

Hazard assessment report –
Perfluorooctane Sulfonate (PFOS),
Perfluorooctanoic Acid (PFOA),
Perfluorohexane Sulfonate (PFHxS)

Summary

The Department of Health contracted Food Standards Australia New Zealand (FSANZ) to provide advice on tolerable daily intake values (TDI) for perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and perfluorohexane sulfonate (PFHxS). These substances belong to a group of compounds known collectively as per- and poly-fluoroalkylated (PFAS) substances.

A TDI is the amount of a chemical in food or drinking water that can be ingested on a daily basis over a life-time without appreciable risk to the consumer.

PFAS have been used since the 1950s in industrial processes, in a range of common household products, and some types of firefighting foams. Their use in firefighting foams has raised some environmental concerns as PFAS have contaminated sites where the foams have been used.

FSANZ considered a number of comprehensive international assessments on the health effects of PFAS. These assessments established TDIs ranging from 20 – 300 ng/kg bw/day for PFOS and 20 – 1,500 ng/kg bw/day for PFOA. TDI's for PFHxS have generally not been established due to a lack of data.

- FSANZ also considered the June 2016 enHealth Statement: *Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia*, and the August 2016 independent *Procedural Review of Health Reference Values Established by enHealth for PFAS*.

Most international agencies have concluded that there is no clear evidence of any adverse health effects of PFAS in humans, including in highly exposed occupational populations. However, the United States Environmental Protection Agency (US EPA) has noted that there appears to be an association between increased serum cholesterol and decreased body weight at birth. FSANZ has reviewed the available human epidemiological information and concluded that while there is evidence of this association, it is not possible to determine whether PFAS causes the changes, or whether other factors are involved.

A literature review commissioned by FSANZ concluded that there are both positive and negative studies showing associations for increasing PFOS and PFOA concentrations to compromise antibody production in humans. However, to date there is no convincing evidence for increased incidence of infective disease associated with PFOS or PFOA effects on human immune function.

Epidemiological studies have not provided convincing evidence of a correlation between PFOS and PFHxS and any cancer type in human beings. Although associations between PFOA and some human cancers have been suggested from some epidemiological studies, results have often been contradictory, and a causal relationship cannot be established with reasonable confidence.

FSANZ concluded that available human epidemiology data are not suitable to support the derivation of TDI for PFOS or PFOA. This is consistent with the findings of other regulatory agencies. Therefore, FSANZ has recommended TDIs based on extensive toxicological databases in laboratory animals.

- For PFOS, the TDI is 20 ng/kg bw/day on the basis of decreased parental and offspring body weight gain in a reproductive toxicity study in rats. Pharmacokinetic modelling was applied to the serum concentrations at the no observed adverse effect level (NOAEL) to calculate the human equivalent dose (HED). An uncertainty factor of 30 was applied to the HED, which comprised a factor of 3 to account for inter-species differences in toxicodynamics and a factor of 10 for intra-species differences in the human population.
- For PFOA, FSANZ has recommended a TDI of 160 ng/kg bw/day on the basis of a NOAEL for fetal toxicity in a developmental and reproductive study in mice. Pharmacokinetic modelling was applied to the serum concentrations at the NOAEL to calculate the HED. An uncertainty factor of 30 was applied to the HED, which comprised a factor of 3 to account for inter-species differences in toxicodynamics and a factor of 10 for intra-species differences in the human population.

There was not enough toxicological and epidemiological information to justify establishing a TDI for PFHxS. In the absence of a TDI, it is reasonable to conclude that the enHealth 2016 approach of using the TDI for PFOS is likely to be conservative and (as an interim measure) will protect public health. Effectively, this means that PFHxS and PFOS exposure should be summed for the purposes of risk assessment.