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NMHRC CEO and the Water Quality Advisory Committee
National Health and Medical Research Council
GPO Box 1421
CANBERRA ACT 2601

RE: Submission on the NHMRC Review of PFAS in Australian Drinking Water

The Australian Sustainable Business Group (ASBG) welcomes the opportunity to comment on The NHMRC Review of PFAS in Australian Drinking Water (the Review).

The Australian Sustainable Business Group (ASBG) is a leading environment and energy business representative body that specializes in providing the latest information, including changes to environmental legislation, regulations and policy that may impact industry, business and other organisations. We operate in NSW and Queensland and have over 100 members comprising of Australia's largest manufacturing and infrastructure companies and other related businesses.

1 Overview

In general, ASBG welcomes the review of PFAS[1] for Australian drinking water guidelines, and fully supports a robust scientific approach that reflects Australia's risks. ASBG believes that NHMRC has put forward a proposed framework that begins to address a number of stakeholder concerns. The proposal serves as a good starting point for setting Health Based Guideline values (HBGV) for PFAS compounds in drinking water.

However, ASBG is concerned that even slight non-scientific based assessment, especially in terms of risk assessment, interpretation of results, international influences and use of safety factors has resulted in some PFAS limits being lower that is necessary. The NHMRC needs to also consider that setting of too tight limits can result in significant costs to the general public, due to removal and management systems required. Also to improve public understanding of the levels set and their safety margins should be put into context, directly and with comparison to other known substances posing health risks —e.g. heavy metals, pathogens, toxins etc. This would assist in placing PFAS into a comparable metric with other controlled substances, helping the public better understand the health risk PFASs pose.

The following issues are identified including:

- Issues with how the proposed limits were reached
- Acceptance of how the new limits will be adopted by Government agencies and others

[1] The term PFAS is broadly used, but varies considerably in its catchment. In this submission it refers to PFOA, PFOS, PFHxS and GenX only.

- Dealing with public perception and placing PFAS risk in context

ASBG is concerned over the public consultation process timeframe, as provided, is limited given the complexity of the science and especially its interpretation.

2 Issues with the Derivation of Proposed Limits

This section discusses issues ASBG has with the methodology used in setting PFAS limits, especially PFOS guideline values.

2.1 Safety Factors

In the Review the Health Based Guideline Values (HBGV) were derived using the following equation:

$$\text{HBGV} = \frac{\text{Benchmark Dose Level (ng/kg bw/day x 70 kg x daily proportional intake (0.1)}}{\text{2 L/day x safety factor}}$$

The Review described the details of the above as:

- *300 is the uncertainty factor applied to the human equivalent dose derived from an animal study. The uncertainty factor incorporates a factor of 3 to account for the uncertainty of extrapolating from animals to humans, a factor of 10 to account for human variability and a factor of 10 for use of a short-term study (SLR 2024c).*
- *70 kg is taken as the average weight of an adult.*
- *0.1 is a proportionality factor based on the conservative assumption that drinking water accounts for 10% of the acceptable daily intake.*
- *L/day is the reference value of water consumed by an adult.*

More explanations were provided for each individual PFAS species. All PFASs had safety factors of 300, Except for PFOA, which used a safety factor of 30. Interestingly, the US EPA used a different set, which derived a safety factor of 1,000, but for PFOS came to the same 4 ng/L HBGV result. Overall, the use of safety factors should follow a common agreed method, which provides for a conservative—not overly conservative— HBGVs based on a credible—not absolute— worst case ingestion model for humans. ASBG has a few issues with this approach as it does not consider Australia's circumstances, which is discussed in section 2.3.

There are a number of studies which are critical of the risk assessment processes used for PFASs. A recent paper[2] on EU PFAS levels where it states:

> *Our study shows that the level of health protection embedded in the studied thresholds may differ by three orders of magnitude, even in similar exposure settings… We also indicate that currently, no consensus exists on the appropriate level of required health protection regarding PFAS and that the recently adopted tolerable intake value in the EU is too cautious.*

[2] Inconsistencies in the EU regulatory risk assessment of PFAS call for readjustment, Environment International 186,(2024) 108614, J Reinikainen et al

While the above paper focuses on the EU's methodology, it does expose that considerable variations can result depending on the parameters of the risk assessment used. The paper proposes simple improvements such as taking into account background PFAS concentrations and PFAS in food consumption rates. ASBG notes the NHMRC has also not conducted such work, unlike the work done by Food Standards Australia and New Zealand (FSANZ)[3] (see also section 2.3).

How the Benchmark Dose Levels (BMDL) and safety factors are derived is also subject to scientific and professional debate and scientific controversy, with claims of lack of transparency on how such BMDL are derived. ASBG notes that your reviewer, A Prof. Brian Priestly, provided specific comments regarding the uncertainty factors applied including that they are possibly overly conservative. Clarification here would be welcomed as these processes can be variable. Variations of these rules of thumb, can be used to introduce bias, which given the differences across international health standard setting organisations appears to be present. Overall, ASBG is concerned that for PFASs there is an international race to have the tightest criteria, which is over riding the science.

To be consistent, the next round of assessments of HBGVs, NHMRC should use the same set of safety factor and BMDL assumptions.

2.2 International Comparison of PFAS Limits

Table 1 compares the proposed NRMHC limits with current and international limits.

Table 1: Comparison of PFAS limits on Drinking Water (ng/L)

	NHMRC proposal	NHMRC current	US EPA	WHO	FSANZ (TDI)
PFOA	200	560	4	100	160 ng/kg bw/day
PFOS	4	70	4	100	20 ng/kg bw/day
PFHxS	30	30	10		
PFBS	1000	1000	10		

ASBG supports NHMRC adoption of the World Health Organisations approach to HBGV, which uses a threshold approach. There is much controversy within the scientific profession[4] with the US EPA use of the non-threshold values for genotoxic carcinogens from both the epidemiological and animal studies as a carcinogen for PFOA, hence their 4 ng/L compared to NHMRC's HBGV of 200 ng/L.

Where ASBG has an issue is the NHMRC general adoption of the US EPA's 4 ng/L limit for PFOS. There is concern that a spate of media coverage[5] citing differences between Australia's and the newly issued US EPA PFOS limit influenced the NHMRC to accept the 4 ng/L HBGV. The American Water Works Association has undertaken a detailed scientific critique of the US EPA's methodology[6], especially its risk assessment processes, choice of safety margins, interpretation of results of scientific studies. It recommended, supported with strong scientific argument, that the PFOS and PFOA drinking water limits should be set at

[3] FSANZ Perfluorinated chemicals in food

[4] Non threshold linear controversy, see: The Linear Non-threshold Extrapolation of Dose-Response Curves Is a Challenge for Managing the Risk Associated with Occupational Exposure to Carcinogenic Agents, more generally https://en.wikipedia.org/wiki/Linear_no-threshold_model

[5] One example: https://www.abc.net.au/listen/programs/radionational-breakfast/high-rates-of-forever-chemical-found-in-aussie-tapwater-/103727942

[6] AWWA Comments on the [US EPA] Proposal

10 ng/L, not 4 ng/L. They note such a change would have reduced drinking water PFAS treatment costs by 65%. Following the release of the US EPA's 4ng/L PFOS and PFOA limit they stated:

> *We are concerned, however, that EPA did not use the best available data and appropriate processes in developing the PFAS regulation. For example, we question the use of a novel 'Hazard Index' in place of a Maximum Contaminant Level for mixtures of certain PFAS, and the issuing of a preliminary determination to regulate certain PFAS simultaneously with the proposed rule.*

While the NHMRC methodology for determining the PFOA, PFHxS and PFBS HBGVs differed, the US EPA approach appears generally accepted by NHMRC for PFOS. This is despite both guideline levels reached being scientifically questionable.

2.3 PFAS in Food in Australia

At the Australasian Land and groundwater Association (ALGA) PFAS Summit in March 2024, FSANZ provided a presentation on why no Australian PFAS limits on foods has been made. The main points made by FSANZ, relevant to the NHMRC's PFAS Review, includes:

- FSANZ found that levels of PFAS in the general Australian food supply are very low
- PFOS was the only congener detected of 30 different PFAS for which analysis was conducted
- PFOS was detected in five of 112 food types and in less than 2% of all samples
- The overall dietary exposure to PFOS for the general Australian population is lower than the TDI
- On the dose escalation trial for PFOA: For levels of PFOA more than four orders of magnitude higher than the levels observed in general populations there was no evidence of any major effects
- No need to establish maximum limits for PFAS in the Australia New Zealand Food Standards Code

FSANZ concluded there are far more important food contaminants to focus on such as cadmium, lead, inorganic arsenic and methyl mercury. FSANZ is of the opinion that HBGVs established in 2017 remain health protective. Should further evidence arise this will be considered.

Given the evidence provided by FSANZ, that only PFOS was detected in food samples, 2% of the time, this should provide reasonable Australian background levels for use in the risk assessment process. For PFOS, this means the intake via food, appears far lower than the 90% attributed to it in the HBGV equation provided in section 2.1 above. 2% in food would indicate that 98% of ingested PFOS comes from drinking water. When given a safety factor, in the Australian context the PFAS HBGV would be 5 or more conservatively, 2.5 times higher, 10 ng/L. Even higher HBGVs could be attributed to the other PFASs.

R1 ASBG recommends the NHMRC reconsider their HBGVs for PFAS, especially for PFOS, given the processes used to determine HBGVs, where Australian contextual data from local sources including from FSANZ was not included.

3 Regulatory Uptake and Implications

The issue of PFAS in drinking water has also become a highly emotional issue with the media and general public. Consequently, NHMRC needs to provide clear unbiased scientific advice to all Australians on drinking water guidelines, to provide scientific leadership based on good evidence and repeatable results.

3.1 Regulatory Use

When published, NHMRC's PFAS HBGVs will be used by environmental and health agencies across Australia, often as maximum hard limits to be adhered to by drinking water suppliers. Use of NRMHC PFAS limits will then expand. largely via other Government agencies, to many other areas, based on any potential to impact on raw waters for drinking water sources. The following is a list of areas where the NHMRC PFAS HBGVs will be used as either hard limits or the basis for a similar set of tightening of existing PFAS criteria including:

- **Clean-up criteria for ground water land and soils levels**. PFAS National Environmental Management Plan 3.0 (PFAS NEMP 3.0) limits[7] will likely be impacted by the NHRMC's final PFAS HBGVs. This will result in considerable increase in costs due to the lower limit concentrations that will be set. Currently soils with low PFAS levels are beneficially reused as fill and or for soil conditioning. With lower limits on PFAS set, large volumes would be required to be sent to landfill.
- **Environmental discharge limits into waters**: This would be again impacted by changes to the PFAS NEMP 3.0. Limits could result in much lower PFAS criteria, such as the % species protection required. Often the 99% species protection is used for raw drinking water catchments. This is set very low for PFAS at 0.03 ng/L[8]. For example, further tightening by 17.5 times would push this to 1.7 pg/L. Laboratories would need to gear up to be able to measure PFAS this low.
- **Sewage acceptance levels**. Sewerage operators will likely revise down their sewage acceptance criteria, for example, by 17.5 times on PFOS, or simply do this across all PFAS. Grit from sewage is a solid waste which must go to landfill. However, many sewage system operators accept leachate from landfills.
- **Landfill acceptance levels**: These are usually set by state and territory environmental agencies, which will also be strongly influenced to tighten landfill acceptance limits for PFAS with NHMRC PFAS changes and the expected knock-on PFAS NEMP 3.0 changes setting the lest stringent. This may in turn place contaminated soils, sewage operators grit, and other wastes, above the new acceptance limits, requiring expensive treatments, which are limited and or long haul distances to hazardous waste landfills. Tightening of sewage limits, including leachate to sewer acceptance criteria, will limit the disposal/management choices of sewage grit, creating a Catch 22 loop for sewerage operators.
- **Recycled materials impacts**: There are many which are directly affected:
    - **Biosolids:** Tightening the PFAS limits via PFAS NEMP 3.0 — another sewer treatment operator's waste—by 17.5 times tighter[9] will likely cause this large waste stream to be sent to landfill, rather than be beneficially reused as a soil conditioner. Around 1.6 MT p.a. of biosolids (wet) is generated in Australia, with most beneficially reused, but a large % would

[7] Likely impacting on Health investigation levels, (HILs) Ecological investigation levels (EILs) etc.
[8] Note the limit was 0.0091 ng/L using the CSIRO Burrlsoz model, the 0.03 ng/L uses the Canadian SSDTools. Both use the same data but differ in their statistical assumptions and methods, a similar issue in the setting of HBGVs.
[9] 17.5 is the current 70 ng/L / proposed 4 ng/L for PFOS

be diverted to landfill if they fail new PFAS acceptance limits. Some may not meet new landfill limits requiring further treatment.

- **Organic wastes:** Australia generates about 14.4 million tonnes of organic waste which is made up of food waste, garden organics, timber waste and biosolids. About 8.29 million tonnes (58%) of this component was either recycled or recovered. Currently, Queensland has issued PFOS & PFHxS limit of 2 µg/L and PFOA at 1 2 µg/L. However, regulators are likely to reduce this considerably due to the NHMRC's PFAS HBGVs outcomes. Placing tighter PFAS limits on organic waste would render a significant portion of organic wastes unrecyclable and unusable as a soil conditioner, sending more to landfill. This would significantly undermine Australia's percent recovery of waste to beneficial reuses.
- **Commercial perception**: Some fast food companies are indicating they will refuse to accept recycled paper and cardboard in their packaging for fear of detection of PFAS. As the limits of detection for PFAS would drop by around 20 times to 0.1 ng/L the amount of positive detects for PFAS will increase exponentially. NHMRC must consider the impacts on public perception of risks when publishing limits with safety factors of 300.

Overall, tightening of PFAS limits will impact on wastes at all levels. Of particular concern is the impact on recycling and beneficial reuse of wastes across Australia. Costs of treatment and management of impacted wastes will increase. Tightening's of PFAS limits will result in far more waste being sent to landfill, which is also running out of available space and sites in many areas across Australia.

3.2 Background PFAS Levels need Recognition

PFASs have been used for over 80 years across many countries, including Australia. Consequently, many PFAS have background levels, which must be recognised. If background PFAS levels are unrecognised, the PFAS limit are often set at or close to background levels, even zero levels. Consequently, the regulatory process can become a Catch 22 position resulting in paralysis.

For example, in New Zealand (NZ), background PFAS levels are not recognised, based on the simple position that PFASs are not naturally occurring. A default zero level results based on Limit of Reporting (LOR). Hence, when remediating land or waters the PFAS is concentrated into a smaller volume for later treatment or disposal. However, with a zero level, the cleaned soils or waters must return below detectable limits. Currently, most laboratories in Australia and NZ have most PFAS LORs at around +-10 ng/L. However, setting PFOS to 4 ng/L will require and LOR of at least 1 or 0.1 ng/L or lower. Consequently, the pass mark for soils and water is reduced by at least an order of magnitude in this case. The Catch 22 in NZ is the >LOR limit for PFAS going to landfill. Consequently, a land remediation of PFAS cannot proceed as there is no reasonable disposal solution for the concentrated PFAS and high costs associated with treatments down to >LOR.

All of the above have costs associated with meeting these new criteria, which generally increases in costs inversely exponentially with the limit set. The NHMRC should also include background levels of the main PFASs they are reviewing.

Also important is to ensure that the definition of PFAS is maintained at the set of substances of concern. For example, under the OECD definition, which is very broad, PFAS would capture over 7 million compounds, which includes all with CF2 bonds in their structure.

3.3 Cost Impacts

For example, a study by Black & Veatch[10] for the American Water Works Association found the costs, in the USA of removing PFAS from drinking water includes:

- CAPX to reach 4 ng/L for PFOS & PFOA is around $34 billion
- CAPX to reach 10 ng/L for PFOS & PFOA is around $12 billion
- OPEX to reach 4 ng/L for PFOS & PFOA is around $2.8 billion
- OPEX to reach 10 ng/L for PFOS & PFOA is around $820 million
- Household annualised costs varies from $65 to $310 depending on PFAS treatment plant scale

This cost study is limited to the USA where 16% of drinking water sources would require PFAS removal systems to reach the 4ng/L PFOS limit.

That these are Guideline Values will be ignored by local regulators as well as they will take a risk adverse approach, and use the HBGV as hard limits. There will be no flexibility used, by regulators, as any level above this hard line will be seen in emotional health damaging terms by the public and the media.

R2 ASBG Recommends that the NHMRC also consider the:

- ***Additional safety levels being added by overseas regulators and others to appease stakeholders, which will increase public fear reinforced by tighter new limits based on NHMRC PFAS position on drinking water.***
- ***Knock-on implications, damage to the circular economy and increased costs to the public in setting new tighter PFAS HBGVs, which will be the basis for new hard PFAS limits especially on wastes.***
- ***Increased public fear and nocebo impacts of an overly conservative PFAS HBGVs***

Overall the NHMRC should be reviewing PFASs in context of their overall risks compared to other substances and not just based on PFAS's health impacts in isolation. A focus on a Government chosen limited set of chemicals for their hazards, removes a holistic approach where resources should be focused and proportioned to the main health risks Australians face. What is required is a much broader assessment of health risks where PFASs can be put into context. For example, there are no know deaths directly associated with PFAS exposure in Australia, only estimated health impacts. All the HBGVs for PFAS are based on are largely on animals with increased risks of human diseases. Linking these to human health impacts is area of lacking clear scientific methods where guestimates can vary by a few orders of magnitude with flow on cost consequences.

[10] See reference 5

4 Placing PFAS Information in Context for the Public

The very low HBGVs given to PFAS need to be placed in context for public consideration. Such contextual information should provide evidence that NHMRC's HBGVs use considerable safety factors and are at least conservative if not highly conservative. Such information should provide a balance against public fears and stakeholders calling for zero PFAS levels to be set. Such information would show that the NHMRC is doing its part well to protect the health of Australians and address concerns it is not.

4.1 Concentration Levels in Context

The US EPA does this in part by citing that 4 ng/L PFOS equals 4 ppt, placing the concentration levels in context. Then explains[11]:

> *For example, one part per trillion in time,* is the equivalent of one second out of nearly 32,000 years.

Hence, 4 ng/L concentration can be expressed as 4 seconds in 32,000 years. Note if a tighter limit of 0.1 ng/L, which the EU uses, represents 1 second in 320,000 years.

4.2 Drinking Water Source of PFAS Assumptions

Other contextual data which could be published by the NHMRC to place its PFAS limits in context include:

- That a 300 times safety factor is used based on conservative estimates of the BMDL for PFOS, PFHxS & PFBS.
- In addition, it is assumed that to reach the drinking water HBGV an individual would:
    - Drink 2 litres per day of drinking tap water is drunk
    - Where 90% of PFAS is ingested from other sources, largely foods and beverages
- In the last point note that FSANZ found only PFOS in 2% of routine food sampling for contaminants, no other PFAS were detected.

ASBG is also concerned that FSANZ has a different set of TDI / BMDL value than NHMRC uses to calculate its HBGV. If such a difference is used for the final HBGVs this will cause considerable confusion with for the scientific community, the professionals and regulators to base their interpretation of what limit will apply and by how much.

4.3 Placing PFAS Risk in Context with Other Australian Health Risks

Contextual information should also include other main health risks to Australians, placing PFAS in context. If possible the role of hazardous chemical intake should also be included as a comparison. For example, the following chart from the Australian Institute of Health and Welfare shows the leading risk factors contributing to disease burden in Australia.

[11] See US EPA Questions & Answers: PFAS National Primary Drinking Water Regulation

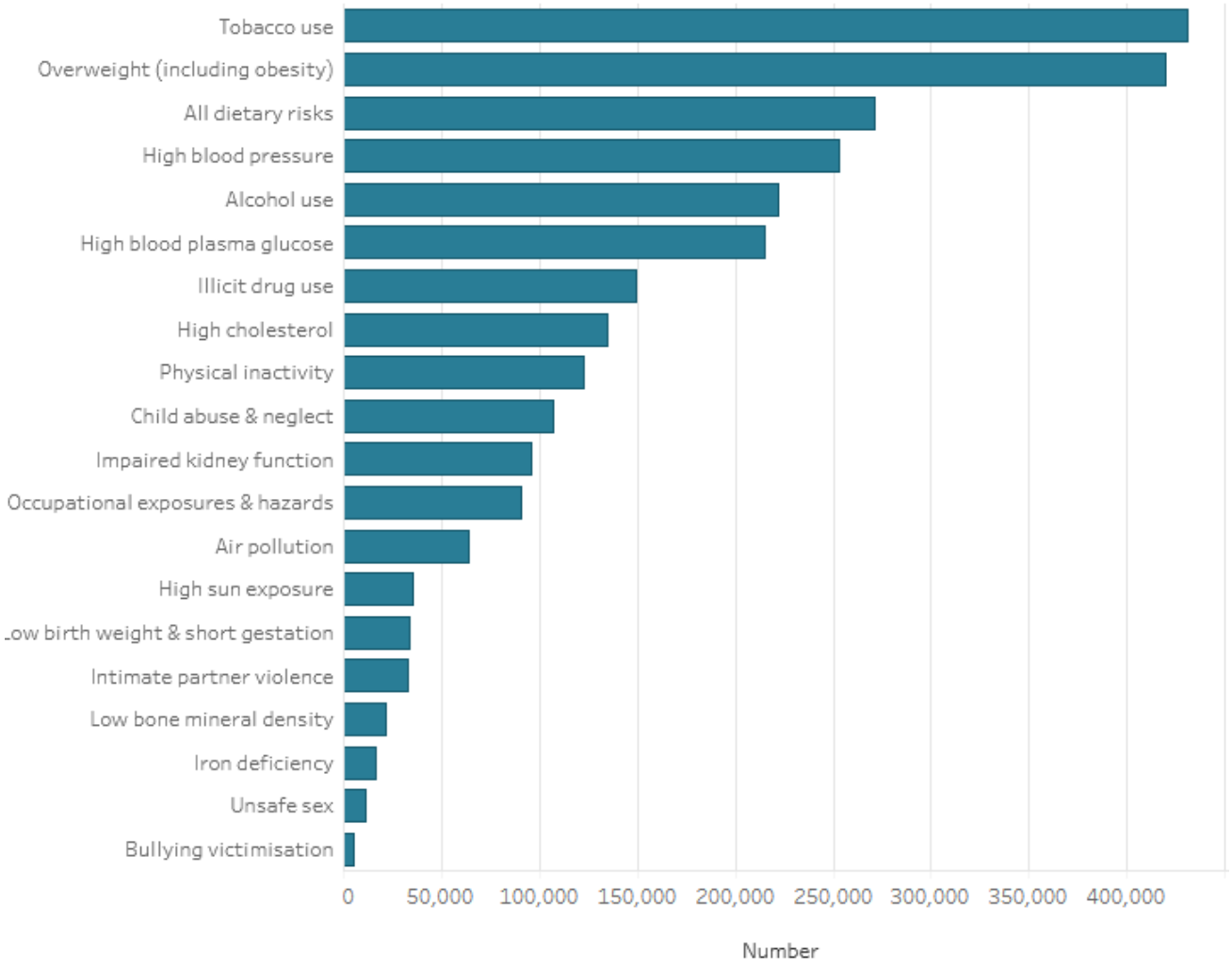

Chart 1: Leading Risk Factors Contributing to Disease Burden showing Disability Adjusted Life Years

The impact of PFASs of concern in the above could be linked to these risk factors. For example, all dietary risks could include PFAS risk. However, a scientifically justifiable portion of this overall risk attributed to PFAS would be required. ASBG considers such risks would be very low in comparison to the large set of dietary risks which are comprehensively listed.

Another comparison source would be from the Australian Bureau of Statistics (ABS) showing health outcomes rather than causes as in Chart 1. Here PFAS is more likely liked to multimorbidity by type of chronic condition, rather than deaths, as deaths attributed to PFAS are not listed due to low exposure rates and lack of any evidence. Chart 2 from ABS could be used as a source for comparison.

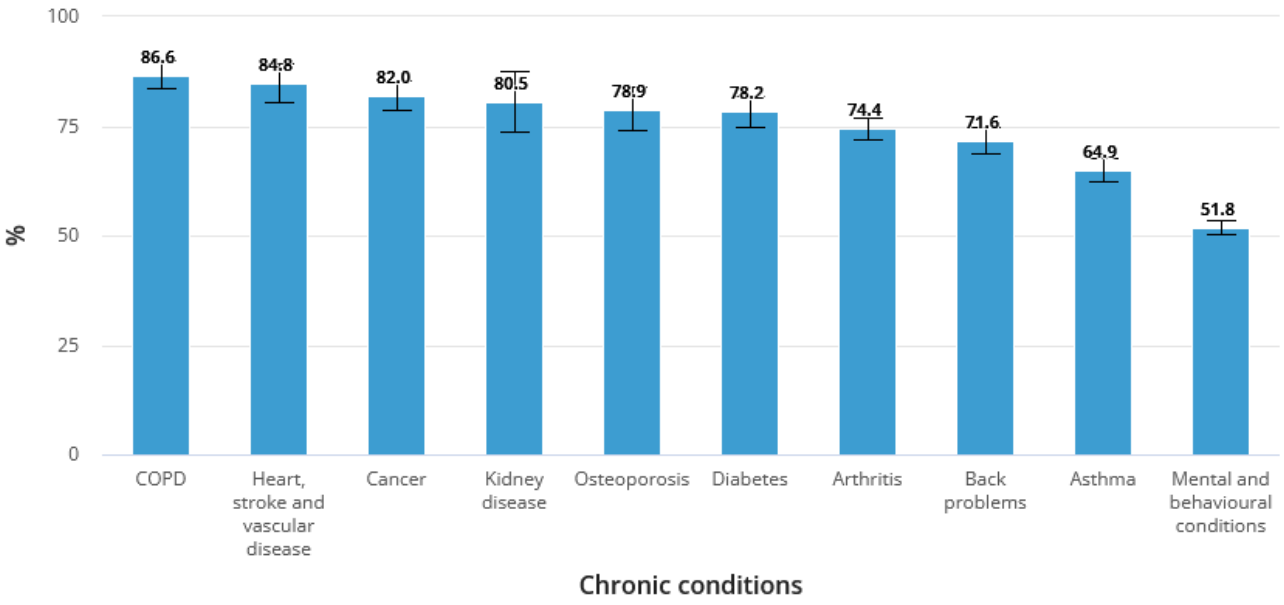

Chart 2: Proportion of People with Multimorbidity by Type of Chronic Condition, 2022

Here PFAS risks can be aligned with the chronic outcome conditions. Chart 2 can be used to compare mortality risk between one or more PFAS and another similar substance, such as a chlorinated pesticide, other halogenated organics or even some heavy metals.

An example of a chemical risk can be mesothelioma caused by asbestos exposure, which can be placed under the cancer risk area and proportioned accordingly to the total. For example, in 2024 an estimated 169,500 cancer cases are expected, of this mesothelioma estimated cases in 2024 is 874, consequently, mesothelioma represents 0.516% of all diagnosed cancers in Australia. Obviously avoidance of asbestos fibre inhalation should prevent mesothelioma, but this places it in perspective with all other cancers.

If PFOA is considered a cancer risk it can be aligned under cancer risk similarly, with a scientifically appropriate proportionated rate compared to all other cancers. The others such as PFOS, PFHxS, etc, may not fit into any of the above categories, but could be proportioned overall if possible.

Some form of contextual information should be published to enable a rational comparison of risks associated with PFAS. At a minimum NHMRC should include a statement along the lines of:

PFAS risks to Australians via drinking water is considered by NHMRC to be very low compared to other health risks.

R3 ASBG recommends the NHMRC provide a fact sheet or equivalent, with contextual information, which places the scale of the PFAS HBGVs in comparison with other significant health risks substances.

Should you require further details and clarification of the contents of this submission please contact me.

Yours Sincerely

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