)? If so, what are they and are they appropriate?	NA	Literature search details are not specified.
	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?	N	No information given regarding whether risk of bias assessment was undertaken for individual studies. However, the shortcomings of some studies (where identified by the authors) have been provided in the text.

Criteria		Y/N/?/NA	Notes
	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.	N	Unclear if this was done for lead.
	Does the organisation assess the overall certainty of the evidence and reach recommendations? If so, provide details.	N	
	Derivation of health-based guideline values		
	Is there justification for the choice of uncertainty and safety factors?	NA	No uncertainty factors applied, as health-based derivation was not undertaken.
	Are the parameter value assumptions documented and explained?	NA	Health-based derivation was not undertaken.
	Are the mathematical workings/algorithms clearly documented and explained?	NA	Health-based derivation was not undertaken.
	Does the organisation take into consideration non-health related matters to account for feasibility of implementing the guideline values (e.g. measurement attainability)?	Y	For lead, non-health related matters have been considered and used in guideline development.
	Is there documentation directing use of mechanistic, mode of action, or key events in adverse outcome pathways in deriving health-based guideline values?	Y	Guidance documentation is not cited. However, guidance document does exist (FAO/WHO 2009, WHO 2005, 2007).
	What processes are used when expert judgement is required and applied? Is the process documented and published?	N	Unclear from documentation consulted.
	Is dose response modelling (e.g. BMDL) routinely used?	Y	Yes, where data permit and where a BMDL would provide greater confidence in the point of departure. Not used for lead.
	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?	NA	For genotoxic carcinogens, the DWG represents an excess lifetime cancer risk of $1x10^{-5}$ for people drinking water containing the chemical at the DWG for 70 yrs. Compounds shown to be a carcinogen are evaluated on a case-by-case basis, where evidence of genotoxicity & human relevance is considered to determine correct approach for risk assessment. Not done for lead as no health-based guideline was derived.
	If applicable: For carcinogens, what is the level of cancer risk used by the organisation to set the health-based guideline value?	NA	

Summary:

Total # of 'Must-Have' criteria met (or not applicable): 14.5/20 = 73%

Total # of 'Should-Have' criteria met (or not applicable): 6/10 = 60%

Total # of 'May-Have' criteria met (or not applicable): 2/2 = 100%

Criteria	Y/N/?/NA	Notes
References: FAO/WHO (2009). Environmental Health Criteria 240: Principles and methods for the risk assessment of chemicals in food. Chapter 5: Dose-response assessment and derivation of health-based guidance values. Geneva: A joint publication of the Food and Agriculture Organization of the United Nations and the World Health Organization. http://www.inchem.org/documents/ehc/ehc/ehc240_chapter5.pdf. JECFA (2017a). Guidance document for WHO monographers and reviewers evaluating contaminants in food and feed. Joint FAO/WHO Expert Committee on Food Additives (JECFA). January 2017. Version 1.0. http://apps.who.int/iris/bitstream/handle/10665/254630/9789241512008-eng.pdf;jsessionid=8AB23D3A0003A624A67704756BB3A938?sequence=1 JECFA (2017b). Guidance to JECFA Experts on Systematic Literature Searches. Prepared by WHO JECFA (Joint FAO/WHO Expert Committee on Food Additives) Secretariat. January 2017. https://www.who.int/foodsafety/chem/jecfa/Litertature_Search.pdf?ua=1. WHO (2005). Harmonization Project Document No. 2: Chemical-specific adjustment factors for interspecies differences and human variability: guidance document for use of data in dose/concentration response assessment. World Health Organization (IPCS). http://www.inchem.org/documents/harmproj/harmproj/harmproj2.pdf. WHO (2007). Harmonization Project Document No. 4. Part 1: IPCS framework for analysing the relevance of a cancer mode of action for humans and case-studies Part 2: IPCS framework for analysing the relevance of a non-cancer mode of action for humans." World Health Organization (IPCS). http://www.who.int/ipcs/methods/harmonization/areas/cancer_mode.pdf?ua=1.		

NHMRC 2015a, b

NHMRC (2015a) NHMRC Information Paper: Evidence on the Effects of Lead on Human Health. Publication reference: EH58A. National Health and Medical Research Council, Commonwealth of Australia, Canberra.

NHMRC (2015b) NHMRC Statement: Evidence on the Effects of Lead on Human Health. NHMRC ref #: EH58. National Health and Medical Research Council, Commonwealth of Australia, Canberra.

	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?	Y	Refer to Appendix and Evidence report of NHMRC (2015a, b). Planning and processes of the evidence review were guided by the Lead Working Committee. Quality assurance aspects described in Appendix C of NHMRC (2015a).
	Are the administrative processes documented and publicly available?	Y	
	Was the work overseen by an expert advisory committee? Are potential conflicts of interest of committee members declared, managed and/or reported?	Y	

Criteria		Y/N/?/NA	Notes
	Are funding sources declared?	Y	
	Was there public consultation on this work? If so, provide details.	Y	
	Is the advice peer reviewed? If so, is the peer review outcome documented and/or published?	Y	
	Was the guidance/advice developed or updated recently? Provide details.	NA	
	Evidence review parameters		
	Are decisions about scope, definitions and evidence review parameters documented and publicly available?	Y	Refer to Appendix and Evidence report of NHMRC (2015a, b).
	Is there a preference for data from studies that follow agreed international protocols or meet appropriate industry standards?	Y	
	Does the organisation use or undertake systematic literature review methods to identify and select data underpinning the advice? Are the methods used documented clearly?	Y	
	If proprietary/confidential studies or data are considered by the agency, are these appropriately described/recorded?	NA	
	Are inclusion/exclusion criteria used to select or exclude certain studies from the review? If so, is justification provided?	Y	
	Does the organisation use or adopt review findings or risk assessments from other organisations? What process was used to critically assess these external findings?	Y	
	Can grey literature such as government reports and policy documents be included?	Y	
	Is there documentation and justification on the selection of a toxicological endpoint for use as point of departure for health-based guideline derivation?	Y	
	Evidence search		
	Are databases and other sources of evidence specified?	Y	Refer to Appendix and Evidence report of NHMRC (2015a, b), i.e. Armstrong et al. (2014).
	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)?	Y	
	Is it specified what date range the literature search covers? Is there a justification?	Y	
	Are search terms and/or search strings specified?	Y	

Criteria		Y/N/?/NA	Notes
	Are there any other exclusion criteria for literature (e.g. publication language, publication dates)? If so, what are they and are they appropriate?	Y	
	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?	Y	Refer to Appendix and Evidence report of NHMRC (2015a, b), i.e. Armstrong et al. (2014).
	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.	Y	
	Does the organisation assess the overall certainty of the evidence and reach recommendations? If so, provide details.	Y	
	Derivation of health-based guideline values		
	Is there justification for the choice of uncertainty and safety factors?	NA	Refer to Appendix and Evidence report of NHMRC (2015a, b), i.e. Armstrong et al. (2014).
	Are the parameter value assumptions documented and explained?	NA	
	Are the mathematical workings/algorithms clearly documented and explained?	NA	
	Does the organisation take into consideration non-health related matters to account for feasibility of implementing the guideline values (e.g. measurement attainability)?	NA	
	Is there documentation directing use of mechanistic, mode of action, or key events in adverse outcome pathways in deriving health-based guideline values?	Y	
	What processes are used when expert judgement is required and applied? Is the process documented and published?	Y	
	Is dose response modelling (e.g. BMDL) routinely used?	Y	
	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?	Y	
	If applicable: For carcinogens, what is the level of cancer risk used by the organisation to set the health-based guideline value?	NA	

Summary:
Total # of 'Must-Have' criteria met (or not applicable): 20/20 = 100%
Total # of 'Should-Have' criteria met (or not applicable): 10/10 = 100%
Total # of 'May-Have' criteria met (or not applicable): 2/2 = 100%

Criteria	Y/N/?/NA	Notes
References: Armstrong R, Anderson L, Synnot A, Burford B, Waters E, Le LB, Weightman A, Morgan H, Turley R, Steele E (2014). Evaluation of evidence related to exposure to lead. 18 February 2014. https://www.nhmrc.gov.au/sites/default/files/2019-03/evaluation-evidence-exposure-lead.pdf		

APPENDIX D

Data extraction tables – Supporting Information in Factsheet

Supporting Information in Lead Factsheet

ATSDR 2004a

Agency Report Reference: ***ATSDR (2020). Toxicological Profile for Lead. US Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. August 2020***		
General Description	Uses	Pb is an element that is found in concentrated and easily accessible Pb ore deposits that are widely distributed throughout the world. A major source of Pb in the US environment has historically been anthropogenic emissions to the atmosphere from combustion of leaded gasoline, which was phased out of use after 1973 and then banned in 1995 (with the exception of fuels for piston-driven aircraft). Pb continued to be used as an anti-knock agent in National Association for Stock Car Auto Racing (NASCAR) fuels until it was phased out beginning in 2008. Deteriorating Pb-based paints from weathered surfaces (which produce highly concentrated Pb debris and dusts) in older housing stock (pre-1978) continues to be a source of childhood Pb poisoning in the United States. The combination of corrosive water and Pb pipes or Pb-soldered joints in either the distribution system or individual houses can create localised zones of high Pb water concentrations. Other anthropogenic sources of Pb have included mining and smelting of ore; manufacture of and use of Pb-containing products (e.g. Pb-based paints, pigments, and glazes; electrical shielding; plumbing; storage batteries; solder; and welding fluxes); manufacture and application of Pb-containing pesticides; combustion of coal and oil; and waste incineration.
	Sources in drinking water	Mainly corrosion of Pb pipes or Pb-soldered joints, or source water contamination.
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	Drinking water: • EPA 2003 Method 200.5 (ICP-AES) (LOR 1.1 µg/L) • EPA 1994f Method 200.8 (ICP-MS) (LOR 0.02 µg/L)
	Limit of determination/ Limit of Reporting (LOR)	See above
	Other	-
Additional information	Any additional non-health related information considered important?	-

EFSA 2012

Agency Report Reference: *EFSA (2012) Lead dietary exposure in the European population. EFSA Journal 2012;10(7):2831.*		
General Description	Uses	In the environment, inorganic Pb predominates over organic Pb and the former is also the only type found in food. Although it is a natural environmental contaminant, its ubiquitous occurrence is the result of anthropogenic activities like mining and smelting, soldering, battery manufacturing and the use of Pb ammunition for hunting, but particularly the use in the past of Pb in paint and petrol and for soldering or making of water pipes. Leaded petrol was banned from use in the European Union in 2000 with exemptions possible until 2005 and continued use only allowed in vintage cars.
	Sources in drinking water	Lead soldered water piping in old buildings.
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	-
	Limit of determination/ Limit of Reporting (LOR)	-
	Other	-
Additional information	Any additional non-health related information considered important?	-

FSANZ 2019

Agency Report Reference: *FSANZ (2019) 25th Australian Total Diet Study. June 2019. Food Standards Australia New Zealand.*		
General Description	Uses	-
	Sources in drinking water	-
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-

Agency Report Reference: *FSANZ (2019) 25th Australian Total Diet Study. June 2019. Food Standards Australia New Zealand.*		
Measurement	Analytical method	For analysis of food and drinking water: ICP acid digest preparation (LOR 0.005 mg/kg in food, 0.0001 mg/L in drinking water).
	Limit of determination/ Limit of Reporting (LOR)	See above.
	Other	-
Additional information	Any additional non-health related information considered important?	-

IARC 2006

Agency Report Reference: *IARC (2006) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 87 - Inorganic and Organic Lead Compounds. World Health Organization (WHO)/International Agency for Research on Cancer (IARC) 10–17 February 2004, Lyon, France.*		
General Description	Uses	Over the centuries the unique properties of Pb have resulted in its use in many different applications. Large quantities of Pb, both as the metal and as the dioxide, are used in storage batteries. Pb is also used for cable covering, plumbing and ammunition. The metal is very effective as a sound absorber and as a radiation shield around X-ray equipment and nuclear reactors. It is also used to absorb vibration. Pb, alloyed with tin, is used in making organ pipes. Pb carbonate ($PbCO_3$), Pb sulfate ($PbSO_4$), Pb chromate ($PbCrO_4$), Pb tetraoxide (Pb_3O_4) and other Pb compounds have been applied extensively in paints, although in recent years this use has been curtailed to reduce health hazards. Pb oxide is used in the production of fine 'crystal glass' and 'flint glass' with a high index of refraction for achromatic lenses. Pb nitrate and acetate are soluble salts that serve as intermediates and in specialty applications. Pb salts such as Pb arsenate have been used as insecticides, but in recent years this use has been almost eliminated. In most countries, Pb is predominantly used as the metal and it may be alloyed with other materials depending on the application.
	Sources in drinking water	Use of Pb piping or Pb solder in plumbing systems. Water with low pH and low concentrations of dissolved salts (referred to as aggressive or corrosive water) can leach substantial quantities of Pb from pipes, solder and fixtures.
	Other	-
Treatment of drinking water	Treatment technology	Not stated.
	Effectiveness	-
	Any special conditions?	-
	Other	-

Agency Report Reference: *IARC (2006) IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 87 - Inorganic and Organic Lead Compounds. World Health Organization (WHO)/International Agency for Research on Cancer (IARC) 10–17 February 2004, Lyon, France.*		
Measurement	Analytical method	Water: • ICP-AES Method D1976 (LOD 42 µg/L) • ICP-MS Method D5673 (LOD 0.08 µg/L) • XRF Method D6502 (LOD 1 µg/L) • AAS Method 239.1 (LOD 100 µg/L)
	Limit of determination/ Limit of Reporting (LOR)	See above.
	Other	-
Additional information	Any additional non-health related information considered important?	The benchmark for analysis of Pb exposure is the determination of BPb concentrations by AAS. By 2001, commercial laboratories used predominantly electro-thermal atomisation atomic absorption spectroscopy, ASV and ICP–MS. For screening purposes, the simplest BPb test is conducted with a capillary blood sample obtained from a finger-prick. Regardless of the method chosen, BPb analysis is the only diagnostic for Pb exposure for which there exists an international standard for quality control.

IPCS 2000

Agency Report Reference: *IPCS (2000). WHO Food Additives Series :44 – Lead. The Joint FAO/WHO Expert Committee on Food Additives (JECFA). World Health Organization (WHO)/International Programme on Chemical Safety (IPCS). Geneva 2000.*		
General Description	Uses	The main uses of Pb are in batteries, cables, pigments, plumbing, gasoline, solder and steel products, food packaging, glassware, ceramic products, and pesticides. The main exposure of the general non-smoking adult population is from food and water.
	Sources in drinking water	Pb plumbing.
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	Not stated.
	Limit of determination/ Limit of Reporting (LOR)	Not stated.
	Other	-
Additional information	Any additional non-health related information considered important?	-

JECFA 2011a, 2011b

Agency Report Reference: ***JECFA (2011a). Safety evaluations of groups of related flavouring agents. Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series 64. World Health Organization.*** ***JECFA (2011b).*** **Evaluation of certain food additives and contaminants.** ***Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*****. WHO** ***Technical Report Series 960. World Health Organization.***		
General Description	Uses	Lead (Pb) occurs in Earth's crust primarily as the mineral galena (Pb(II)sulfide) and, to a lesser extent, as anglesite (Pb(II) sulfate) and cerussite (Pb carbonate). It occurs in the environment both naturally and, to a greater extent, from anthropogenic activities such as mining and smelting, battery manufacturing and the use of leaded petrol (gasoline). Pb contamination of food arises mainly from the environment or from food processing, food handling and food packaging. Atmospheric Pb can contaminate food through deposition on agricultural crops. Water is another source of Pb contamination of food. Although Pb exists in both organic and inorganic forms, only inorganic Pb has been detected in food.
	Sources in drinking water	-
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	Not stated.
	Limit of determination/ Limit of Reporting (LOR)	Not stated.
	Other	-
Additional information	Any additional non-health related information considered important?	Blood is the tissue used most frequently to estimate exposure to Pb and its association with health outcomes. This is largely because blood is easily sampled and the methods for measuring BPb concentration are well developed. The elimination half-life of Pb in blood is approximately 30–40 days in adults, however, so the BPb level provides information primarily about an individual's exposure in recent months. The exposure averaging time will vary among individuals, depending on the extent to which endogenous pools of Pb, representing past exposure, are contributing to BPb. Under conditions of steady-state exposure, only a small percentage of total body burden of Pb is in blood (~5%), and nearly all of this is bound to erythrocytes (96–99%), with the balance in plasma. The ratio of erythrocyte to plasma Pb decreases as Pb levels increase owing to saturation of binding sites on erythrocytes. Typically, whole BPb concentration is measured. Although the fraction in plasma is thought to be more relevant than whole BPb to lead's toxicity, it has rarely been used as the exposure biomarker owing to the analytical challenges and the cost of measuring such low concentrations accurately.

NHMRC 2015a, b

Agency Report Reference: NHMRC (2015a) NHMRC Information Paper: Evidence on the Effects of Lead on Human Health. Publication reference: EH58A. National Health and Medical Research Council, Australia. *NHMRC (2015b) NHMRC Statement: Evidence on the Effects of Lead on Human Health. NHMRC ref #: EH58. National Health and Medical Research Council, Australia.*		
General Description	Uses	Pb is a naturally occurring metal found in the earth's crust and has a wide variety of uses in manufacturing due to its properties of being soft, malleable and corrosion resistant. Pb occurs in the environment as a wide variety of compounds and remains permanently in dust and soil until it is physically removed. In some communities with a history of high traffic flow, soil may still contain Pb deposited from traffic fumes prior to the removal of Pb from petrol. In some cases Pb based paints in older residential areas are the source of Pb in the environment. When old houses and buildings are renovated, Pb paint is often stripped or sanded which creates very fine particles of Pb in dust that may be inhaled or consumed by people living or working inside or nearby the property. Although the use of Pb in petrol and paints in Australia has been restricted, it may still be found in some fuels (aviation gasoline for piston engines and some racing fuels) and paints and finishes on some products (e.g. cars and boats). P is still used in Pb-acid batteries and some ceramic glazes.
	Sources in drinking water	Drinking water may contain small amounts of Pb due to the existence of Pb in the solder and fittings of older pipes.
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	Not stated.
	Limit of determination/ Limit of Reporting (LOR)	Not stated.
	Other	-
Additional information	Any additional non-health related information considered important?	-

OEHHA 2009

Agency Report Reference: OEHHA *(2009). Public Health Goal for Lead in Drinking Water. Pesticide and Environmental Toxicology Branch. Office of Environmental Health Hazard Assessment. April 2009.*		
General Description	Uses	Pb is easily obtained from its most common ore, galena (PbS). The many commercial uses of Pb follow from its physical and chemical properties. Pb has been used in piping, roofing and other structural uses because of the malleability. Pb is also used in making containers for corrosive liquids. Metallic Pb and Pb dioxide are used in storage batteries for automobiles and other applications. In the past, organolead compounds were used to boost octane (reduce knock) in gasoline, but this use has now been eliminated for car, truck, and boat fuel in the US. Pb and Pb salts have been widely used in paints and pigments, and in glazes for ceramics. Cable coverings have been made from Pb because of its electrical resistance and ductility. Pb is used to make bullets and shot. Because of its low melting point, Pb is used (with other metals) to make solder. Pb is used for radiation shielding around diagnostic x-ray machines and other sources of radiation. In the past Pb was included in a number of medicines such as antiseptics and astringents, but these are no longer recommended because of the cumulative toxic effects of Pb in the body.
	Sources in drinking water	In drinking water, the major source of Pb is leaching from the plumbing and solder. Pb enters drinking water from Pb in pipes and fixtures and from Pb solder used to join pipes. This is particularly troublesome in older homes. Older public buildings such as schools and theatres may also have problems with Pb contamination of drinking water.
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	Not stated.
	Limit of determination/ Limit of Reporting (LOR)	Not stated.
	Other	-
Additional information	Any additional non-health related information considered important?	-

WHO 2011

Agency Report Reference: *WHO (2011). Lead in Drinking Water. Background document for development of WHO Guidelines for Drinking-water Quality. World Health Organization.*		
General Description	Uses	Pb is used in the production of Pb acid batteries, solder, alloys, cable sheathing, pigments, rust inhibitors, ammunition, glazes and plastic stabilizers. Tetraethyl and tetramethyl Pb are important because of their extensive use as antiknock compounds in petrol, but their use for this purpose has been almost completely phased out in North America and western Europe, although not in eastern Europe or many developing countries. From a drinking-water perspective, the almost universal use of Pb compounds in plumbing fittings and as solder in water distribution systems is important. Pb pipes may be used in older distribution systems and plumbing.
	Sources in drinking water	Pb is present in tap water to some extent as a result of its dissolution from natural sources, but primarily from household plumbing systems in which the pipes, solder, fittings or service connections to homes contain Pb. Polyvinyl chloride (PVC) pipes also contain Pb compounds that can be leached from them and result in high Pb concentrations in drinking-water. The amount of Pb dissolved from the plumbing system depends on several factors, including the presence of chloride and dissolved oxygen, pH, temperature, water softness and standing time of the water, soft, acidic water being the most plumbosolvent.
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	Pb is exceptional in that most Pb in drinking-water arises from plumbing in buildings, and the remedy consists principally of removing plumbing and fittings containing it, which requires both time and money. In the interim, all practical measures to reduce total exposure to Pb, including corrosion control, should be implemented. It is extremely difficult to achieve a concentration below 10 µg/L by central conditioning, such as phosphate dosing.
Measurement	Analytical method	Atomic absorption spectrometry and anodic stripping voltammetry are the methods most frequently used for determining the levels of Pb in environmental and biological materials. Detection limits of less than 1 µg/L can be achieved by means of atomic absorption spectrometry.
	Limit of determination/ Limit of Reporting (LOR)	<1 µg/L
	Other	-
Additional information	Any additional non-health related information considered important?	Because corrosion of plumbing systems is an important source of excessive Pb in drinking-water, Pb levels in water should be measured at the tap, rather than at the drinking-water source, when estimating human exposure.

Chapman et al. 2008, Rodrigo et al. 2009, Nadebaum et al .2004

Agency Report Reference:		
Chapman H, Cartwright T, Huston R, and O'Toole (2008). Water quality and health risks from urban rainwater tanks. Research Report 42. Cooperative Research Centre for Water Quality and Treatment. CRC for Water Quality and Treatment 2008. ***Rodrigo S., Sinclair M. I., and Leder K. S., (2009). Quality of stored rainwater used for drinking in metropolitan South Australia. Research Report No 84. Cooperative Research Centre for Water Quality and Treatment, Australia.*** ***Nadebaum R., Chapman M., Morden R., and Rizak S., (2004) A Guide to Hazard Identification & Risk Assessment for Drinking Water Supplies. Research Report Number 11. Cooperative Research Centre for Water Quality and Treatment.***		
General Description	Uses	-
	Sources in drinking water	-
	Other	-
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	Not stated.
	Limit of determination/ Limit of Reporting (LOR)	0.002 mg/L
	Other	-
Additional information	Any additional non-health related information considered important?	Due to the soft and sometimes acidic nature of rainwater, when used in hot water systems, it leads to increases in Pb concentrations in the hot water.

ICON Water 2019

Icon Water (2019). Drinking Water Quality Report 2018-19. Icon Water. Canberra.		
General Description	Uses	-
	Sources in drinking water	Pb is a naturally occurring metal and can enter drinking water from catchment sources or from household plumbing systems containing Pb. Pb is used in the manufacture of a range of plumbing products such as brass fittings. Pb can dissolved into drinking water if it has been sitting in contact with these brass fittings for a long time.

Icon Water (2019). Drinking Water Quality Report 2018-19. Icon Water. Canberra.		
	Other	The Australian Government Department of Health recommends flushing cold water taps used for drinking and cooking for about 30 seconds first thing in the morning or after periods of absence. This will draw fresh water into the tap and reduce your potential exposure to Pb.
Treatment of drinking water	Treatment technology	-
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	US EPA 200.8
	Limit of determination/ Limit of Reporting (LOR)	0.0002 mg/L
	Other	-
Additional information	Any additional non-health related information considered important?	-

PWNT 2020

PWNT (2020). Drinking Water Quality. Annual Report 2020. Power and Water Corporation Northern Territory.		
General Description	Uses	-
	Sources in drinking water	The presence of Pb in household plumbing is a problem worldwide, as any Pb in brass fittings is dissolved into the water. Pb is not found in the source water used for public water supplies. Instead, Pb can enter tap water when plumbing materials containing Pb start to corrode. Pb was not detected from most of the water samples taken in the Northern Territory. However where the sample site plumbing has started to corrode Pb can be detected.
	Other	-
Treatment of drinking water	Treatment technology	Water treatment in general is primarily through disinfection such as sodium hypochlorite, chlorine gas and UV disinfection. Other treatment systems such as sand filters and clarifiers are used in communities that also use surface water sources.
	Effectiveness	-
	Any special conditions?	-
	Other	-
Measurement	Analytical method	-
	Limit of determination/ Limit of Reporting (LOR)	<0.001 mg/L.
	Other	-

PWNT (2020). Drinking Water Quality. Annual Report 2020. Power and Water Corporation Northern Territory.		
Additional information	Any additional non-health related information considered important?	-

Scopus Literature Search

A comprehensive search for lead treatment in drinking water undertaken in the Scopus database resulted in 709 publications, out of which 64 were taken forward after the preliminary screen. Further literature screening resulted in a total of 22 potentially relevant papers (references provided below). These studies described mostly commercially used water treatment techniques with small adjustments in order to improve Pb removal efficiency. The following approaches to remove Pb in drinking water were described in these papers:

- Metal organic framework (MOF)
- Polymerisation in MOF pore structure
- Aggregation of Pb phosphate particles
- Stabilised FeS nanoparticles
- Oxidised Fe_3O_4 membranes
- Gravitation filtration using granular activated carbon
- Adsorption (sawdust, magnetic adsorption, silicates, cellulose metallothionein)
- Iron oxide modified clay activated carbon beds
- Sand filtration; GAC and non-woven geotextile
- Zeolite based nano-composite
- Blended phosphate treatment
- Fabricated magnetic filters with mesh structure

The majority of studies demonstrated Pb removal efficiency in a range between 93-100%, therefore meeting the WHO Drinking Water Guideline of 0.01 mg/L.

Even though some of the engineered nanostructured materials (e.g. structured nanotubes, nanosheets, membranes) demonstrated a high efficiency (up to 100% in some instances) these papers have been excluded because these sophisticated methods are unlikely to be commercially applied in industrial settings due to their experimental nature and management costs associated with changing treatment technologies in facilities of large scale.

References:

Bazana S., Shimabuku-Biadola Q., Arakawa F., Gomes R., Cossich E. and Bergamasco R. (2019). Modified activated carbon with silver–copper mixed oxides nanoparticles for removal of heavy metals from water. International Journal of Environmental Science and Technology 16(11): 6727-6734.

Botoman L., Shukla E., Johan E., Mitsunobu S. and Matsue N. (2018). Sorbent-embedded sheets for safe drinking water in developing countries: a case study of lead (II) removal by a zeolite-embedded sheet. Journal of water and health 16(1): 159-163.

Davis A. D., Webb C. J., Sorensen J. L., Dixon D. J. and Hudson R. (2018). Geochemical thermodynamics of lead removal from water with limestone. Water, Air, & Soil Pollution 229(6): 1-7.

Doré E., Formal C., Muhlen C., Williams D., Harmon S. M., Pham M., Triantafyllidou S. and Lytle D. A. (2021). Effectiveness of point-of-use and pitcher filters at removing lead phosphate nanoparticles from drinking water. Water Research: 117285.

Guo J., Liu X., Han M., Liu Y. and Ji S. (2020). Poly (N-acryloyl-l-histidine)-modified wood sawdust as an efficient adsorbent for low-level heavy metal ions. Cellulose 27(14): 8155-8167.

Hashemi S. A., Mousavi S. M. and Ramakrishna S. (2019). Effective removal of mercury, arsenic and lead from aqueous media using Polyaniline-Fe3O4-silver diethyldithiocarbamate nanostructures. Journal of Cleaner Production 239: 118023.

Korshin G. and Liu H. (2019). Preventing the colloidal dispersion of Pb(iv) corrosion scales and lead release in drinking water distribution systems. Environmental Science: Water Research & Technology 5(7): 1262-1269.

Lamaiphan N., Sakaew C., Sricharoen P., Nuengmatcha P., Chanthai S. and Limchoowong N. (2021). Highly efficient ultrasonic-assisted preconcentration of trace amounts of Ag (I), Pb (II), and Cd (II) ions using 3-mercaptopropyl trimethoxysilane-functionalized graphene oxide–magnetic nanoparticles. Journal of the Korean Ceramic Society 58(3): 314-329.

Li B., Trueman B. F., Rahman M. S. and Gagnon G. A. (2021). Controlling lead release due to uniform and galvanic corrosion—an evaluation of silicate-based inhibitors. Journal of Hazardous Materials 407: 124707.

Mwandira W., Nakashima K., Togo Y., Sato T. and Kawasaki S. (2020). Cellulose-metallothionein biosorbent for removal of Pb (II) and Zn (II) from polluted water. Chemosphere 246: 125733.

Ndiweni S. N., Chys M., Chaukura N., Van Hulle S. W. and Nkambule T. T. (2020). PARAFAC model as an innovative tool for monitoring natural organic matter removal in water treatment plants. Water Science and Technology 81(8): 1786-1796.

Pawar R. R., Kim M., Kim J.-G., Hong S.-M., Sawant S. Y. and Lee S. M. (2018). Efficient removal of hazardous lead, cadmium, and arsenic from aqueous environment by iron oxide modified clay-activated carbon composite beads. Applied Clay Science 162: 339-350.

Pineda Puglla E., Osorio Robles F. and García-Ruiz M. J. (2020). Biochar from Agricultural by-Products for the Removal of Lead and Cadmium from Drinking Water.

Siwila S. and Brink I. C. (2018). A small-scale low-cost water treatment system for removal of selected heavy metals, bacteria and particles. Water Practice & Technology 13(2): 446-459.

US EPA (2003). Response Protocol Toolbox: Planning for and Responding to Drinking Water Contamination Threats and Incidents, US Environmental Protection Agency.

Wangi G., Olupot P., Byaruhanga J. and Kulabako R. (2020). A Review for Potential Applications of Zeolite-Based Nanocomposites in Removal of Heavy Metals and Escherichia coli from Drinking Water. Nanotechnologies in Russia 15(11): 686-700.

Wasserstrom L. W., Miller S. A., Triantafyllidou S., Desantis M. K. and Schock M. R. (2017). Scale formation under blended phosphate treatment for a utility with lead pipes. Journal-American Water Works Association 109(11): E464-E478.

Wei X., Sugumaran P. J., Peng E., Liu X. L. and Ding J. (2017). Low-field dynamic magnetic separation by self-fabricated magnetic meshes for efficient heavy metal removal. ACS applied materials & interfaces 9(42): 36772-36782.

Yu C.-X., Wang K.-Z., Li X.-J., Liu D., Ma L.-F. and Liu L.-L. (2020). Highly Efficient and Facile Removal of Pb2+ from Water by Using a Negatively Charged Azoxy-Functionalized Metal–Organic Framework. Crystal Growth & Design 20(8): 5251-5260.

Zhang Y., Zheng H., Zhang P., Zheng X. and Zuo Q. (2021). A facile method to achieve dopamine polymerization in MOFs pore structure for efficient and selective removal of trace lead (II) ions from drinking water. Journal of Hazardous Materials 408: 124917.

Zhao C., Wang X., Zhang S., Sun N., Zhou H., Wang G., Zhang Y., Zhang H. and Zhao H. (2020). Porous carbon nanosheets functionalized with Fe 3 O 4 nanoparticles for capacitive removal of heavy metal ions from water. Environmental Science: Water Research & Technology 6(2): 331-340.

Zhu M., Zhu L., Wang J., Yue T., Li R. and Li Z. (2017). Adsorption of Cd (II) and Pb (II) by in situ oxidized Fe3O4 membrane grafted on 316L porous stainless steel filter tube and its potential application for drinking water treatment. Journal of environmental management 196: 127-136.

APPENDIX E

Data extraction tables – Evidence Scan for Recent (Health-based) Studies

Hemmativaghef 2020

Publication Reference: *Hemmativaghef E (2020). Exposure to lead, mercury, styrene and toluene and hearing impairment: evaluation of dose-response relationships, regulations and controls. Journal of Occupational and Environmental Medicine. 17(11-12): 574-597.*		
General Information	Date of data extraction	10/11/2021
	Authors	Hemmativaghef E
	Publication date	2020
	Publication type	Review
	Peer reviewed?	Yes (published in peer-reviewed journal)
	Country of origin	Canada
	Source of funding	No financial support declared.
	Possible conflicts of interest	No conflict of interest declared.
Study characteristics	Aim/objectives of study	To investigate dose-response relationships between exposure to Pb, mercury, toluene and styrene and hearing impairment based on current epidemiological evidence, conduct cross-jurisdictional comparisons, and investigate control measures for exposure to ototoxic chemicals.
	Study type/design	Literature Review
	Study duration	Time parameters were not considered in the search.
	Type of water source (if applicable)	Not applicable – various occupational & non-occupational exposures.
Population characteristics	Population/s studied	Occupational and non-occupational populations (for Pb, n=33 studies).
	Selection criteria for population (if applicable)	Studies were eligible for inclusion if they measured exposure to one of the four substances of interest and hearing loss or auditory functions as the health outcome.
	Subgroups reported	-
	Size of study	Varying sizes. Participants ranging from 3-6,409
Exposure and setting	Exposure pathway	Not stated; exposure assessed by BPb levels.
	Source of chemical/contamination	Not stated.
	Exposure concentrations (if applicable)	Exposure assessed by BPb levels.
	Comparison group(s)	Various.
Study methods	Water quality measurement used	-
	Water sampling methods (monitoring, surrogates)	-
Results (for each outcome)	Definition of outcome	Hearing loss frequency (kHz)
	How outcome was assessed	
	Method of measurement	Pure Tone Audiometry (n=27 studies) was the most frequently used assessment technique for measuring outcome.

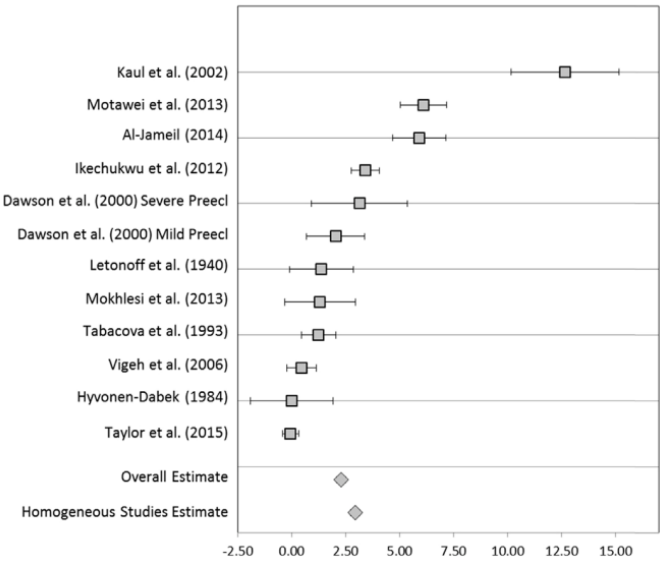
Publication Reference: *Hemmativaghef E (2020). Exposure to lead, mercury, styrene and toluene and hearing impairment: evaluation of dose-response relationships, regulations and controls. Journal of Occupational and Environmental Medicine. 17(11-12): 574-597.*		
	Number of participants (exposed/non-exposed, missing/excluded) (if applicable)	Participants ranging from 3-6,409
Statistics (if any)	Statistical method used	When significant associations were identified, exposure levels were evaluated to determine whether concentrations associated with increased risk of hearing loss could be identified including the No Observed Adverse Effect Level (NOAEL) and/or the Lowest Observed Adverse Effect Level (LOAEL). NOAEL is the highest exposure level at which there are no statistically significant increases in the frequency or severity of adverse effects between the exposed group and its appropriate control. LOAEL is the lowest exposure level at which there are statistically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control. When evaluating studies which used multiple regression analysis, if odds ratios were found to be above 1 and the 95% CI did not span 1, it was concluded that the increased odds of outcome from exposure reaches statistical significance.
	Details on statistical analysis	
	Relative risk/odds ratio, confidence interval?	
Author's conclusions	Interpretation of results	Approximately, 75% of current epidemiological evidence (N = 25) regarding auditory effects induced by Pb exposure consistently demonstrated that Pb is ototoxic to humans. Based on five studies, the highest BPb levels which were associated with no significant increases in hearing thresholds between the exposed groups and controls (NOAELs) ranged from 1–1.99 µg/dL up to 2.148–2.822 µg/dL (Choi and Park 2017). On the other hand, the lowest BPb levels at which significant increases in hearing thresholds between the exposed population and controls (LOAELs) were identified was 2 µg/dL up to 2.823–26.507 µg/dL. Based on the NOAEL and LOAELs identified, a biological exposure index of 2 µg/dL is recommended for prevention of hearing impairment from Pb exposure.
	Assessment of uncertainty (if any)	Cross-sectional design was predominantly used in studies on substances of interest including 85% of studies on Pb (N = 21). These studies are associated with limitations for sampling without regard to exposure or outcome or establishing cause–effect relationships. Some studies used more than 1000 participants including 27% of studies on Pb (N = 9). The studies used to derive NOAELs and LOAELs for hearing loss based on BLL recruited between 2,387 (Huh et al. 2018) and 7,596 (Huh et al. 2016) participants.
Reviewer comments	Results included/excluded in review (if applicable)	

Publication Reference: *Hemmativaghef E (2020). Exposure to lead, mercury, styrene and toluene and hearing impairment: evaluation of dose-response relationships, regulations and controls. Journal of Occupational and Environmental Medicine. 17(11-12): 574-597.*		
	Notes on study quality, e.g. gaps, methods	The literature review is well-documented providing a forest plot of available odds-ratios. The study authors used statistical significance of a certain interquartile range of measured BPb associations with hearing loss to define a NOAEL and LOAEL. In some instances, the interquartile ranges were quite broad. With the majority of studies finding a statistically significant association between BPb and hearing loss, it is suggestive of a causal effect between the two parameters. However individual study bias and confounding was not evaluated by study authors. Therefore, this study is considered as supportive evidence to limit Pb exposure but is not recommended to underpin DWG derivation on its own.

Poropat et al. 2018

Publication Reference: *Poropat AE, Laidlaw MAS, Lanphear B, Ball A, Mielke HW (2018). Blood lead and preeclampsia: A meta-analysis and review of implications. Environmental Research. 160: 12-19.*		
General Information	Date of data extraction	12/11/2021
	Authors	Poropat AE, Laidlaw MAS, Lanphear B, Ball A, Mielke HW
	Publication date	2018
	Publication type	Meta-analysis and review
	Peer reviewed?	Yes (published in peer-reviewed journal)
	Country of origin	Australia, Canada, USA
	Source of funding	Mark A.S. Laidlaw received funding from the RMIT University Vice Chancellor's Postdoctoral Research Fellowship. Funding for the remaining authors was sourced from their salaries at their respective universities.
	Possible conflicts of interest	No conflict of interest declared.
Study characteristics	Aim/objectives of study	To undertake a systematic review and meta-analysis to summarise information on the association between preeclampsia and Pb poisoning.
	Study type/design	Meta-analysis
	Study duration	Not stated. Blood Pb collected at various times during pregnancy.
	Type of water source (if applicable)	-
Population characteristics	Population/s studied	Women with or without preeclampsia
	Selection criteria for population (if applicable)	The criteria for assessing reports included: original research; direct measurement of blood lead levels rather than proxy measures, assessment of preeclampsia rather than hypertension alone, sufficient data to enable conversion to a common effect size.
	Subgroups reported	-

Publication Reference: *Poropat AE, Laidlaw MAS, Lanphear B, Ball A, Mielke HW (2018). Blood lead and preeclampsia: A meta-analysis and review of implications. Environmental Research. 160: 12-19.*		
	Size of study	11 studies; total sample size ranged from 4-91 (controls 17-4067) depending on relevant sensitivity analysis.
Exposure and setting	Exposure pathway	Not specified (exposure measure was BPb).
	Source of chemical/contamination	Not specified (exposure measure was BPb, which could arise from all routes of exposure).
	Exposure concentrations (if applicable)	Mean BPb measured in preeclampsia samples: 1.32 – 60.2 µg/dL, with almost all studies >5µg/dL. Mean BPb in controls: 0.94 – 8.5 µg/dL.
	Comparison group(s)	-
Study methods	Water quality measurement used	Not applicable.
	Water sampling methods (monitoring, surrogates)	Not applicable.
Results (for each outcome)	Definition of outcome	Preeclampsia: ≥140 mm Hg systolic & /or ≥90 mm Hg diastolic plus proteinuria on at least 2 visits after week 20. Outcome assessed via meta-analysis of existing studies.
	How outcome was assessed	Study quality was assessed using the Risk of Bias in Non-randomised Studies–of Interventions (ROBINS-I) tool advocated by Sterne et al. (2016).
	Method of measurement	Not stated.
	Number of participants (exposed/non-exposed, missing/excluded) (if applicable)	Total sample size ranged from 4-91 (controls 17-4067) depending on relevant sensitivity analysis.
Statistics	Statistical method used	

Publication Reference: *Poropat AE, Laidlaw MAS, Lanphear B, Ball A, Mielke HW (2018). Blood lead and preeclampsia: A meta-analysis and review of implications. Environmental Research. 160: 12-19.*		
(if any)	Details on statistical analysis	Data were extracted from the studies in the meta-analysis, along with initial secondary analyses based upon the primary data. Where primary studies did not report the specific statistics required, these were calculated on the basis of reported data. For example, one study reported scores from individual cases, enabling statistics for that study to be calculated from raw scores, while another study cited confidence intervals that were used to estimate standard deviations. Estimates of Cohen's d (adjusted for unequal sample sizes) were calculated using sample means and standard deviations for BPb levels, and number of participants, and estimates of Pearson's r were calculated from Cohen's d using equations provided by Borenstein et al. (2009). Initial reports typically did not provide sufficient data to directly calculate odds-ratios, so all odds-ratios and their associated confidence intervals were calculated from corresponding values for Cohen's d using equations provided by Borenstein et al. (2009). The results were meta-analysed using Hunter and Schmidt (2014) random effects analysis. Normally, Hunter-Schmidt analysis uses sample sizes as a proxy for estimation reliability to weight estimates but many of the studies are highly unbalanced: on a study-by-study basis, the control samples are more than ten times larger than the preeclamptic samples. The values for Cohen's d were adjusted for unbalanced sample size, and the standard errors of Cohen's d are likewise adjusted, so their inverse was used as the weighting variable instead of sample size. The results of the overall meta-analysis revealed a strong association between maternal BPb levels and preeclampsia. The overall meta-analysis demonstrated substantial and highly statistically-significant heterogeneity, so a series of sensitivity analyses were conducted by removing divergent studies.
	Relative risk/odds ratio, confidence interval?	

Publication Reference: *Poropat AE, Laidlaw MAS, Lanphear B, Ball A, Mielke HW (2018). Blood lead and preeclampsia: A meta-analysis and review of implications. Environmental Research. 160: 12-19.*		
Author's conclusions	Interpretation of results	BPb concentrations were significantly and substantially associated with preeclampsia (k = 12; N = 6069; Cohen's d = 1.26; odds ratio = 9.81; odds ratio LCL = 8.01; odds ratio UCL = 12.02; p = 0.005). Eliminating one study produced a homogeneous meta-analysis and stronger estimates, despite the remaining studies coming from eight separate countries and having countervailing risks of bias. BPb concentrations in pregnant women are a major risk factor for preeclampsia, with an increase of 1 µg/dL associated with a 1.6% increase in likelihood of preeclampsia, which appears to be the strongest risk factor for preeclampsia yet reported. Pregnant women with historical Pb exposure should routinely have BPb concentrations tested, especially after mid-term. Women with concentrations higher than 5 µg/dL should be actively monitored for preeclampsia and be advised to take prophylactic calcium supplementation. All pregnant women should be advised to actively avoid lead exposure.
	Assessment of uncertainty (if any)	Meta-analysis was not able to control for known risk factors of preeclampsia, namely antiphospholipid syndrome, diabetes, parity, family history of preeclampsia, renal disease, hypertension, obesity, and elderly primigravida. Although several of the studies in the meta-analysis actively excluded participants on the basis of one or more of these risk factors, there was no consistency in how this was conducted across studies. However, with the exception of a prior history of preeclampsia, hypertension and renal disease, there is no credible causal pathway by which such risk factors would be associated with an elevated BPb. The research indicates that BPb is more likely to act as a cause of renal disease and hypertension rather than the reverse, which implies that exclusion of women with these symptoms may have reduced study variance and consequently reduced observed associations between BPb and preeclampsia.
Reviewer comments	Results included/excluded in review (if applicable)	Study was appropriately undertaken and followed best available methods. Mean BPb in the majority of preeclampsia samples was >5µg/dL. This paper does not provide evidence to indicate BPb <5µg/dL is associated with preeclampsia, which suggests this paper would not alter the conclusions made in the evidence evaluation report.
	Notes on study quality, e.g. gaps, methods	

Wilson and Wilson 2016

Publication Reference: *Wilson IH and Wilson SB (2018). Confounding and causation in the epidemiology of lead. International Journal of Environmental Health Research. 26(5-6): 467-482.*		
General Information	Date of data extraction	12/11/2021
	Authors	Wilson IH and Wilson SB
	Publication date	2018

Publication Reference: *Wilson IH and Wilson SB (2018). Confounding and causation in the epidemiology of lead. International Journal of Environmental Health Research. 26(5-6): 467-482.*		
	Publication type	Review
	Peer reviewed?	Yes (published in peer-reviewed journal)
	Country of origin	Australia
	Source of funding	Not stated
	Possible conflicts of interest	No conflict of interest reported
Study characteristics	Aim/objectives of study	Clarification of the definition of confounding, identifying evidence of confounding (or possible reverse causation in one study) and showing that confounding has not been adequately addressed in most perspective and pooled studies. The paper examines why statistical tests and models applied by previous researchers failed to identify confounding.
	Study type/design	Review
	Study duration	Not applicable
	Type of water source (if applicable)	Not applicable
Population characteristics	Population/s studied	Existing studies which have investigated low level BPb effects on cognitive function in children.
	Selection criteria for population (if applicable)	Not stated
	Subgroups reported	Not stated
	Size of study	Several studies, exact number not stated.
Exposure and setting	Exposure pathway	-
	Source of chemical/contamination	-
	Exposure concentrations (if applicable)	-
	Comparison group(s)	-
Study methods	Water quality measurement used	-
	Water sampling methods (monitoring, surrogates)	-
Results (for each outcome)	Definition of outcome	Cognitive function in children.
	How outcome was assessed	
	Method of measurement	The study clarified the definition of confounding, identified evidence of confounding (or possible reverse causation in one study) and showed that confounding has not been adequately addressed in most perspective and pooled studies by way of several examples. The paper examines why statistical tests and models applied by previous researchers failed to identify confounding with the use of examples (raw data were not provided by authors of the studies reviewed, so the paper relied on published information).

Publication Reference: *Wilson IH and Wilson SB (2018). Confounding and causation in the epidemiology of lead. International Journal of Environmental Health Research. 26(5-6): 467-482.*		
	Number of participants (exposed/non-exposed, missing/excluded) (if applicable)	-
Statistics (if any)	Statistical method used	-
	Details on statistical analysis	
	Relative risk/odds ratio, confidence interval?	-

Publication Reference: *Wilson IH and Wilson SB (2018). Confounding and causation in the epidemiology of lead. International Journal of Environmental Health Research. 26(5-6): 467-482.*		
Author's conclusions	Interpretation of results	Many researchers who claimed to have tested and adjusted for confounding had only considered the covariance effects of the potential confounders. This addressed the 'omitted variable' problem. However, by not correcting for interaction, bias in the BPb data could remain and confound their results. The effect of relevant product terms on effect estimates has rarely been explored in the papers on Pb epidemiology. When tested, these terms were apparently found to be not statistically significant. That may partly be because of high variance caused by multiplication of variables; varied sources of exposure producing trends that either cancel each other out or add to variance; poor measuring tools for SES variables; non-linear relationships; or more complex interactions. Inaccurate statements about confounding occur widely in peer-reviewed papers and have been accepted by policy-makers. There are *a priori* grounds for expecting that factors such as quality of parental care and parental IQ, education and income would confound epidemiological studies of Pb (especially at lower BPbs) because these variables are known to influence both Pb exposure and IQ. Evidence of such interaction by several covariates is provided by the few tables of correlation coefficients and categorical data that have been published. The more likely confounding that has been confirmed by correlation coefficients and categorical data would occur at lower BPb and could be contributing to the negative supralinear associations found by most studies. Future studies need much more rigorous sampling protocols to avoid confounding and to ensure BPb measurements reflect maximum exposure unless exposure at other ages can be shown to actually affect IQ. Better sampling protocols and application of appropriate corrections for interaction effects of confounders would probably make a threshold more evident and reduce or remove the apparent effect of Pb on IQ at low BPbs. If the aggregation of data-sets has reduced the usefulness of statistical adjustments, the data may require stratification by Pb sources and exposure paths. Future research could reassess the existing high-quality data-sets to establish whether inclusion of product terms actually reduces significance of the effect estimates in log-linear models using children who have had low Pb exposure. The non-linearity of the 'dose – response' curves if a threshold is present cannot be represented by a log-linear model and therefore partitioning the data at relevant cut points or non-parametric models may be required. If removal of spurious results shows that effects are much smaller or non-existent at BPbs <10 µg/dL, policy-makers may need to review recent changes to regulations. The paper examines why statistical tests and statistical models applied by previous researchers failed to identify confounding and concludes that effects of low Pb exposure (BPb <10 µg/dL) have been exaggerated.

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	Assessment of uncertainty (if any)	-
Reviewer comments	Results included/excluded in review (if applicable)	This study provides an interesting perspective on the use (or inappropriate use) of statistical analysis methods in Pb epidemiological studies which may have affected interpretation of there not being a demonstrable threshold for Pb effect on child cognition. It provides support for not recommending the OEHHA (2009) guideline value for adoption/adaptation in Australia, and basing the recommended guideline value for Pb on a reduction/ minimisation of Pb exposures, consistent with current Australian science policy.
	Notes on study quality, e.g. gaps, methods	

ASIA PACIFIC OFFICES

ADELAIDE
60 Halifax Street
Adelaide SA 5000
Australia
T: +61 431 516 449

BRISBANE
Level 16, 175 Eagle Street
Brisbane QLD 4000
Australia
T: +61 7 3858 4800
F: +61 7 3858 4801

CANBERRA
GPO 410
Canberra ACT 2600
Australia
T: +61 2 6287 0800
F: +61 2 9427 8200

DARWIN
Unit 5, 21 Parap Road
Parap NT 0820
Australia
T: +61 8 8998 0100
F: +61 8 9370 0101

GOLD COAST
Level 2, 194 Varsity Parade
Varsity Lakes QLD 4227
Australia
M: +61 438 763 516

MACKAY
21 River Street
Mackay QLD 4740
Australia
T: +61 7 3181 3300

MELBOURNE
Level 11, 176 Wellington Parade
East Melbourne VIC 3002
Australia
T: +61 3 9249 9400
F: +61 3 9249 9499

NEWCASTLE CBD
Suite 2B, 125 Bull Street
Newcastle West NSW 2302
Australia
T: +61 2 4940 0442

NEWCASTLE
10 Kings Road
New Lambton NSW 2305
Australia
T: +61 2 4037 3200
F: +61 2 4037 3201

PERTH
Grd Floor, 503 Murray Street
Perth WA 6000
Australia
T: +61 8 9422 5900
F: +61 8 9422 5901

SYDNEY
Tenancy 202 Submarine School
Sub Base Platypus
120 High Street
North Sydney NSW 2060
Australia
T: +61 2 9427 8100
F: +61 2 9427 8200

TOWNSVILLE
12 Cannan Street
South Townsville QLD 4810
Australia
T: +61 7 4722 8000
F: +61 7 4722 8001

WOLLONGONG
Level 1, The Central Building
UoW Innovation Campus
North Wollongong NSW 2500
Australia
T: +61 2 4249 1000

AUCKLAND
Level 4, 12 O'Connell Street
Auckland 1010
New Zealand
T: 0800 757 695

NELSON
6/A Cambridge Street
Richmond, Nelson 7020
New Zealand
T: +64 274 898 628

WELLINGTON
12A Waterloo Quay
Wellington 6011
New Zealand
T: +64 2181 7186

SINGAPORE
39b Craig Road
Singapore 089677
T: +65 6822 2203