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20 November 2024

Robin Benson

By email: fyi-request-29072-0cc08097@requests.fyi.org.nz Ref: H2024055415

### Tēnā koe Robin

### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health – Manatū Hauora (the Ministry) on 5 November 2024 for information regarding water quality in New Zealand. You requested:

The most recent advice the Ministry of Health has given in respect of the current international approach to PFAS in public water supplies, acceptable levels, etc. The "international evidence" that advice was based on or confirmed by. Any discussions, advice or material concerning the consideration of the advice referred to above "in a New Zealand context".

The Ministry has identified one document within scope of your request, titled: '*PFOS and PFOA* – *interim guidance level for DW*'. This document is appended to this letter and is released to you in full.

On 29 October 2024, the Ministry commissioned an updated review of the health evidence for a range of chemicals in drinking water, including Per-fluoroalkyl and Poly-fluoroalkyl Substances (PFAS). Once completed, this review will form the basis of policy advice to Taumata Arowai regarding the drinking water standards.

The Ministry for the Environment - Manatū Mō Te Taiao is the lead agency for the government regarding PFAS chemicals. Further information is available on their website at: <u>https://environment.govt.nz/what-government-is-doing/areas-of-work/land/per-and-poly-fluoroalkyl-substances-pfas/latest-updates-on-pfas/</u>

Information about PFAS is also available on Health New Zealand – Te Whatu Ora's website at: <a href="http://www.tewhatuora.govt.nz/health-services-and-programmes/environmental-health/hazardous-substances/persistent-organic-pollutants-pops/per-and-poly-fluoroalkyl-substances-pfas">www.tewhatuora.govt.nz/health-services-and-programmes/environmental-health/hazardous-substances/persistent-organic-pollutants-pops/per-and-poly-fluoroalkyl-substances-pfas</a>

I trust this information fulfils your request. If you wish to discuss any aspect of your request with us, including this decision, please feel free to contact the OIA Services Team on: <a href="mailto:oiagr@health.govt.nz">oiagr@health.govt.nz</a>.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Manatū Hauora website at: <u>www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</u>

Nāku noa, nā

Lachanlies

Jane Chambers Group Manager, Public Health Policy and Regulation Public Health Agency | Te Pou Hauora Tūmatanui



### Poly-fluoroalkyl substances (PFASs), also called perfluoroalkyl substances (PFASs)

Perfluorooctane sulphonic acid (PFOS), and perfluorooctanoic acid (PFOA) belong to a group of man-made compounds called perfluoroalkyl substances (PFASs). There are thousands of different compounds classed as PFAS. PFAS accumulate in the human body and without further exposure the levels decrease slowly over time. The ability of these compounds to be stored in the body increases concerns about the possible effects on human health. However, there is currently no consistent evidence that environmental exposures to PFOS and PFOA causes adverse human health effects.

Adverse health effects have been demonstrated in animals exposed to much higher levels of PFAS than are known to occur in people. Changes in the liver, thyroid, and pancreatic function, and some changes in hormone levels were reported. However, the results of these animal studies and their relevance to humans are not always clear. Potential adverse health effects in humans cannot be excluded but further research is needed to understand whether the adverse effects seen in animals have any implications for human health.

In 2010, the Ministry of Health commissioned Massey University's Centre for Public Health Research to carry out a biomonitoring study to quantify the concentrations of selected persistent organic pollutants (POPs) in the blood serum of adult New Zealanders. The study was completed in 2013 and the results showed that the concentrations of PFOA in adult serum are generally similar to, or lower than, those in the USA, Canada, Germany, and Australia, while the concentrations of PFOS are considerably lower than those in USA, Canada, Germany, and Australia.

#### How the maximum acceptable values for determinands in drinking-water are established

The Health Act 1956 provides for the Minister of Health to issue or adopt standards applicable to drinking-water. Drinking-water Standards may (among other things) provide for maximum amounts of substances or organisms or contaminants or residues that may be present in drinking water; and maximum acceptable values (MAVs) for chemical, radiological, microbiological, and other characteristics of drinking water:

When Health officials recommend a MAV, this is usually adopted from the current guideline value advised by the World Health Organization (WHO). If drinking water does not exceed the WHO value it is considered safe for a 70 kg person for a lifetime of 70 years, drinking 2 L per day. The general procedure for developing a MAV is described in Chapter 10 of the *Guidelines for Drinking-water Quality Management for New Zealand* (MoH 2017), see Appendix 1.

The *Drinking-Water Standards for New Zealand 2005 (Revised 2008)* (the Standards) are under review. Until a MAV appears in the Standards, Health officials propose adopting <u>interim guidance</u> <u>levels</u> for drinking-water. (The term 'guideline value' is already used in the Standards to refer to aesthetic determinands.)

To develop an interim guidance level we have looked at the equivalent values established in other countries.

## What guidance values have been established elsewhere?

- World Health Organization: WHO does not have guideline values in the 2017 Guidelines for Drinking-water Quality.
- Australia: *Per- And Poly-Fluoroalkylated Substances*: (NHMRC). 2017. 4 pp. https://consultations.nhmrc.gov.au/files/consultations/drafts/publicconsultationdocumentdraftpfasfactsheet.pdf
- United States: Fact Sheet: PFOA and PFOS Drinking Water Health Advisories. U.S. Environmental Protection Agency (USEPA). 2016. 5 pp. From https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories\_pfoa\_pfos\_updated\_5.31.16.pdf
- Germany: Taken from *PFAS Water Supply Testing. Drinking Water Monitoring Report. New Zealand Defence Force.* Reference: 500307, Revision: 0, 29 September 2017. Document prepared by: Aurecon New Zealand Ltd.
- Denmark: Perfluoroalkylated substances: PFOA, PFOS and PFOSA evaluation of health hazards and proposal of a health based quality criterion for drinking water, soil and ground water. Danish EPA 2015. Environmental project No. 1665, 2015. https://www2.mst.dk/Udgiv/publications/2015/04/978-87-93283-01-5.pdf

The "guidance values" used in these four countries are:

Units μg/L	Australia 2017	USEPA 2016	Germany 2015	Denmark 2015	MEAN
PFOS	0.07	0.07	0.23	0.1	0.12
PFOA	0.56	0.07	0.30	0.3	0.31

Note: We did not consider *enHealth Statement: Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia.* June 2016. http://www.health.nsw.gov.au/environment/factsheets/Documents/pfasinterim-health-values-ahppc.pdf This recommended interim health reference values for drinking water of 0.5 µg/L for PFOS/PFHxS and 5 µg/L for PFOA based on the 2008 European Food Safety Authority's (EFSA) derivation of Tolerable Daily Intake (TDI) values for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). However, this was not accepted by the National Health and Medical Research Council (NHMRC), which is the body that prepares the Australian drinking-water guidelines.

# Comments:

Australia

- Fact sheet published by the National Health and Medical Research Council (NHMRC)
- Used a similar process to that the Ministry of Health uses for developing MAVs in the Standards (see Appendix 1 and 2).
- Termed a health-based guideline value.
- Based on Food Standards Australia New Zealand (FSANZ) total daily intakes (TDIs) with an uncertainty factor (UF) of 30, 70 kg body weight, 2 litres per day, with 10 percent from drinking water.
- Separate values for PFOS and PFOA.
- The guideline value for PFOS applies to the sum of PFOS + PFHxS (perfluorohexane sulphonic acid).

**United States** 

- Fact sheet published by the US Environmental Protection Agency.
- Called (non-regulatory) drinking water health advisories, protecting the most sensitive populations with a margin of protection from a life-time of exposure. These replace the provisional health advisories of 2009.
- Based on the drinking water intake of lactating women, who drink more water than other people and can pass these chemicals along to nursing infants through breast milk.
- Same values for PFOS and PFOA.
- Because these two chemicals cause similar types of adverse health effects, USEPA recommends that when both PFOA and PFOS are found in drinking water the combined concentrations of PFOA and PFOS be compared with the 0.07 µg/L HA level.
- No value for PFHxS.

### Germany

- Not seen original publication data taken from Aurecon NZ Ltd report. Report possibly called Bavarian (Germany) State Office for Environment Provisional Evaluation Criteria for selected PFAS in groundwater.
- Called provisional threshold value.
- Separate values for PFOS and PFOA.
- Based on human health models for drinking water.
- They developed threshold for six further PFASs, four of which were clearly of lower toxicity.

### Denmark

- Fact sheet published by Danish EPA.
- Called health based quality criteria in drinking water.
- Based on TDIs, with 10% from drinking water, for toddlers drinking 0.03 L per kg per day.
- Despite this different approach, the Danish values are very close to the mean values.
- Separate values for PFOS and PFOA.
- No value for PFHxS, but the PFOS health value applies also to PFOSA (perfluorooctanesulfonamide).
- Because these substances are toxicologically similar they also have a criterion where the sum of the concentration/limit value ratios for PFOA, PFOS and PFOSA should be kept below the value of 1.
- WHO and the Standards use this standard approach too, for trihalomethanes and nitrate/nitrite.

## **CONCLUSION**

For the sake of **interim guidance levels** for use in New Zealand, it would seem logical to adopt the same values being proposed in Australia as their guideline values were very recently developed, and are based on a 70kg adult drinking two litres of water per day, which is consistent with how MAVs are derived in New Zealand.

If we decide to develop **maximum acceptable values (MAV)** for the next Drinking-Water Standards for New Zealand we will need to decide on the toxicological pathways most suited to NZ (and the World Health Organization may have developed guideline values by then).

	Units µg/L
PFOS + PFHxS	0.07
PFOA	0.56

Ministry of Health 22 November 2017

## Appendix 1 Guidelines for Drinking-water Quality Management for New Zealand. Excerpt from Chapter 10

For most kinds of toxicity, it is generally believed that there is a dose below which no adverse effects will occur. The MAVs for the determinands that are non-carcinogenic or non-genotoxic carcinogens have been calculated on the basis of a tolerable daily intake (TDI) approach. This is also called an acceptable daily intake (ADI).

The overall process for deriving the MAVs is presented in the following sections. Information has been assessed to select the most suitable study to use as the basis for choosing a NOAEL (no observed adverse effects level) or, if that is not available, a LOAEL (lowest observable adverse effect level). Sometimes the literature refers to the NOEL (no observed effects level). This value is divided by an uncertainty factor (UF) reflecting the level of uncertainty associated with the NOAEL or LOAEL to determine a tolerable daily intake (TDI). The MAV is determined by multiplying this value by the average weight of a person (BW) and by the proportion (P) of the TDI that a person is likely to ingest in drinking-water, and by dividing by the average volume of water that a person will drink during one day (C). Definitions appear at the end of section 10.2.5.1.

TDI = <u>NOAEL (LOAEL)</u> and MAV = <u>TDI x BW x P</u>

UF

С

In the individual datasheets the derivation of the MAV of each chemical which has been based on a TDI approach is shown as a combination of the above two equations as shown below:

ICIA

UF x C

where:

	TDI/ADI:	tolerable/acceptable daily intake (mg/kg body weight/day)
	NOAEL:	no observable adverse effect level
	LOAEL:	lowest observable adverse effect level
	MAV:	Maximum Acceptable Value in mg/L
	BW:	body weight (70 kg for adult; 10 kg for two-year old children; 10 kg calculation is used for infants for DDT + isomers and 5 kg is used for lead and short-term nitrite)
	P:	proportion of tolerable daily intake attributable to drinking-water
	C:	the average volume of water consumed per day (adults two litres; children one litre; infant 0.75 litre)
of the	UF:	uncertainty factor
<b>~</b>		

# Appendix 2 Derivation of Guideline (Australia)

# PFOS

The health-based guideline value of 70 ng/L (0.07  $\mu$ g/L) for PFOS was determined as follows:

## 70 ng/L = 20 ng/kg body weight/day x 70 kg x 0.1

2L/day

where:

- A Tolerable Daily Intake of 20 ng/kg bodyweight per day has been established by FSANZ on the basis of decreased parental and offspring body weight gains in a multigenerational reproductive toxicity study in rats.
- 70 kg is taken as the average weight of an adult.
- 0.1 is a proportionality factor based on the conservative assumption that 10% of the TDI will arise from the consumption of drinking water.
- L/day is the estimated maximum amount of water consumed by an adult.
- Because of the large differences observed in the half-lives of PFOS in humans compared to animals, pharmacokinetic modelling was applied to the serum PFOS concentrations measured in experimental animals at the NOAEL to calculate the human equivalent dose. The FSANZ TDI incorporates an uncertainty factor of 30, applied to the HED, which includes a default factor of 3 to account for interspecies differences in toxicodynamics and a default factor of 10 for intraspecies differences in the human population.

# PFOA

The health-based guideline value of 560 ng/L ( $0.56 \mu g/L$ ) for PFOA was determined as follows:

# 560 ng/L = $\frac{160 \text{ ng/kg body weight/day x 70 kg x 0.1}}{160 \text{ ng/kg body weight/day x 70 kg x 0.1}}$

2L/day

where:

- A Tolerable Daily Intake of 160 ng/kg bodyweight/day has been established by FSANZ on the basis of a NOAEL for fetal toxicity in a developmental and reproductive study in mice.
- 70 kg is taken as the average weight of an adult.
- 0.1 is a proportionality factor based on the conservative assumption that 10% of the TDI will arise from the consumption of drinking water.
- L/day is the estimated maximum amount of water consumed by an adult.
- Because of the large differences observed in the half-lives of PFOA in humans compared to animals, pharmacokinetic modelling was applied to the serum PFOS concentrations measured in experimental animals at the NOAEL and above to calculate the human equivalent dose. The FSANZ TDI incorporates an uncertainty factor of 30, applied to the HED, which includes a default factor of 3 to account for interspecies differences in toxicodynamics and a default factor of 10 for intraspecies differences in the human population.
- The rounding conventions described in Chapter 6 have not been applied in the derivation of the health based guideline value for PFOA.

# PFHxS

FSANZ found that there was insufficient toxicological and epidemiological evidence to justify establishing a TDI for PFHxS. In the absence of a TDI, FSANZ concluded that it is reasonable to consider that the TDI for PFOS is likely to be conservative and protective of human health as an interim measure. Effectively this means that the guideline value for PFOS should apply to the sum of PFOS and PFHxS.