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21 November 2024

NHMRC

Attention: NHMRC

Re: Draft PFAS Drinking Water Guidelines – comments

1 Introduction

Environmental Risk Sciences Pty Ltd (enRiskS) is pleased to provide the following comments on the draft drinking water guidelines for various per- and polyfluoroalkyl substances (PFAS) as published by the National Health and Medical Research Council (NHMRC).

In October 2024, the NHMRC published draft drinking water guidelines for public comment (the "guidelines") for 4 key PFAS. The proposed guidelines are:

- PFOS = 0.004 µg/L
- PFHxS = 0.03 µg/L
- PFOA = 0.2 µg/L
- PFBS = 1 µg/L.

Comments are requested by 22 November. The information provided by NHMRC indicates that they will review the comments provided and publish the guidelines in final form in April 2025.

The documents provided for public comment include:

- Draft fact sheet – PFAS (NHMRC)
- NHMRC Statement on PFAS in Drinking Water
- SLR Consulting (2023) Research Protocol
- SLR Consulting (2024a) Technical Report
- SLR Consulting (2024b) Evidence Evaluation Report
- SLR Consulting (2024c) Addendum to Evidence Evaluation Report.

Existing drinking water guidelines for PFOS+PFHxS and PFOA are provided in the current version of the NHRMC Drinking Water Guidelines (NHMRC 2011 updated 2022). These values are:

- PFOS+PFHxS = 0.07 µg/L
- PFOA = 0.56 µg/L.

PFOS is arguably the key PFAS in Australia. The draft guideline for PFOS is around 20-fold lower than the existing guideline for PFOS.

A review of the NHMRC materials has been undertaken and a summary of that information and the issues arising is provided in the following sections.

From an overall perspective, we think it is important to acknowledge that the fundamental building blocks for the entire planet are chemicals. Whether it is the water we drink, the air we breathe, the food we eat, the ground we walk on, the houses we live in, the things we have inside our houses or workplaces or what we ourselves are made of, everything is made of chemicals. Some chemical substances like water, oxygen and nutrients are essential to keeping us alive or to let plants or other animals live. Other chemical substances are naturally occurring, but they can kill us – like spider and snake venoms or well-known poisons like arsenic or mercury. The same applies to the chemical substances we manufacture – some substances are quite benign, and some are quite toxic. A range of chemical substances are used to manufacture things we use every day like food, clothes, computers, kitchen appliances, cars, houses, roads, trains, planes, hair dyes, beauty products, toothpaste, shampoo, flea rinse for our pets and many other things.

Given that everything in the world is made from chemicals, the presence or detection of a chemical in the environment does not equal an unacceptable risk to people or the environment. Risk assessment is used to determine if the amount of a chemical present in the environment could pose a risk to people or the environment. Assessing risk requires detailed consideration of how much of a chemical can reach a place where people or ecosystems can be exposed. This includes consideration of where and how a chemical is used along with whether it can escape into the environment and what happens to the chemical when it is released into the environment. Important considerations in understanding fate are the properties of a chemical e.g. whether it bioaccumulates, sticks to soil, can be taken up over human skin etc. Such assessments are also designed to be conservative (precautionary i.e. designed to overestimate risks). In the case of PFAS, it is acknowledged that even with the large amount of information about potential effects of PFAS in people or the environment that has been added over the last decade, it is still not particularly clear how these chemicals cause effects.

In Australia we have well established Government guidance on how to undertake a human health and environmental risk assessment. This guidance is not chemical specific, hence, is valid for all chemicals, including PFAS. There is no reason for PFAS to be treated any differently to other chemicals. In fact, it is our experience that treating PFAS differently to other chemicals can create practical, logistical, financial and risk communication issues. These issues can outweigh any positive effects and benefits that may be gained from applying an overly cautious approach to PFAS management.

Setting a drinking water guideline for PFOS at or below ambient concentrations and at (and below) commercially available laboratory limits of reporting indicates that whenever PFOS is detected in the environment, there are unacceptable risks to human health. Where there is strong evidence that this is the case, then such situations need to be acknowledged and addressed but where there is much discussion and disagreement about how a chemical causes toxic effects and at what doses such effects might be seen, then this is not a reasonable approach. It is important to note the extremely high concentrations used in the toxicity studies in laboratory animals before any effects are seen and to compare that with other chemicals to put toxicity reference values for PFAS into an appropriate context. These are just another class of chemicals, not something strange that has never been seen before.

Hence, we consider it is critically important to carefully consider the basis of the draft guidelines from NHMRC.

We appreciate the opportunity to provide these comments.

2 Summary of comments

Sections 3 to 10 of this submission provide detailed comments in relation to the draft NHMRC guidelines for PFAS.

Overall, a number of key issues have been identified, which are summarised as follows:

- The approach adopted by NHMRC to determine appropriate drinking water guidelines included commissioning detailed reviews form an independent consultant, with independent peer-review, however the NHMRC has been inconsistent in how the recommendations from these reviews have been adopted for each of the PFAS evaluated, specifically the recommendation for PFOS was ignored by NHMRC with no explanation (refer to **Sections 3 and 4** for further detail).
- A major issue has been identified with the toxicity reference value adopted for PFOS, which is relied on for deriving the drinking water guideline. We are concerned that the toxicity study and toxicity reference value chosen by NHMRC are not robust/relevant for use in setting guidelines (refer to **Section 6** for further detail).
- Another major issue with the proposed drinking water guideline for PFOS is the lack of consideration of people's current exposure to background sources of PFAS. Where background exposures are a significant proportion of the relevant toxicity reference value, the source allocation term included in the calculation needs to be carefully considered (refer to **Section 7** for further detail).
- There are a range of flow on impacts that would occur as a result of the NHMRC adopting a lower toxicity reference value, as proposed in the draft guideline. More specifically risk-based guidelines adopted for recreational water, soil, organic products and food would need to be revised. Such revisions would result in guidelines that are similar to or below ambient levels in the environment, which would mean that many waterways may no longer be suitable for recreational use, soil in many areas would not be suitable for residential purposes, organic products (such as biosolids, compost etc) would not be able to be used for any purpose (impacting on a circular economy), and existing food products may no longer be considered safe for consumption or export. Further many of the revised guidelines would not be able to be measured by commercial laboratories in Australia (refer to **Section 10** for further detail).
- Establishing a very low guideline for PFOS drinking water, and resultant impacts to other media (summarised above), would increase already elevated levels of concern, stress and anxiety regarding PFAS in the environment. The NHMRC needs to be very certain that the proposed drinking water guideline is supported by robust science and toxicity studies to justify such increased levels of concern, stress and anxiety in the community (refer to **Section 11** for further detail).

3 Approach adopted by NHMRC

It is our understanding that the NHMRC has responsibility for publishing guidance regarding protecting the quality of drinking water quality across Australia. State and territory health departments are then responsible for ensuring drinking water provided to communities complies with the published guidelines from NHMRC.

The NHMRC has published a large guidance document which provides this information which is regularly updated (under rolling revision). The document includes guidelines for many chemicals including PFAS. The most recent version of this document is:

- Australian Drinking Water Guidelines 6, Version 3.8 Updated September 2022, National Water Quality Management Strategy, National Health and Medical Research Council, National Resource Management Ministerial Council., Canberra.

As noted above, the existing guidelines for PFOS+PFHxS and PFOA in the current version of the NHRMC Drinking Water Guidelines (NHMRC 2011 updated 2022) are:

- PFOS+PFHxS = 0.07 µg/L
- PFOA = 0.56 µg/L.

These guidelines were first published by the Commonwealth Department of Health who made use of the findings of FSANZ in relation to toxicity reference values for use in developing such guidelines (FSANZ 2017a). These guidelines were then published in Version 1 of the PFAS National Environmental Management Plan (NEMP) in early 2018 (HEPA 2018), and officially included in the full version of the NHMRC Australian Drinking Water Guidelines later in 2018 (i.e. Version 3.5) (NHMRC 2011 updated 2018). This means Australia has had drinking water guidelines for these chemicals in force since 2018.

The NHMRC has been considering the relevant toxicological literature since 2023 via the use of an independent expert toxicologist from SLR Consulting. SLR Consulting was engaged as an independent expert to provide a range of information to the NHMRC. In the various reports they prepared, they provide a detailed review of the guidance provided by international bodies such as the United States Environmental Protection Agency (USEPA), US Agency for Toxic Substances and Disease Registry (ATSDR), the European Food Safety Authority (EFSA) and the World Health Organisation (WHO). NHMRC also engaged Professor Brian Priestley to undertake a review of the work by SLR Consulting.

Determining a toxicity reference value is the first step in calculating a drinking water guideline. Where toxicity can be assessed on the basis of a threshold, the toxicity reference value describes the amount of a chemical that a person can be exposed to daily via all potential exposure pathways without any effects – i.e. the "acceptable or tolerable" intake.

As noted above, it is important to remember that the world is made of chemicals. Everything we see and feel around us is made of chemicals and the target of chemicals management is to ensure that the levels of a chemical to which people may be exposed remain low and pose a negligible risk. It is on this basis that chemicals are assessed i.e. what levels can people be exposed to before adverse health effects are expected. This also means that just because a chemical is present in the environment or in the food we eat, it does not mean that adverse effects will occur (there must be enough of the chemical present to trigger adverse changes in our systems). This is why determining a toxicity reference value is such a key step in determining a drinking water guideline.

In line with normal practice for such reviews, SLR Consulting determined which toxicity studies were robust and appropriate for use in determining a toxicity reference value for each of the 4 PFAS. For these PFAS, the review resulted in classifying 2 to 4 studies as of appropriate quality for establishing a toxicity reference value. It was not possible to choose only 1 key study as even the most robust studies had issues. This means that there were multiple results describing the toxicity of

each of the PFAS and that those results could not be separated – they were all equally suitable for determining a toxicity reference value.

SLR Consulting then calculated toxicity reference values for each of the studies and endpoints that they considered relevant and robust and then they calculated drinking water guidelines using those toxicity reference values.

For PFOS, they calculated the following range of guidelines using the various key studies:

- 0.0034 µg/L
- 0.027 µg/L
- 0.077 µg/L
- 0.095 µg/L.

For PFOA, they calculated the following range of guidelines using the various key studies:

- 0.063 µg/L
- 0.075 µg/L
- 0.172 µg/L
- 0.111 µg/L
- 0.227 µg/L
- 0.402 µg/L
- 0.554 µg/L.

For PFHxS, they calculated the following range of guidelines using the various key studies:

- 0.0085 µg/L
- 0.034 µg/L.

For PFBS, they calculated the following range of guidelines using the various key studies:

- 2.939 µg/L
- 2.252 µg/L
- 1.041 µg/L.

SLR Consulting then made the following recommendation about which value to choose for the drinking water guideline for each of the PFAS based on their understanding of the details of each toxicity study:

- PFOS = 0.07 µg/L (i.e. retain current guideline for PFOS+PFHxS)
- PFHxS = 0.07 µg/L (i.e. retain water guideline for PFOS+PFHxS)
- PFOA = 0.2 µg/L (i.e. change from current guideline of 0.56 µg/L)
- PFBS = any value between 1 and 2.9 µg/L (no guideline currently exists).

The NHMRC, however, made different choices for each PFAS choosing the following guidelines:

- PFOS = 0.004 µg/L
- PFHxS = 0.03 µg/L
- PFOA = 0.2 µg/L
- PFBS = 1 µg/L.

The guideline for PFOS recommended by NHMRC is significantly different to that recommended by SLR Consulting.

In addition, it can be seen from the guidelines presented above that the NHMRC decided to choose:

- PFOS and PFBS: the lowest/most conservative guideline calculated by SLR Consulting
- PFHxS: the highest/least conservative guideline calculated by SLR Consulting
- PFOA: the guideline recommended by SLR Consulting.

So, the approach adopted by NHMRC is inconsistent between PFAS. Rationale for the approach adopted by NHMRC is not provided.

In addition to the above, it appears that the NHMRC has targeted the USEPA maximum contaminant limit (MCL) of 4 ng/L (0.004 µg/L) as the guideline for Australia. While this may not have actually occurred, it appears this way to the community and the media, in particular.

It is not normal practice for Australia to directly adopt US guidelines. In fact, for drinking water guidelines, NHMRC guidance indicates the following:

- Section 6.4 of the Australian Drinking Water Guidelines notes that the Australian guidelines take as their point of reference the WHO Guidelines for Drinking Water Quality – with variations from WHO values based on a different assumption about body weight (70 kg for Australia vs 60 kg for WHO) and a different assumption about negligible risk for genotoxic carcinogens ($1x10^{-6}$ for Australia vs $1x10^{-5}$ for WHO).
- Section 6.5 of the Australian Drinking Water Guidelines notes that there is a hierarchy to follow when choosing guidelines for chemicals that are not listed in the Australian Drinking Water Guidelines – that hierarchy places USEPA guidance as the 5th or 6th choice. Guidelines in WHO, New Zealand and Canada are all to be preferred above USEPA values.

4 Issues with the proposed toxicity reference value and guideline for PFOS

The toxicity reference value and drinking water guideline proposed by the NHMRC for PFOS is particularly problematic for the following reasons:

- The guideline proposed by NHMRC is different to that recommended by the independent expert engaged by NHMRC (SLR Consulting), without a stated rationale.
- SLR Consulting found the following:
  - SLR calculated the PFOS guideline using 4 different toxicity reference values
  - these 4 different values were based on different ways to interpret the data from 2 studies
  - SLR Consulting considered the data used to calculate these toxicity reference values as essentially equivalent in regard to quality of the study and relevance of the endpoint
  - SLR Consulting considered these values to all be protective of people's health as the differences were based on slightly different interpretations of the same data
  - this process (i.e. calculating the guideline value using multiple toxicity reference values) is commonly used when there are many studies available for a particular chemical and several studies cannot be excluded from consideration as the key study driving the assessment
  - when this is undertaken it is usually considered that all of the values calculated would be equally health protective and so any of the values in the range could be chosen

- SLR Consulting recommended leaving the drinking water guideline at the value as currently listed in the NHMRC guidelines as there was not robust evidence that it should be changed
- this advice has not been adopted by NHMRC but no rationale has been provided to explain the approach taken.

- There are many issues with the choice of endpoint for the calculation of the toxicity reference value chosen by NHMRC including the following (see discussion in **Section 2.3.2** of this letter for more information):
  - issues with the quality of the study
  - whether the endpoint chosen is actually adverse
  - how to determine the relevant dose for the endpoint based on statistical issues with the data.
- Lack of consideration of the large background exposure to PFOS that already exists in the Australian population, based on data from studies of PFAS in pooled blood samples which impacts on how a drinking water guideline should be calculated (see discussion in **Section 2.5** of this letter; this is an issue due to the proposed very low toxicity reference value).
- Currently, Australia has used a toxicity reference value of 20 ng/kg bw/day for calculating guidelines for drinking water, recreational water, soil, biosolids and food. If the toxicity reference value proposed by NHMRC for PFOS (i.e. 0.98 ng/kg bw/day) is formally adopted, then the implications for other types of guidelines are extremely significant and include:
  - lack of available analytical methods for measuring PFOS at relevant concentrations in most media
  - potential closure of swimming areas due to levels of PFOS above a revised recreational water guideline
  - significantly increased costs for contaminated sites investigations and remediation
  - background ambient soil and surface water concentrations in many locations already above the relevant guideline (i.e. identification of urban ambient concentrations of chemicals as "contaminated", with associated management requirements and risk of property blight)
  - water authorities not able to comply with requirements for reuse of biosolids or treated wastewater meaning these materials will need to be disposed – this will impact on the potential for appropriate management of sewage in Australia
  - resource recovery for a range of other materials (compost, FOGO, etc etc) will no longer be permitted as the materials will never be able to comply with criteria based on the new toxicity reference value essentially shutting down any potential for a circular economy in Australia
  - foods (e.g. seafood, beef) not being able to demonstrate compliance with trigger points which raises questions about the safety of many food types in Australia and may have impacts on international trade
  - escalation in stress and anxiety felt by the community about PFAS, which is already at very high levels and noting that stress/anxiety have recognised adverse health effects.

While these issues may also be present in the draft guidelines for PFOA, PFHxS and PFBS, they have the most impact on the PFOS guideline, so this commentary has focused on the issues in the calculation of the draft drinking water guideline for PFOS.

More detailed discussion of these issues is provided in the following sections.

5 Derivation of the drinking water guideline

The draft NHMRC fact sheet lists the following information about the calculation of the drinking water guideline for PFOS:

- Benchmark dose (modelled) of 294 ng/kg bw/day from 28 day study in rats undertaken by the National Toxicology Program in the US – the modelling determined the dose that would result in a 10% change to the key endpoint (i.e. $BMDL_{10}$) (NTP 2022).
- Uncertainty factors applied to this $BMDL_{10}$ to generate the toxicity reference value were 10 fold for human variability, 3 fold for extrapolating from rats to people and 10 fold as the study was a very short term study compared to the toxicokinetics of these chemicals – giving a total uncertainty factor of 300.
- This gives a toxicity reference value of 294/300 = 0.98 ng/kg bw/day.
- This value was then used with the standard assumptions incorporated into the drinking water guidelines – a water ingestion rate of 2 L/day, a body weight of 70 kg and a source allocation to drinking water of 10%.

The calculation of the guideline value is, therefore:

$$\text{Drinking water guideline} = \frac{\text{Toxicity reference value } \left(\frac{294}{300}\right) \text{ x bodyweight x fraction allocated to dw}}{\text{daily water ingestion rate}}$$

$$\text{Drinking water guideline} = \frac{0.98 \text{ x } 70 \text{ x } 0.1}{2}$$

Drinking water guideline= 3.4 ng per L (rounded up to 4 ng per L)

The main questions to address when considering the appropriateness of this assessment are:

- Is the endpoint adopted the most appropriate one, i.e. is the endpoint adverse? Is the study of appropriate quality? This is further discussed in **Section 6**.
- Are the uncertainty factors chosen comprehensive and appropriate? These appear toi be reasonable and no comments are provided.
- Is the allocation of 10% of the toxicity reference value from drinking water appropriate? This is further discussed in **Section 7**.

6 PFOS chosen endpoint

SLR Consulting identified several new studies about the toxicity of PFOS which they considered as key for this review:

- US National Toxicology Program (NTP 2022)
- Zhong et al. (2016) (Zhong et al. 2016).

These studies were in addition to the single key study previously adopted by Food Standards Australia and New Zealand (FSANZ) (and other agencies) in 2017 (Luebker et al. 2005).

NTP (2022) was the driver for the choices made by NHMRC.

This study was a 28-day study in rats. This is a common type of study undertaken by the NTP. These types of studies look at hundreds of different effects in the animals from mortality to minor

changes in blood chemistry when the rats are exposed to a chemical of interest. This agency is well qualified to undertake such studies.

SLR Consulting did review the way USEPA (and other agencies) assessed the quality of the relevant toxicity studies, however, they did not undertake an independent detailed review of the quality of this study. Instead, they relied on the fact that the USEPA determined that this was a high quality study. It is unclear if NMHRC has undertaken a detailed review of this study. A detailed review of NTP (2022) by enRiskS has identified a range of issues with this study in regard to the chosen endpoint from this study, including:

- The use of a short-duration study:
  - The study was only 28 days long which is considered too short for studies of persistent chemicals like PFAS. Other studies available in the literature have been undertaken for 2 years for rats and 6 months for monkeys – this is much more relevant for these chemicals. It is not clear why the short-term study was considered in preference to these other (longer) studies (noting the longer duration studies were not considered by NHMRC in this round of evaluation).
  - The key effects identified by NHMRC were not seen in the longer studies, so it is not clear that they could be considered to be relevant or adverse.
- Animal studies only identifying effects at very high doses:
  - The NTP study looked at many effects in rats but only a small number of effects were different in treated rats compared to control rats, and only at very high doses (>1,000,000 ng/kg bw/day). Such high concentrations are not environmentally relevant but are commonly used in such studies to actually see effects. Often such doses are required when chemicals cause general types of toxicity rather than toxicity via specific mechanisms such as inhibition of enzymes or interactions with receptors etc. The fact that such high doses were required in the study to see any effects potentially points to generalised toxicity rather than toxicity via a specific mechanism of importance.
  - The reason the toxicity reference value for people is so low based on this endpoint is not due to the dose that caused the endpoint effect but is due to the toxicokinetic considerations that have been incorporated in the calculation by the USEPA to convert from a dose in rats to a dose in people. These considerations have effectively resulted in a 1,000,000 fold factor (based on an exposure to 1,250,000 ng/kg bw/day where the relevant effects were seen in the rats compared to the toxicity reference value used of 0.98 ng/kg bw/day. For most chemicals, a default factor of 10 is applied to convert animal data to human equivalent data.
- Quality of the NTP study:
  - Review of the NTP study noted that equipment used in the experiment included Teflon – i.e. a source of PFAS. It is common practice in laboratories to remove all Teflon from studies wherever possible. In addition, a single round of chemical analysis was undertaken on the treatment solutions used in the experiment, even though the solutions were made up at the beginning of the experiment, accessed every day and stored for the whole study period potentially in contact with Teflon containing materials. Good data quality is an important aspect of ensuring robust data are used in guideline development.

- Analysis was not undertaken using the normal analytical method for environmental samples (i.e. LC/MS or LC/MS/MS) as per USEPA guidance. Instead, the analysis was undertaken using LC with either an ion chromatography detector or a UV spectrophotometer detector. This is because the concentrations required for this experiment were so extremely high that it was not necessary to use the sort of sensitive method required for low level environmental samples. Using these other types of detectors is not covered by the USEPA standard methods for analysis of PFOS (or other PFAS). It is not clear that these are appropriate, validated methods.

- Immunotoxicity endpoint:
  - Immunotoxicity was initially considered as a key endpoint for PFOS, PFHxS and PFBS by SLR Consulting and NHMRC.
  - This type of endpoint was determined to not be clinically relevant for PFOS, so a different key effect appears to have been adopted by NHMRC for the calculation of the guideline – changes in red blood cell production processes.
  - However, the same type of immunotoxicity endpoints remain as the key endpoints for PFHxS and PFBS without any explanation as to why such effects were not clinically relevant for PFOS but are relevant for PFHxS and PFBS i.e. the decision-making process is inconsistent between PFAS.
- Critical endpoint chosen:
  - For PFOS, the key endpoint chosen was related to changes in the production of red blood cells – the NTP authors decided that the level of this effect was minimal at all treatment levels where a change from the controls was noted – i.e. there was a likely flat, dose response relationship for this effect which makes statistical analysis difficult.
  - There is not a lot of information available as to the potential for this endpoint to actually be adverse. The NTP study reported that there was no overall change in the red blood cell count at any treatment level and no anaemia was reported. This may have been due to the length of the study but it could also be due to the observed changes in the production of red blood cells not being a particularly important effect as other processes address those observed changes automatically over time.
  - The statistical analysis of the data for PFOS was identified as problematic by SLR Consulting and Professor Brian Priestley:
    - there are 2 sets of values that can be used to indicate a negligible change in the effect of interest (i.e. the key value for use in calculating the toxicity reference value)
    - one value (NOAEL) comes from the actual observations in the study – the measured concentrations of PFOS in the blood when the rats were exposed at the dose that did not change red blood cell production
    - the other value (BMD_{10}) comes from a statistical calculation of what the concentration of PFOS in blood would be when there was a 10% change in the red blood cell production
    - using the BMD_{10} gives a drinking water guideline of 0.0034 µg/L and using the NOAEL gives a drinking water guideline of 0.077 µg/L i.e. a 20-fold difference
    - these 2 types of values should be similar as they are designed to be an estimate of the same thing – the dose that results in a negligible change in the parameter of interest. This significant difference indicates a likely issue

with the dose response relationship i.e. not a strong relationship and one impacted by variability.

Based on the above, the recommended guideline for PFOS should, therefore, have been 0.077 µg/L which is based on the NOAEL (i.e. same as recommended by SLR Consulting and Professor Brian Priestley; retain the existing value) as this is the value based on actual measured blood concentrations in animals where the change in red blood cell production did not occur.

These issues mean that we are concerned that the toxicity study and toxicity reference value chosen by NHMRC as the basis of the proposed drinking water guideline is not a robust value relevant for use in setting guidelines.

Issues with using non-robust data as critical endpoints

Australia has already had a situation where, in 2016, an inappropriate study/endpoint was included in the dataset used to calculate the water quality guideline for ecosystem protection (i.e. to protect aquatic organisms). This study was included the dataset as it was a multi generation study and it appeared to be of appropriate quality. However, the study was not undertaken in accordance with appropriate methods and there was no dose response relationship identified for any of the effects considered for the endpoints. It was, therefore, assumed that the lowest dose was the lowest observed effect level for use in the dataset.

The inclusion of this data point resulted in difficulties with the statistical analysis. The determined 99% species protection value was 0.00023 ng/L, which was around 1,000 times lower than the calculated 95% species protection value, instead of around 10 times lower as is the case for a range of other bioaccumulative chemicals. This very low 99% species protection value was then required to be used by several state regulators for contaminated sites assessment and surface water/groundwater assessment resulting in huge costs for investigation and remediation ($100 millions).

Detailed review of the paper of interest in 2016 (and since) indicated that there were many issues with the quality of that study and with the statistics for the guideline calculation, but these issues were not addressed in a timely manner nor has the guideline value for PFOS to protect aquatic organisms been finalised to this day.

Such technical issues should not be allowed to muddy the waters for yet another national guideline value.

7 Background exposures

Unlike many chemicals in Australia, biomonitoring information on background levels of PFAS in serum in the general population is available. The team of researchers at the Queensland Alliance for Environmental Health Sciences undertook biomonitoring of PFAS in serum for pooled blood samples taken from waste blood at pathology providers from early 2000s through to 2017 (Kärrman et al. 2006; Thompson et al. 2010; Toms, L-ML et al. 2009; Toms, LML et al. 2019; Toms, LML et al. 2014). The samples were pooled based on age and, for some monitoring events, urban versus regional patients.

Blood collected in 2002/2003 was reported to contain around 20 ng/mL of PFOS. Similar levels were reported in 2006/2007 although levels in women had decreased slightly (Kärrman et al. 2006;

Toms, L-ML et al. 2009). Levels of PFOS were also measured in 2008/2009, 2010/2011, 2013/2014 and 2015/2016. Levels in adults had decreased to around 10 ng/mL in 2008/2009 and 2010/2011. Levels in adults were around 4-8 ng/mL in 2013/2014 and 2015/2016 (Toms, LML et al. 2019; Toms, LML et al. 2014).

Figure 1 is taken from (Toms, LML et al. 2019) and it shows the changing concentrations of individual PFAS in pooled blood samples in Australia. These graphs show little change in PFHxS, a decrease for both PFOS and PFOA and an increase and then a decrease for PFNA over this time.

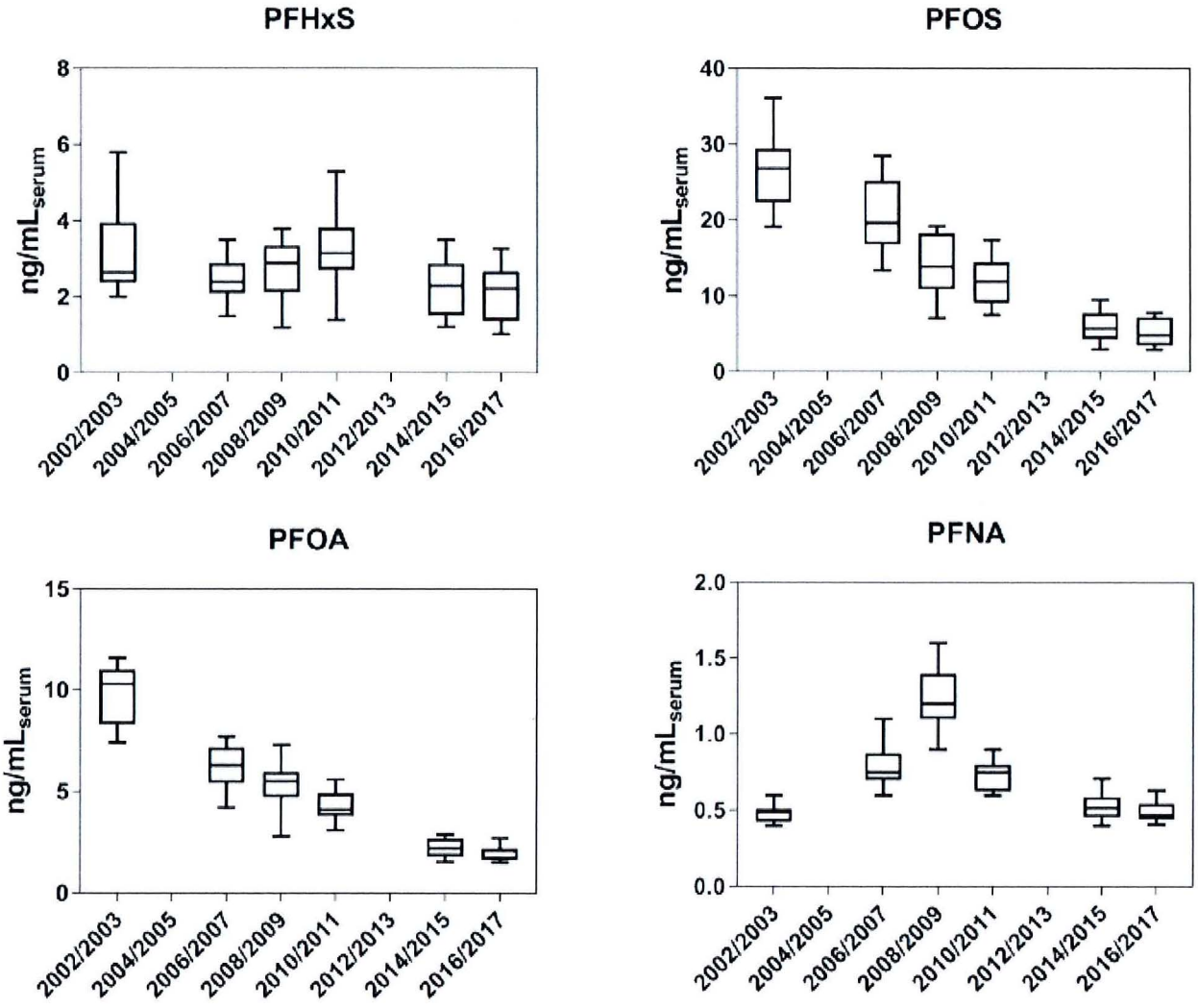

Figure 1: Changing serum concentrations in Australian population for key PFAS

These researchers calculated likely daily intakes for the various PFAS based on these serum concentrations (Thompson et al. 2010).

Using a simple pharmacokinetic model, they calculated intakes for PFOS and PFOA for the first 2 monitoring periods.

The calculation used the following equation:

Daily intake = Serum conc x volume of distribution (Vd) x elimination rate (kP)

Where the units for each parameter include:

Daily intake – ng/kg bw/day
Serum concentration – ng/mL
Volume of distribution (Vd) – mL/kg bw
Elimination rate (kP) – per day

This calculation is relevant at steady state. The researchers used an elimination rate of 0.0008 per day for PFOA and 0.0003 per day for PFOS based on serum half lives from occupational studies (2.3 years for PFOA and 5.4-5.9 years for PFOS). The volume of distribution used was 170 mL/kg bw for PFOA and 230 mL/kg bw for PFOS.

Using the same approach, estimated daily intakes have been calculated for all monitoring periods using the serum concentration data for the adult groupings (i.e. >16 years). The calculated intakes are listed in **Table 1**.

Table 1: Estimated daily intakes for PFOS and PFOA in the Australian population

Monitoring period	Serum PFOS (ng/mL)	PFOS Intake (ng/kg bw/day)	Serum PFOA (ng/mL)	PFOA Intake (ng/kg bw/day)
2002-2003[1]	13-30	1-2.3	5.8-9.9	0.6-1.3
2006-2007	13-29	1.1-2.2	4.2-7.7	0.6-1
2008-2009	5.3-19.2 (11.9 mean)	0.4-1.3 (0.8 mean)	2.8-7.3 (5.2 mean)	0.4-1 (0.7 mean)
2010-2011	4.4-17.4 (10.2 mean)	0.3-1.2 (0.7 mean)	3.1-6.5 (4.5 mean)	0.4-0.9 (0.6 mean)
2013-2014	8.7 mean/ 17.4 P95 averaged across adult groupings	0.6 (mean)/ 1.2 (P95)	2.3 mean/ 5.4 P95 averaged across adult groupings	0.3 (mean)/ 0.7 (P95)
2015-2016	5.2 mean/ 12.1 P95 averaged across adult groupings	0.4 (mean)/ 0.8 (P95)	2.0 mean/ 4.3 P95 averaged across adult groupings	0.3 (mean)/ 0.6 (P95)

Notes:

1 There was one pooled sample with a significantly elevated PFOS concentration (88 ng/mL) which gave an intake of 6.8 ng/kg bw/day. This value was considered an outlier by the researchers so has not been included in the data for this table.

These calculations indicate the following:

- PFOS – daily intake has ranged from 0.3-2.3 ng/kg bw/day since 2000
- PFOA – daily intake has ranged from 0.3-1 ng/kg bw/day since 2000.

Background exposure is likely to occur because these chemicals are used in a wide range of products present in homes and workplaces. These chemicals are present in water, stain and oil repellent, so they have been used in food packaging, furniture textiles, carpets, paints, outdoor clothing (hiking, skiing), cosmetics, personal care products, plastics etc. These many uses have resulted in widespread low levels throughout urban environments.

There is no organised national biomonitoring program in Australia. These biomonitoring data have been determined using limited numbers of pooled blood samples from limited parts of Australia. The studies have mostly accessed pooled blood from Queensland pathology providers. While these data are useful for this discussion, it is noted that these data do not result from a statistically designed study of the entire Australian population such as is undertaken in USA – the NHANES program. They do indicate, however, that Australians have a background intake of these chemicals that is

high enough that it should be considered (or at least discussed) when setting guidelines such as drinking water guidelines.

These measurements indicate that people in Australia have a background intake of PFOS around 0.8 ng/kg bw/day (high end value from most recent monitoring round). Comparing this background intake to the toxicity reference value used in the proposed NHMRC guidelines indicates that 80% of the proposed toxicity reference value is already taken up by these background exposures.

The normal calculation for drinking water guidelines in Australia allows 10% of the toxicity reference value to come from drinking water. This ensures protection of health for those who may be exposed to higher levels of the same chemical at work or at a contaminated site or due to other exposure pathways.

If people are already exposed to around 80% of the toxicity reference value, then some adjustment should have been made to the basic drinking water guideline calculation, but this has not occurred for PFOS, nor has it even been discussed in the NHMRC fact sheet.

It is noted, that if the current toxicity reference value is retained (as per SLR Consulting recommendation), then this background existing intake corresponds to around 5% of the toxicity reference value and there is no need to address this issue in the calculation of the drinking water guideline.

It is important that these intakes get considered when establishing tolerable daily intakes and drinking water guidelines to ensure the drinking water guidelines are sufficiently protective, if the proposed toxicity reference value is to be adopted.

It is recommended that background exposures are more appropriately considered when calculating this guideline. More recent data on PFOS concentrations in the blood of Australians could also be useful to assist this process.

8 WHO drinking water guidelines

Given that the World Health Organisation drinking water guidelines are considered to be the point of reference for the Australian drinking water guidelines, it is important to consider the views of the WHO in regard to the toxicity of PFOS.

The WHO published a draft background document on PFOS and PFOA in drinking water in September 2022.

This document noted that PFOS and PFOA were regularly detected in Australian drinking water sources and that the highest reported concentrations were 16 ng/L for PFOS and 9.7 ng/L for PFOA in a study from 2011.

The findings of this document about the toxicity of these chemicals were summarised as follows:

Acknowledging the significant uncertainties and absence of consensus with identifying the critical health endpoint to calculate a HBGV and the rapidly evolving science, a pragmatic solution is therefore proposed for the derivation of provisional guideline values (pGVs).

Individual pGVs of 0.1 µg/L for PFOS and PFOA (i.e. 100 ng/L) are proposed and a combined pGV of 0.5 µg/L is proposed for total PFAS (i.e. 500 ng/L).

This approach has been widely criticised, and this draft document has been withdrawn from the WHO website. However, this acknowledgement of the difficulties in determining the toxicity of these chemicals is to be applauded.

The values chosen for these provisional guidelines are based on what is routinely achievable by the sort of water treatment technologies likely to be relevant/affordable for most water authorities which is a relevant matter to consider when determining drinking water guidelines.

This is an approach that could be considered by NHMRC when determining revised drinking water guidelines for PFAS. However, in this case, this approach should be clearly acknowledged in the documentation supporting the drinking water guidelines. i.e. if such an approach were adopted, it would not be appropriate to infer, imply or state that the drinking water guidelines were derived based on toxicity reference values.

9 Guidelines from other international organisations

There are a wide range of guidelines available from international organisations. The values vary considerably which shows that obtaining clarity from the toxicology literature for these chemicals is extremely difficult. **Attachment A** provides a summary of evaluations provided by IARC, USEPA and Europe. These evaluations do not demonstrate consensus in relation to the mechanism of action, relevant studies or the critical endpoints that are relevant for establishing such guidelines.

10 Impacts of changing the toxicity reference value on other Australian guidelines

10.1 Summary

It is anticipated that, should the proposed toxicity reference values be finalised as part of the review of the drinking water guideline, these toxicity reference values would then need to be used to update the following Australian guidelines:

- Recreational water quality guidelines (provided by NHMRC).
- Soil quality guidelines (provided by ASC NEPM and PFAS NEMP).
- Food quality guidelines (trigger points provided by FSANZ – particularly those for fish and meat).
- Biosolids guidelines (provided as draft values in version 3 of the PFAS NEMP).
- Landfill guidelines (provided in the PFAS NEMP).

The toxicity reference value for PFOS proposed by NHMRC is 20 times lower than the current toxicity reference value used to develop these guidelines. For PFOS, updating these guidelines would result in a 20 fold decrease due simply to the change in toxicity reference value as well as additional decreases depending on the choice made in regard to existing background exposure to PFOS.

Such a change will result in completely unworkable guidelines for soil in a residential setting as well as for various types of food.

The guidelines will be unworkable as no commercial laboratory will be able to provide appropriate limits of reporting (noting that a limit of reporting at a guideline value is not useful as it can be hard to accurately measure chemical concentrations around the value of the limit of reporting).

Should they try and update their methods to provide lower limits of reporting, the issue of background contamination in the laboratories and the equipment and consumables they use in the analysis will become problematic. This will have serious and wide-ranging implications as outlined below.

10.2 Recreational water guidelines

Adopting the proposed toxicity reference value for drinking water should trigger an update to the recreational water quality guidelines, given that NHMRC are the body responsible for these guidelines as well as the drinking water guidelines.

Currently, the recreational water quality guideline for PFOS+PFHxS is 2 µg/L and for PFOA is 10 µg/L (NHMRC 2019). Using the new reference doses/tolerable daily intakes and the same approach as used in the current guidelines, the following equation is relevant:

$$\text{Recreational water guideline} = \frac{\text{Reference dose x Days per year x Body weight x Source allocation}}{\text{Ingestion rate per year}}$$

Where:

Reference dose = relevant value from updated NHMRC fact sheet (ng/kg bw/day)
Days per year = 365 days per year (used to convert ingestion rate per day to per year)
Body weight = 70 kg (standard assumption used by NHMRC)
Source allocation = 10% (i.e. 0.1) (fraction of tolerable daily intake that can come from this exposure pathway) (standard assumption used by NHMRC)
Ingestion rate = 30 L per year (standard assumption used by NHMRC)

Table 2 shows the existing and proposed recreational water guidelines for PFAS.

Table 2: Updated recreational water guidelines

Chemical	Current (µg/L)	Updated (µg/L)
PFOS	2	0.085 (i.e. 85 ng/L)
PFHxS		0.85 (i.e. 850 ng/L)
PFOA	10	5.5 (i.e. 5,500 ng/L)

Applying a recreational water guideline of 0.085 µg/L for PFOS will have significant implications for the acceptability of recreational use at some locations.

For example, enRiskS is aware that concentrations of PFOS in marine water in Port Phillip Bay (off the southeastern suburbs of Melbourne, Victoria) are in the range 0.086 to 0.37 µg/L. Many Victorians use Port Phillip Bay for recreational activities, including swimming, every day of the year (and often despite pollution warnings from EPA Victoria on days following heavy rainfall). A revised recreational water quality guideline of 0.085 µg/L for PFOS would communicate to Victorians that it is unsafe to swim in their major marine waterway.

10.3 Soil guidelines

Adopting the proposed toxicity reference value for drinking water should also trigger an update to the soil quality guidelines in the PFAS NEMP (HEPA 2020). These guidelines are protective of human health and use the approach from the ASC NEPM (National Environment Protection (Assessment of Site Contamination) Measure (NEPC 1999 amended 2013a, 1999 amended 2013b). i.e. are generally consistent with the HILs published in the ASC NEPM.

Currently, the HILs for soil for low-density residential land use are 10 µg/kg for PFOS+PFHxS and 100 µg/kg for PFOA (0.01 mg/kg and 0.1 mg/kg respectively).

Using the HIL Calculator (supplied as part of the ASC NEPM) as well as the assumptions built into the current soil quality guidelines in the PFAS NEMP and the proposed TDI for PFOS, the health investigation level for low density residential land use would change from 10 µg/kg to 0.5 µg/kg for PFOS (or PFOS+PFHxS) i.e. 0.0005 mg/kg.

Table 3 shows the existing and proposed soil quality guidelines for these chemicals in relation to low density residential land use only.

Table 3: Updated soil quality guidelines for low density residential land use

Chemical	Current (µg/kg)	Updated (µg/kg)
PFOS	10	2
PFHxS		3
PFOA	100	100

The updated value listed here is still based on assuming 20% of the toxicity reference value can come from contact with soil and consumption of home grown backyard produce. If 10% of that toxicity reference value is allocated to drinking water (and another 10% is allocated to recreational water), then there is very little left to allocate to exposure via soil. This aspect (i.e. existing background will need to be carefully considered in preparation of any update to this soil guideline.

If the allocation to the soil at a specific site is changed from 20% to 10% (i.e. background changes from 80% to 90%), then the soil guideline (HIL-A) changes to 1 µg/kg (0.001 mg/kg) for PFOS (or PFOS+PFHxS). The current commercially available limit of reporting for PFOS in soil is 0.2 µg/kg (0.0002 mg/kg). As noted above, a guideline close to or at the commercially available limit of reporting is not useful as it can be hard to be confident whether the chemical of interest is actually present or not.

Analytical methods for PFOS in soil may be able to reach this level using trace approaches and the latest most sophisticated equipment for some sites/media. However, this stringent limit of reporting is not routinely provided and would require additional costs. It is also noted that soil in many locations, particularly in urban areas, already has concentrations of PFOS in soil at or around this level.

This change will have significant cost implications for many contaminated land investigations and management. Costs will be higher due to:

- increased analytical costs to reach these more stringent concentrations (more labour-intensive methods and, potentially, more sophisticated equipment)
- increased sampling/analysis costs to ensure adequate sampling to characterise background levels in soil to show a site is or is not different to the whole region (i.e. more samples)
- increased issues with ensuring cross contamination does not occur
- increased remediation costs if regulators or auditors require clean up to reach HIL-A levels even if the site is not a source site for contamination by these chemicals (i.e. if clean-up of sites that just have background levels is required)
- increased costs associated with the off-site disposal of soil to landfill, as landfill guidelines are also expected to decrease in value.

For many sites, the source of contamination by these chemicals is regional and diffuse that apply equally to all the soil in the vicinity of the site being investigated as well at the site being investigated. A specific site should not be required to clean up such contamination where activities at that site did not introduce these chemicals (i.e. site is not source), especially given that the next rain event will wash these chemicals from one site back onto the specific site if clean up does not occur on all the sites in an area.

In addition, contaminated land regulations may trigger the identification of sites with ambient levels of PFAS as "contaminated". This would be the case in Victoria, and where contamination is identified, the landowner then has a Duty to Manage the identified contamination. Issues such as property blight (decrease in property values) are also relevant.

This will also move resources away from risk issues that may be of more concern, as well as causing stress and anxiety (with recognised adverse health effects) for affected people (of which they are expected to be many). Costs for major projects would also be expected to increase and more soil would need to be sent to landfill (noting that Australia is currently working towards diverting soil from landfill).

The following specific examples from Victoria are provided:

- In Victoria, fill material is classified as soil with concentrations of PFOS of 2 µg/kg. (https://www.epa.vic.gov.au/about-epa/publications/1828-3-waste-disposal-categories). Fill material (i.e. compliant with this value) can be used without restriction in Victoria. However, soil classified as fill material would not meet the revised HIL-A value.
- The revised HIL-A value would be more stringent (i.e. lower) than the ambient concentrations reported by EPA Victoria in Publication 2049 (https://www.epa.vic.gov.au/about-epa/publications/2049-report-on-pfas-in-the-environment). A snapshot of Table 3 from this publication is provided as **Figure 2** (i.e. ambient concentrations across Victoria already exceed the revised HIL-A value).

EPA has conducted two ambient sampling campaigns to date (see further details in publications: Sardiña et al. 2019; EPA publication 1879: Emerging contaminants assessment 2019–20: Summary of results). As a summary of our findings, here we present ambient concentrations and detection frequency for the three main PFAS compounds in riparian soil, freshwater and sediments in Victoria based on land-use class (Table 3).

Table 3. Ambient concentrations and detection frequency for PFOS, PFHxS, and PFOA in riparian soil*, freshwaters and sediments in Victoria according to land-use classes

		PFOS			PFHxS			PFOA		
Matrix and Tier 2 land-use classes	n	Range		Detected (%)	Range		Detected (%)	Range		Detected (%)
RIPARIAN SOIL		mg/kg			mg/kg			mg/kg		
Remote-ambient	5	<0.002	<0.002	0	<0.001	<0.001	0	<0.001	<0.001	0
Agricultural-ambient	16	<0.002	0.003	12	<0.001	<0.001	0	<0.001	<0.001	0
Urban-ambient	42	<0.002	0.029	23	<0.001	0.001	1	<0.001	<0.001	0
Mixed-ambient	24	<0.002	0.016	21	<0.001	<0.001	0	<0.001	<0.001	0
FRESHWATER		µg/L			µg/L			µg/L		
Remote-ambient	5	<0.0002	0.0002	20	<0.0002	<0.0002	0	<0.0005	<0.0005	0
Agricultural-ambient	16	<0.0002	0.009	75	<0.0002	0.004	69	<0.0005	0.023	62
Urban-ambient	42	0.0007	0.081	100	0.0005	0.044	100	0.0005	0.036	100
Mixed-ambient	24	<0.0002	0.048	87	<0.0002	0.037	83	<0.0005	0.006	71
SEDIMENT		mg/kg			mg/kg			mg/kg		
Remote-ambient	5	<0.002	<0.002	0	<0.001	<0.001	0	<0.001	<0.001	0
Agricultural-ambient	16	<0.002	0.005	19	<0.001	<0.001	0	<0.001	0.001	6
Urban-ambient	41	<0.002	0.039	27	<0.001	0.001	2	<0.001	<0.001	0
Mixed-ambient	24	<0.002	0.005	21	<0.001	0.001	4	<0.001	<0.001	0

*Note: Soil samples were collected adjacent to freshwater sampling locations (Sardina et al 2019) and are therefore called 'riparian soils'. Riparian soil land-use was based on the land-use classification of the freshwater location.

Figure 2: Ambient soil, freshwater and sediment concentrations of PFAS in Victoria

- PFOS was reported in many soil samples collected from the project areas for 2 major Victorian infrastructure projects in which enRiskS has been involved. One of these projects was in north-east Melbourne and PFOS concentrations of up to 60 µg/kg were detected in soil. The other project was in south-east Melbourne and PFOS concentrations of up to 38 µg/kg were reported in soil. No major sources of PFAS were reported in these project areas i.e. these levels have arisen from diffuse sources. These values are well in excess of the revised HIL-A guidelines discussed above.
- Soil and sediment along the Bremer River and Warrill Creek floodplains in Queensland, or in parks where surface water was used for irrigation, reported detectable PFOS+PFHxS concentrations in the range 4 to 590 µg/kg. This included on private property and in public parks. While some of these concentrations are obviously associated with RAAF Base Amberley, these data illustrate the extent of the issue with identifying very low concentrations of PFOS as contamination that may have potential for risks to human health.

10.4 Food guidelines

FSANZ has provided trigger points for PFOS+PFHxS and PFOA for the main food groupings to assist contaminated land investigations. These values use the existing toxicity reference values and assume 100% of the toxicity reference value comes from each of the food types (i.e. 100% of the toxicity reference value comes from eating fish with 5.2 µg/kg PFOS+PFHxS where a child who weighs 19 kg eats 73 g per day of such fish every day of the year and 100% of the toxicity reference value also is taken in by a child who weighs 19 kg eating 108 g of meat containing 3.5 µg/kg PFOS+PFHxS every day of the year).

Both the existing trigger points and the updated values using the proposed NHMRC toxicity reference values are as listed in **Table 4**.

Table 4: FSANZ trigger points (FSANZ 2017b) and calculated updated trigger points

Criteria Type	PFOS+PFHxS (µg/kg)			PFOA (µg/kg)	
	Current	Updated – PFOS	Updated – PFHxS	Current	Updated
Finfish	5.2	0.3	2.6	41	2
Fish liver	280	3.7	38	2,240	112
Crustaceans/Molluscs	65	3.1	32	520	26
Meat	3.5	0.2	1.8	28	1.4
Milk	0.4	0.02	0.2	2.8	0.1
Honey	33	1.6	16	264	13
Offal	96	1.3	13	765	38
Eggs	11	0.5	5.3	85	4.3
Fruit	0.6	0.03	0.3	5.1	0.3
Vegetables	1.1	0.05	0.5	8.8	0.4

Many of these updated values are well below available limits of reporting from the most reputable commercial laboratories in Australia. The National Measurement Institute offers a limit of reporting of around 0.3 µg/kg while other laboratories offer a limit of reporting for food samples of around 1 µg/kg.

It would, therefore, not actually be possible to measure PFOS to demonstrate compliance with the trigger points for vegetables, fruit and milk.

The trigger points for PFOS in fish, meat and eggs are essentially the same as the best limits of reporting currently available in Australia (i.e. at NMI). While it might be possible to target these concentrations, it is very difficult to get robust, reliable results at the limit of reporting especially at such low limits of reporting (refer to **Section 10.5** for further details).

We recall well the disaster for the NSW fishing commercial communities that was widely published in the media in 2016 when PFOS contamination around RAAF Williamtown site was identified[1]. Commercial fishing activities were impacted based on the current toxicity reference value for PFOS in Australia. If the draft toxicity reference value proposed by NHMRC is adopted, we would expect similar adverse impacts in many more locations.

Recreational fishing advisories for PFOS are already in place in many waterways in Australia, and much data are available from PFAS investigations at nearby source sites. This includes data for ambient concentrations of PFOS in fish (i.e. upstream of the source sites). These data indicate ambient PFOS concentrations in fish as follows:

- samples collected from 6 km upstream of HMAS Cairns (location BIO04; the upstream reference site) reported detectable concentrations of PFOS in edible fish were in the range 0.3 to 3.5 µg/kg[2]
- samples collected from the upstream reference site in the Bremer River for RAAF Base Amberley PFAS investigation (in Queensland), reported concentrations in edible fish (catfish) were around 18 µg/kg (PFOS concentrations in surface water at this location were reported at 0.24 µg/L (i.e. 240 ng/L). The source of these concentrations in this reference locations was not likely to be RAAF Base Amberley)[3]
- samples collected from the upstream reference site in Warrill Creek for RAAF Base Amberley PFAS investigation reported detectable concentrations in edible fish of 0.6 to 3.5 µg/kg.

Except for catfish from the Bremer River, the above concentrations of PFOS reported in edible fish at upstream reference locations are below the current trigger point of 5.2 µg/kg but well above a potential updated trigger value of 0.3 µg/kg (PFOS was also not detected in some samples). The reported concentrations of PFOS in catfish in the Bremer River illustrate the complexity of undertaking human health risk assessments when they are many sources of PFAS to the environment. These assessments will become more complex again where trigger levels for foodstuffs are reduced.

Studies of ambient PFOS concentrations in fish in areas unrelated to contaminated land investigations have also been undertaken by some state regulators, particularly in Queensland (Baddiley et al. 2020). The Queensland study found that PFOS concentrations in fish in the Caboolture River were in the range 2 to 39 µg/kg and in fish in the Brisbane River concentrations of PFOS were in the range 0.3 to 120 µg/kg.

If the PFOS toxicity reference value as proposed by NHMRC were to be adopted, recreational fishing advisories would also need to be expanded. The map below[4] shows the current fishing

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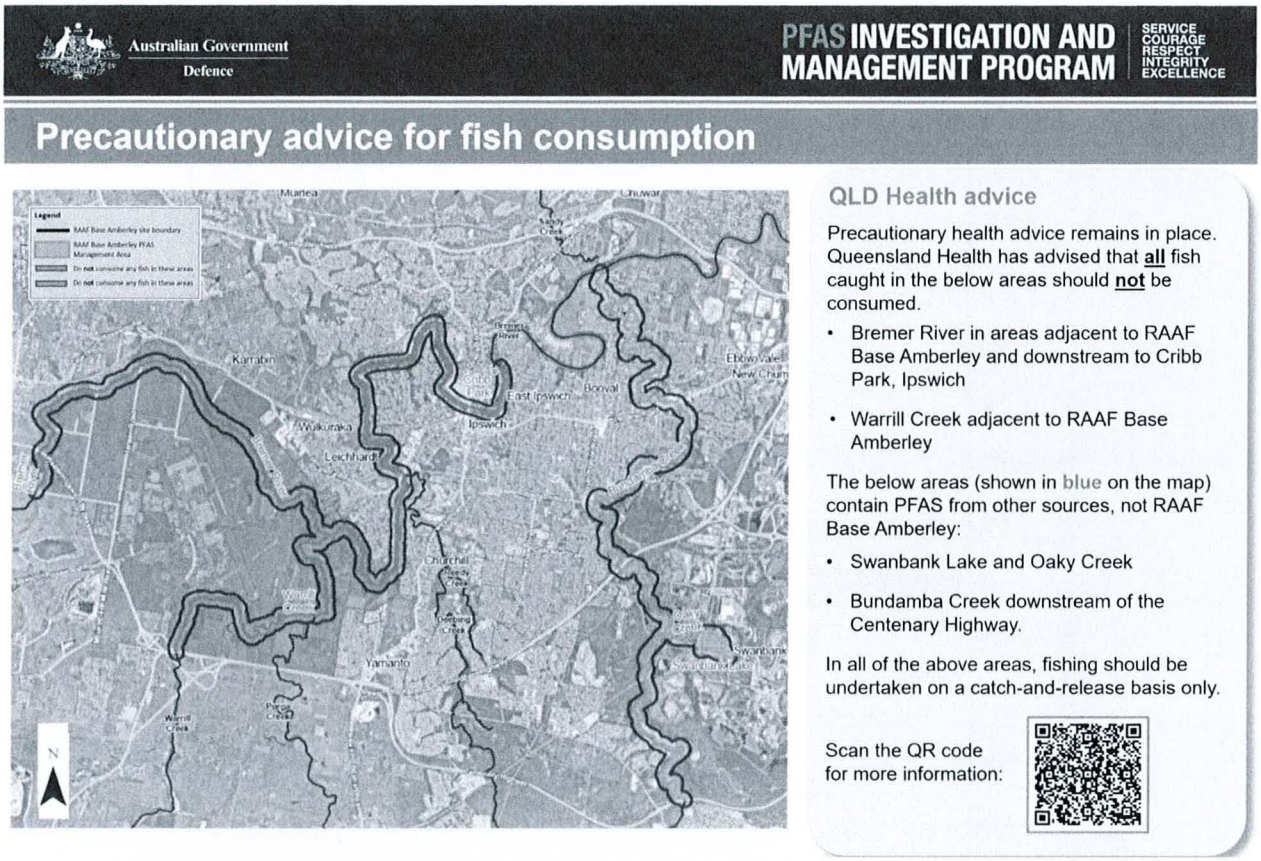
[1] https://www.abc.net.au/news/2016-08-31/flow-on-effect-of-williamtown-contamination-fishing-ban/7798196
[2] https://www.defence.gov.au/about/locations-property/pfas/pfas-management-sites/hmas-cairns
[3] https://www.defence.gov.au/about/locations-property/pfas/pfas-management-sites/raaf-base-amberley
[4] https://www.defence.gov.au/sites/default/files/2024-08/RAAFBaseAmberleyCommunityConsultationSessionPostersAugust2024.pdf

advisories in place downstream of RAAF Base Amberley and emphasises the complexity of such advisories when multiple sources of PFAS are present.



In relation to beef, some data have been collected in studies in Victoria but there is a lack of data on PFOS in livestock in other states and territories. Such studies are often perceived as having potential to raise international trade concerns. This adds complexities to, and creates uncertainty in, human health and ecological risk assessments for PFAS in livestock products as modelling uptake of these chemicals is used instead of measured values. However, this also emphasises the sensitivity of this issue. As noted above, the updated trigger levels for beef presented in **Table 4** are at the lowest commercially available limits of reporting. Setting a drinking water guideline that is overly health protective and creates issues for Australia's recreational and commercial food supply is not considered appropriate.

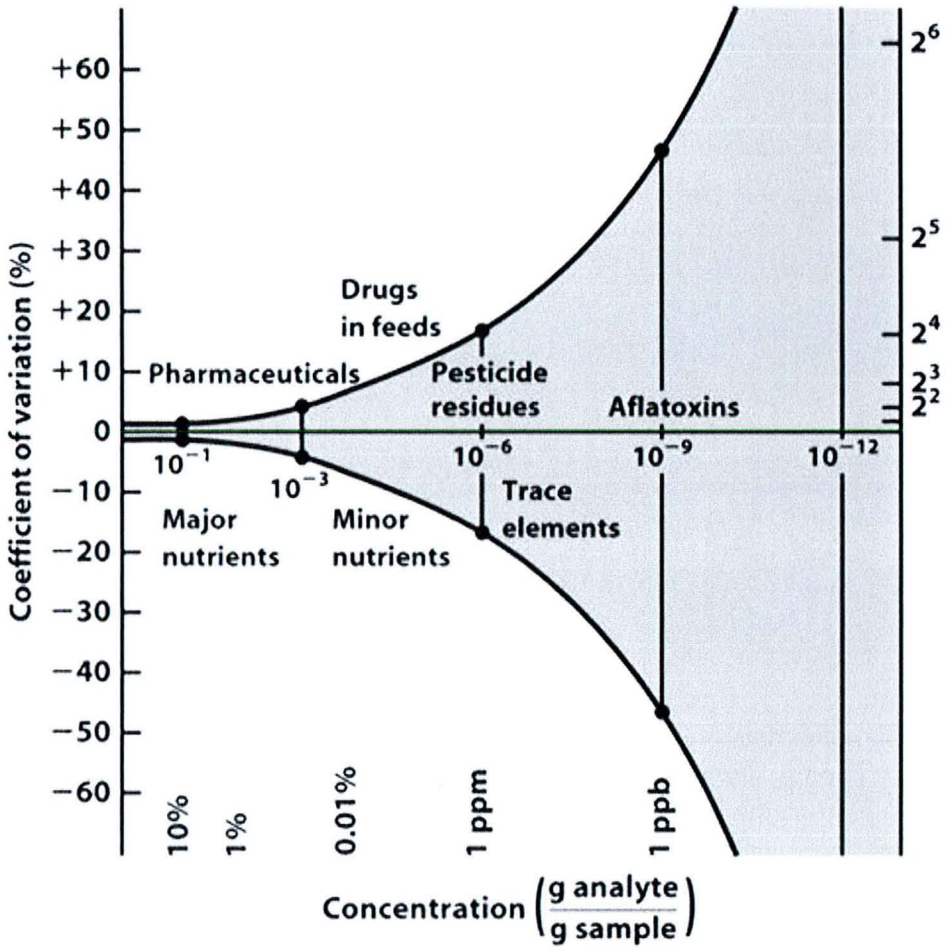
10.5 Sampling issues and cross contamination

There are a range of other issues that become apparent when updated guidelines at or below existing ambient PFAS concentrations and/or at or below limits of reporting currently offered by Australian laboratories are considered (as would be the case if the existing guidelines are updated with the toxicity reference value for PFOS proposed by the NHMRC).

Such issues include:

- Guidelines close to (or less than) the commercially achievable laboratory limits of reporting create issues in regard to the ability to demonstrate compliance.

- It is a well known characteristic of analytical methods that uncertainty/ measurement error increases as the concentration of a chemical in the sample of interest approaches the limit of reporting and as the limit of reporting gets smaller. This was identified by a US Food and Drug Authority statistician/analyst in 1980 – W. Horwitz. A figure to illustrate the concept is called the Horwitz Trumpet as shown in figure below.



It can be seen in this figure that, at concentrations around 1 ppb (i.e. 1 mg/kg), the coefficient of variation is around 50%. At concentrations around 1 ppt (i.e. µg/kg), the coefficient of variation is well in excess of 60%. This means the actual concentration in a sample could be ±100% of the reported value. This makes it very difficult to reliably monitor and demonstrate compliance with such strict guideline values.

- In addition to the potential size of measurement error, it is also important that guidelines are sufficiently above a relevant limit of reporting so that it can be demonstrated that a sample is in compliance with a guideline value or not. Often it is mentioned that a limit of reporting around 10 times lower than the relevant guideline value.
- Pushing limits of reporting lower and lower also drives up costs of analysis as the effort to achieve lower limits of reporting increases significantly.

- Laboratories are already having issues with background concentrations of PFAS in the laboratory building and equipment and consumables used in PFAS analysis such as solvents. These background levels are impacting on their ability to achieve current best practice LORs.
- When attempting to drive limits of reporting lower, the potential for matrix effects in some environmental samples (e.g. water with sediment, tannins or high concentrations of non-PFAS chemicals) and in foodstuffs is significant. There are already matrix effects in some samples that limit the limits of reporting that can be applied. This will get worse when attempting to achieve even lower limits of reporting.
- Collecting samples that are appropriate to achieve extremely stringent limits of reporting is also problematic. Australia already has extensive guidance on equipment, materials and foodstuffs that should not be used or present in the field during sampling for PFAS. This is to limit the potential for cross contamination of samples. For example, the guidance suggests that staff undertaking sampling must only wear clothing made of natural fibres that has been washed multiple times prior to going into the field to collect samples for PFAS analysis. There are a range of other quite extreme requirements. It is not clear how much further we can practically go in relation to minimising sources of PFAS in our everyday items that may cross contaminate samples. The lower the guidelines and the limits of reporting, the more important minimising cross contamination becomes and the more difficult it becomes to eliminate/control. For example, will it be expected that field staff will not use sunscreen as this may contain PFAS which may contaminate samples? How does this fit in with broader occupational health and safety protocols in relation to protection from the sun – a risk with a much more robust evidence base.

Setting a drinking water guideline that is overly health protective, and creates other practical issues is not considered appropriate.

10.6 Issues for our circular economy

PFAS risk issues, or perceived PFAS risk issues, are already impacting on Australia's ability to move towards a circular economy, particularly in relation to the use of compost, FOGO and biosolids. This is particularly the case in Queensland, where regulators have long held the view that "any PFAS is bad PFAS" and the only PFAS concentration allowable in the environment is "zero" (which, as an aside, is not scientifically valid).

Should the toxicity reference values proposed by NHMRC in the draft drinking water guidelines be finalised as is and then used to derive guideline values for materials such as compost, FOGO and biosolids, this would bring the rest of Australia in line with the approach adopted by Queensland to date[5]. **This would effectively end any potential for beneficial reuse of these products and would require all of these materials to be disposed to landfill instead.**

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5 https://wmrr.asn.au/common/Uploaded%20files/Submissions/QLD/2023/Qld%20PFAS%20Organics%20Joint%20Letter%2030102023.pdf

The key risk issues in relation to the beneficial reuse of these materials is the estimated uptake of these chemicals into foodstuffs following the use of these materials in an agricultural setting or when growing home-grown produce (refer to **Section 2.6.4** for updated trigger points for foodstuffs).

The reuse of other recycled materials such as recycled aggregates would also become problematic e.g. the revised HIL-A value would be at the current PFAS guidelines for fill material in Victoria (refer to **Section 2.6.3**).

Disposal of these materials to landfill not only removes all benefits to society but is in opposition to Australia's agreed policy to divert 80% of waste from landfill by 2030.[6]

Setting a drinking water guideline that is overly health protective and significantly impacts on Australia's plan for a circular economy is not considered appropriate.

11 Community anxiety and stress

enRiskS has been involved in many community activities relating to PFAS risk issues as well as risk issues associated with other chemicals (talking to the communities about risks from chemicals in the environment is a core part of our business). This has included meetings with individual landowners e.g. with properties around Department of Defence sites, meetings with small groups of people to discuss proposed waste to energy facilities and attendance at larger walk in sessions associated with PFAS risk issues for major infrastructure projects.

During these activities, we have observed firsthand the high levels of stress and anxiety that PFAS risk issues can create. We have encountered people that were in tears, people that were angry/aggressive (yelling) and people that were sincerely afraid for their own health or the health of their children. In most cases, the relevant PFOS concentrations were those we would consider to be ambient concentrations in Australia and concentrations that are unlikely to be sufficient to cause health effects.

Parts of the media have targeted stories (and series of stories) on the "forever" nature of these chemicals and the potential for health effects of these chemicals without explaining the science correctly or in detail. This has increased the levels of stress and anxiety in people who may be living in areas where investigations are occurring, or even in areas where PFAs is detected in drinking water supplies. Stress and anxiety are known to cause health effects, so these media stories are actually generating health effects, but those effects are completely unrelated to the presence (or not) of PFAS. Journalists need to take their responsibilities seriously – including checking out all sides of a story especially when they do not have sufficient training or qualifications to properly evaluate what they are being told by the experts they speak too.

As noted, chronic or extreme stress and anxiety can result in adverse health effects that are independent of chemical concentrations[7]. Hence, it is critical that we clearly communicate the following to the community:

- what we know about the toxicity of PFAS to humans (and what we don't know)

[6] https://wastemanagementreview.com.au/australia-faces-a-residual-waste-dilemma/
[7] https://www.healthdirect.gov.au/stress

- that we have methods documented in national guidance from government authorities that allow assessment of risks to human health from chemicals based on the state of knowledge
- that we have all been exposed to ambient PFAS concentrations in our environment, as well as through our use of consumer products, for many years
- that the presence of a chemical in the environment does not mean the chemical will cause an unacceptable health risk – *dose makes the poison*
- that we take a precautionary approach to the management of chemicals in Australia
- that we need to balance this precautionary approach to ensure we are health protective, without being misleading and adding adverse health impacts to society.

It is also important to note that our experience is that the generally public can understand the basic principles of toxicology and risk assessment if adequate explanation is provided in the right language and at the right level. This can take time but, if successful, allows the community to understand the issues and form their own view on potential risks. This in turn removes the negative impacts that are commonly associated with involuntary risks, and often has a calming and empowering effect.

Where we have experienced examples of community anger and stress, it has generally been because of one or more of the following:

- lack of any community engagement and consultation, or rushed/inadequate engagement and consultation
- lack of adequate guidance, or conflicting guidance, from regulators
- inflammatory media reporting on PFAS risk issues
- inappropriate actions from individuals or companies that were politically and/or financially motivated (e.g. inflating PFAS risk issues to create community concern by one tenderer for a major project).

Setting a drinking water guideline that is overly health protective from a chemical toxicity perspective but actually results in adverse health effects from stress and anxiety is not considered appropriate.

We consider that NHMRC, as the Australian government's leading expert on health, has a critical role to play in assisting the Australian community to understand PFAS risk issues (and risks from other chemicals), and to not over inflate PFAS risk issues.

We also consider it is critical that NHMRC emphasise that our environment is made of chemicals, and PFAS risk issues require consideration and management similar to many other chemicals in our environment. One way that NHMRC can do this is to ensure that the drinking water guideline factsheets for PFAS are a similar length to the factsheets for all other chemicals. A chemical with a factsheet of many pages is automatically seen to be more important than a chemical with a factsheet of 2-3 pages.

12 Closure

Thank you for the opportunity to provide comment on the draft NHMRC guidelines. We would be happy to discuss any aspect of this submission in further detail, if required.

Yours sincerely,

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Attachment A: International guidelines

A1 IARC classifications

In December 2023, IARC published a short news article in The Lancet Oncology about their updated classification for PFOA and their new classification for PFOS (Zahm et al. 2024). The article is 2 pages long and provides only a very short description of the work to assess the potential for these chemicals to cause cancer. The team that looked at these chemicals included 30 scientists from 11 countries including Professor Jack Ng from the Queensland Alliance for Environmental Health Sciences.

Information about the documentation

The full assessment for these 2 chemicals is to be published in Monograph Volume 135, however, even though it is almost a year later, this volume has not yet been published.

The short summary of the assessment of chemicals included in Volume 134 was published in The Lancet Oncology in July 2023. It is not clear at what time the full assessment was published on the website (i.e. Volume 134) but, looking at the following webpage (https://www.iarc.who.int/featured-news/aspartame-hazard-and-risk-assessment-results-released), it is possible it was quite quickly after publication of the short summary. The short summary of the assessment of chemicals included in Volume 133 was published in The Lancet Oncology in March 2023. It is not clear at what time the full assessment was published on the website (i.e. Volume 133) but the volume is available on the site and is dated 2024. Both Volume 133 and 134 have been available for most of 2024 (based on personal experience).

Hence, there appears to be a delay in the release of Monograph Volume 135 (almost a year has passed after initial publication of the short summary). There is no information on the IARC website about whether there is a delay in the release of the full assessment, and if so, the reasons.

Mechanistic information

One thing that is clear in this short summary from IARC and in the information provided by the USEPA is that both PFOS and PFOA are not genotoxic carcinogens which is a critical point when considering the potential carcinogenic effects for these chemicals.

In 2016, IARC published guidance about the key characteristics that chemicals have if they are likely to be carcinogens (Smith et al. 2016). These characteristics are:

- is electrophilic/or metabolically activated
- is genotoxic
- alters DNA repair or causes genomic instability
- induces epigenetic alterations
- induces oxidative stress
- induces chronic inflammation
- is immunosuppressive
- modulates receptor-mediated effects
- alters cell proliferation, cell death or nutrient supply
- cause immortalisation.

While this appears to be a helpful approach to ensuring that chemicals that could cause cancer are appropriately classified, there is much discussion in the literature about the difficulties in applying this approach without consideration of the potency of a chemical to cause some of these changes. Potency is not normally considered by IARC.

Where chemicals are genotoxic, there is confidence that they should be treated as carcinogens. However, for some of the other characteristics, there are good examples of chemicals that have some of these characteristics but do not cause cancer and examples of chemicals that do not have any of these characteristics but have been found to cause cancer.

Regardless, IARC has indicated in the summary article that the strong evidence for these chemicals is from the mechanistic information which is their terminology as to whether a chemical has any of the key characteristics listed above.

The characteristics which both PFOS and PFOA appear to have are:

- they can cause oxidative stress
- they are immunosuppressive
- they may induce epigenetic alterations.

The discussion in the short article, however, does not provide any information on the potency of these chemicals to cause these issues. Consideration of potency and exposure is not commonly included in IARC assessments as the approach is a hazard assessment – i.e. the assessment looks at whether there is evidence (at any dose/concentration) that these chemicals could cause cancer.

This is an important point to note because sometimes the evidence for cancer used in IARC assessments requires exposure at concentrations/doses that would never occur for people because of the way a chemical is used. Consideration of the risk that cancer could occur should include an evaluation of the likely exposure concentrations/doses.

Until Monograph Volume 135 is available in full, it is not possible to appropriately consider the strength of the evidence in regard to the risk of cancer for PFOS and PFOA.

A2 USEPA drinking water guidelines

The final USEPA drinking water guidelines (USEPA 2024a, 2024b, 2024c) for PFOS and PFOA are based on IARC's classification of these chemicals as carcinogens (Zahm et al. 2024). They are based on a policy approach to guideline setting for genotoxic carcinogens rather than using a specific calculation based on toxicology data to be health protective.

None of the mechanistic information on which the IARC classifications are based indicate these chemicals are genotoxic. These chemicals would be considered threshold carcinogens under USEPA guidance.

For chemicals that are genotoxic, it is normal practice in the USA to set a maximum contaminant limit goal (MCLG) of zero and a maximum contaminant limit (MCL) at the limit of reporting considered to be sensitive but routinely achievable. This is because it is assumed genotoxic carcinogens may have impacts on DNA even at very low concentrations (i.e. it is assumed there is no threshold), whereas chemicals that act via a threshold do not have adverse effects if exposure remains below the threshold.

The US does not normally use the same approach for determining the MCLG and MCL for threshold carcinogens. Hence, it appears the US has not followed their own normal approach when setting these drinking water guidelines for PFOS and PFOA.

This is in contrast to the approach adopted by the USEPA in 2022 when they released draft drinking water guidelines for these 2 chemicals (USEPA 2022a, 2022b). These draft guidelines were based on threshold effects – primarily ones related to immune system effects. The assessments

recommended drinking water guidelines of 0.02 ng/L for PFOS and 0.004 ng/L for PFOA. These values are 200 and 1,000 fold lower/more stringent than the values published as finals by USEPA.

The reference doses/tolerable daily intakes used to calculate the 2022 draft drinking water guidelines from 2022 were:

- 0.0079 ng/kg bw/day for PFOS (compared to 0.98 ng/kg bw/day for PFOS in the proposed NHMRC guidelines)
- 0.0015 ng/kg bw/day for PFOA (compared to 65 ng/kg bw/day for PFOA in the proposed NHMRC guidelines).

These values were not adopted as the basis of the actual promulgated drinking water guidelines for the US. The USEPA acknowledged a range of practical issues that made adoption of these draft values highly problematic. Such issues included that there were no analytical methods that could achieve measurements at these levels, background levels were already well in excess of these values and effects that would be expected based on this understanding of the nature of these chemicals were not seen in the population at large. A wide range of other issues were raised in comments on the draft determination.

As described above, the policy choice based on carcinogen classification was then determined to be the most appropriate approach to adopt.

Potential issues related to the practicalities of analysis have been noted in some discussions in the literature. Previous rounds of monitoring in drinking water in the US used limits of reporting of 20-40 ng/L for these chemicals but the most recent round of relevant monitoring did use the 4 ng/L limit of reporting. The data from this most recent round of monitoring were not available in April 2024 when USEPA published the MCLs for PFOS and PFOA, so it is not clear how many laboratories were able to achieve this limit of reporting. It is noted that laboratory equipment manufacturers are indicating that routine achievement of a limit of reporting of 4 ng/L may need updated expensive equipment.

A3 European guidelines

A3.1 General

There are 2 areas where European agencies have determined guidelines for PFAS relevant to human health:

- European Council, DIRECTIVE (EU) 2020/2184 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2020 on the quality of water intended for human consumption (EC 2020).
- EFSA has determined a tolerable weekly intake for use in evaluating the presence of PFAS in food (EFSA Panel on Contaminants in the Food Chain et al. 2020).

The most relevant one for this submission is the drinking water guideline – i.e. EC (2020).

A3.2 Drinking water

Drinking water guidelines that apply across the EU for PFAS are:

- PFAS total = 0.5 µg/L (it is still to be determined what PFAS should be summed for this parameter, so it is not in use at this time).

- Sum of PFAS = 0.1 µg/L (this value applies to the sum of PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, PFBS, PFPeS, PFHxS, PFHpS, PFOS, PFNS, PFDS, PFUnDS, PFDoDS, PFTrDS).

The second guideline is 100 ng/L.

A detailed description of how this value was calculated has not been found but it appears that the recommendations from WHO have been adopted.

Using the same approach as NHMRC, a toxicity reference value can be calculated.

The relevant equation from NHMRC is:

$$\text{drinking water guideline} = \frac{\text{tolerable daily intake x body weight x source allocation}}{\text{ingestion rate}}$$

Which can be rearranged as follows:

$$\text{tolerable daily intake} = \frac{\text{ingestion rate x drinking water guideline}}{\text{body weight x source allocation}}$$

$$\text{tolerable daily intake} = \frac{\text{2 litres per day x 100 ng/L}}{\text{70 kg x 0.1}}$$

$$\text{tolerable daily intake} = 29 \text{ ng/kg bw/day}$$

This value is 30 times higher than the NHMRC proposed value for PFOS of 0.98 ng/kg bw/day.

It is applied to the full set of PFAS as listed (i.e. PFBA, PFPeA, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA, PFBS, PFPeS, PFHxS, PFHpS, PFOS, PFNS, PFDS, PFUnDS, PFDoDS, PFTrDS). If the main (or only) PFAS reported in a drinking water source is PFOS, this value is still designed to be protective of human health.

A3.3 Food

EFSA undertook a separate evaluation of the toxicity of these chemicals and derived a different tolerable daily intake for use in assessing exposure via food. They also derived a value to be applied to the sum of several PFAS. The EFSA value is to be used to assess these chemicals in food based on the sum of PFOS, PFOA, PFHxS and PFNA.

EFSA has recommended a toxicity reference value based on weekly exposures of 4.4 ng/kg bw/week be applied to the sum of PFOS, PFOA, PFHxS and PFNA. This equates to a toxicity reference value based on daily exposures of 0.6 ng/kg bw/day. This value is based on data for immune systems effects which have been questioned as to their clinical relevance.