

enHealth Statement: Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia

Background and context:

In March 2016, the Australian Health Protection Principal Committee (AHPPC) endorsed the Standing Committee on Environmental Health (enHealth) *Guidance Statements on Perfluorinated Chemicals* (Guidance Statements) to support jurisdictional responses to incidents of environmental contamination with per- and poly-fluoroalkyl substances (PFAS)¹. Guidance Statement 3 concerned the development of human health reference values for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) for consistent use in the undertaking of human health risk assessments in Australia.

In April 2016, enHealth convened a national workshop to review overseas standards and draft Australian human health toxicity reference values for PFOS and PFOA. The workshop was attended by toxicologists, enHealth members, representatives of the Cooperative Research Centre for Contamination Assessment and Remediation of the Environment (CRC CARE), Food Standards Australia New Zealand, and the Australian Government Department of Health and Australian Government Department of the Environment.

Workshop participants considered various approaches to the development of toxicity reference values for PFOS and PFOA, including the approach of:

1. European Food Safety Authority (EFSA) 2008;
2. United States Environmental Protection Agency (USEPA);
 - a. Health Effects Support Document for PFOS 2014 (draft);
 - b. Health Effects Support Document for PFOA 2014 (draft);
 - c. Provisional Health Advisories for PFOA and PFOS 2009;
 - d. Soil screening levels for PFOA and PFOS 2009;
3. United States Agency for Toxic Substances and Disease Registry (ATSDR) 2015 (draft);
4. Danish Ministry of the Environment 2015;
5. German Ministry of Health Drinking Water Commission and Federal Environment Agency, 2006;
6. Swedish Environmental Protection Agency, 2012 and 2014 (cited in Danish Ministry of the Environment document);
7. United Kingdom Committee on Toxicity of Chemicals in Food (COT) 2006a, 2006b, 2009, 2014;
8. Minnesota Department of Health (2009a, 2009b); and
9. CRC CARE 2016 (draft).

The workshop discussions informed the development of this Statement. In addition, in May 2016, enHealth considered the USEPA Drinking Water Health Advisories and Health Effects Support Documents for PFOS and PFOA (2016).

¹ The acronym to identify this group of chemicals has recently changed – “perfluorinated chemicals” or “PFCs” are now referred to as “per- and poly-fluoroalkyl substances” or “PFASs”.

enHealth Statement

1. enHealth considers that the 2008 European Food Safety Authority's (EFSA) derivation of Tolerable Daily Intake (TDI) values for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) is appropriate as interim national guidance for use in site investigations in Australia.
2. enHealth considers the use of the 2008 EFSA approach is consistent with relevant Australian science policy, as per enHealth's 2012 publication, *Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards*. enHealth also considers the 2008 EFSA approach is relevant to the exposure pathways of concern in Australia, which include contaminated food. EFSA TDI values for PFOS and PFOA are used for the assessment and management of these hazards in the food chain in Europe. This approach was validated by EFSA's 2012 comprehensive assessment of dietary exposure to the PFAS group of chemicals.
3. enHealth notes that the EFSA, USEPA and US ATSDR approaches considered the same collection of toxicological studies. EFSA's method to derive a TDI uses a similar approach to that generally used in Australia.
4. enHealth notes that the US EPA has recently released the *US EPA 2016 Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)* and *US EPA 2016 Health Effects Support Document for Perfluorooctanoic Acid (PFOA)*. enHealth considers that the final 2016 versions of the US EPA Health Effects Support Documents do not change its recommendation to use the EFSA TDI. The US EPA 2016 versions contain the same studies and methods as the 2014 draft documents considered at the April 2016 enHealth workshop and therefore do not invalidate enHealth's reasoning to recommend the EFSA TDI values.
5. enHealth recommends that the EFSA TDI values are used by jurisdictions in site investigations in Australia to determine interim drinking water and recreational water guideline values using the methodology described in Chapter 6.3.3 of the National Health and Medical Research Council (NHMRC) *Australian Drinking Water Guidelines*. enHealth considers that calculating an interim drinking water guideline value in this way is more appropriate for the Australian context than using the 2016 US EPA Drinking Water Health Advisories.
6. The interim drinking water guideline values are not intended to be a guide for drinking water utility providers across Australia, but rather for use to confirm the quality of drinking water supplies potentially affected by specific instances of site contamination.
7. enHealth has also considered the available information on perfluorohexane sulfonate (PFHxS) and agreed that the EFSA TDI for PFOS also be applied to PFHxS exposures. In practice this means PFOS and PFHxS exposures should be summed and the total compared to the TDI for PFOS.

enHealth recommended interim health reference values

8. enHealth recommends that Food Standards Australia New Zealand (FSANZ) undertakes an assessment of the available toxicity data on PFOS, PFOA and PFHxS and publishes relevant reference values in the Australia New Zealand Food Standards Code. Values published by FSANZ will immediately replace interim toxicity reference values recommended by enHealth.
9. The recommended enHealth interim values are:

Toxicity reference value	PFOS/PFHxS	PFOA
Tolerable Daily Intake (µg/kg/d)	0.15	1.5
Drinking Water Quality Guideline (µg/L)	0.5	5
Recreational Water Quality Guideline (µg/L)	5	50

References

enHealth (2012), *Environmental Health Risk Assessment, Guidelines for assessing human health risks from environmental hazards*, enHealth, Commonwealth of Australia, Canberra.

enHealth (2016), *Guidance Statements on Per- and Polyfluoroalkyl Substances*. [enHealth publications](#)

EFSA (2008), *Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts*, *Scientific Opinion of the Panel on Contaminants in the Food chain*. EFSA Journal (2008);653:1-131. [European Food Safety Authority](#)

EFSA (2012), *Perfluoroalkylated substances in food: occurrence and dietary exposure*. EFSA Journal (2012);10(6):2743. [European Food Safety Authority](#)

NHMRC (2008), *Guidelines for Managing Risks in Recreational Water*, National Health and Medical Research Council, Commonwealth of Australia, Canberra. [NHMRC](#)

NHMRC (2011), (updated February 2016), *Australian Drinking Water Guidelines*, National Health and Medical Research Council and Natural Resource Management Ministerial Council, Commonwealth of Australia, Canberra. [NHMRC](#)

US EPA (2016), *Health Effects Support Document for Perfluorooctane Sulfonate (PFOS)* [USEPA](#)

US EPA (2016), *Health Effects Support Document Perfluorooctanoic Acid (PFOA)* [USEPA](#)