TECHNICAL INFORMATION PAPER

APHC
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ENVIRONMENTAL CRITERIA
PERFLUORINATED ALKYL COMPOUNDS

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PURPOSE. To provide environmental criteria for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS).

POINTS OF MAJOR INTEREST AND FACTS.

Background and Summary

PFOA and PFOS are two of a large group of Perfluoronated Alkyl Compounds (PFACs). They are synthetic chemicals used in many industrial processes and consumer products. PFACs were widely used by the military in Aqueous Film Forming Foams as firefighting agents. PFOA and PFOS are soluble in water and are very stable and resistant to degradation. Because of their persistence in the environment and mobility in water systems, these compounds are worldwide environmental contaminants and are ubiquitous in soil, water and air throughout the United States (reference 1).

Beginning in 2015, most production and use of these materials began a voluntary phase out (reference 1). However, even though manufacturing and use of PFOA and PFOS have declined, the chemical stability and persistence in the environment will mean that humans will continue to face environmental exposures.

There are no Federal regulations governing the levels of PFACs allowed in drinking water. In 2009, the U.S. Environmental Protection Agency (EPA) published provisional Health Advisories (HA) for PFOA and PFOS. A number of states have also published guideline levels for PFOA and PFOS (reference 2). EPA Region 4 published Regional Screening Levels (RSLs), which provide guidelines for safe concentrations of these compounds in soil (reference 3).

In 2016, the EPA updated the toxicity criteria for PFOA and PFOS and published final Lifetime Health Advisories (references 1 and 4). Table 1 shows the final HAs. The EPA Region 4 has not updated the 2009 soil-screening concentrations. This paper provides a summary of the EPA calculations for the HAs and updated recommendations on safe soil concentrations using the 2016 toxicity criteria and EPA-provided software.

PFOA Health Advisory

The EPA publishes HA; these HAs represent concentrations of contaminants in drinking water which are not expected to cause adverse health effects. The EPA derives and publishes 1-day, 10-day and lifetime HA values. These criteria are not regulations, but many state and local regulators use these criteria until regulatory values become available.

There is an extensive toxicity database on PFOA from both experimental animals and occupational exposures. Animal studies have shown that PFOA is toxic to the liver and kidney and can cause effects in the developing fetus. Human data from epidemiology studies suggest effects on the liver, thyroid, immune system, and cancer, but the data are inconclusive (reference 1).

The first step in deriving a risk-based water concentration, such as an HA, is to develop a Reference Dose (RfD). The RfD is an estimate of a daily human dose that is not expected to cause adverse health effects over a lifetime of exposure (reference 5). The EPA chose several developmental and reproductive studies to model PFOA toxicity. Endpoints included histopathological changes, effects on fertility, developmental effects on offspring, and immune effects. From these studies, the EPA modeled Human Equivalent Doses (HED) and then applied Uncertainty Factors [UFs] to these doses to calculate candidate RfDs. The EPA performed this analysis and derived six-candidate RfDs ranging from 0.00002 milligrams per kilograms per day (mg/kg/day) to 0.0015 mg/kg/day. They selected 0.00002 mg/kg/day as the final RfD, a value which was supported by multiple studies and multiple developmental toxicity endpoints.

To derive a lifetime health advisory, the RfD was combined with intake estimates to calculate the Drinking Water Equivalent Level (DWEL). For PFOA, the EPA assumed a lactating female consuming 0.054 liters per kilograms per day (L/kg-day) as the most protective exposure scenario. The DWEL assumes 100 percent of the total daily intake comes from water ingestion. Using these assumptions, the EPA estimated a DWEL of 0.00037 milligrams per liter (mg/L).

Since humans are likely to be exposed to PFOA through multiple sources including food, air, and water, the EPA typically adjusts the DWEL by a factor called a relative source contribution (RSC) to account for these multiple exposure routes. The default RSC is 20 percent and that is the factor chosen for the PFOA HA. Correcting the DWEL with the 20 percent RSC yields a PFOA lifetime HA of 0.07 micrograms per liter (µg/L) (reference 1).

Carcinogenicity

Exposures to high concentrations of PFOA have been associated with several types of cancer, but the data are inconclusive. There are also limited animal data indicating potential carcinogenic effects. Based on the 2006 EPA Carcinogen Assessment Guidelines, the EPA determined that there was Suggestive Evidence for Carcinogenic Potential for PFOA. For compounds in this category, the EPA typically does not perform quantitative risk estimates. In the case of PFOA, one of the key studies used in deriving the non-cancer HA level also investigated its carcinogenic potential in rodents. The data were judged adequate to perform a dose response extrapolation, and the EPA proceeded with this analysis. Using the estimated cancer slope factor from this study and default exposure estimates, the EPA estimated that a water concentration of 0.5 µg/L was associated with a cancer risk of about 1 in a million. This cancer risk-based water concentration is an order of magnitude higher than the non-cancer HA value; therefore, the HA should be protective of potential carcinogenic effects.

PFOS Health Advisory

To derive an HA for PFOS, the EPA followed the same steps used for PFOA. PFOS shares many of the toxic properties of PFOA. Multiple animal studies in multiple species reported toxicity to the liver, kidney and immune system, developmental toxicity, and reproductive effects. The EPA performed dose-response assessments on six studies; toxic effects included liver toxicity, behavioral effects, and developmental toxicity. The analysis followed through with the development of an HED followed by the RfD. The RfD for PFOS was determined to be 0.00002 mg/kg/day, the same value as the PFOA RfD. The PFOS HA was derived using the same exposure assumptions, and the HA value is identical to PFOA: 0.07 ug/L.

Carcinogenicity

Carcinogenicity data for PFOS is more limited than for PFOA. The EPA considers the data to be Suggestive Evidence of Carcinogenic Potential in humans, but there was no clear dose-response relationship that could be modeled (reference 4).

Soil Criteria

The soil values presented are RSLs. The RSLs are non-regulatory, risk-based criteria, which are derived using standard default exposure assumptions and appropriate toxicity values. In 2009, EPA Region 4 published Regional Soil Screening Levels for PFOA and PFOS (reference 3). These values were derived using the RSL calculator software available from the EPA (reference 5). The 2009 Soil RSL values were based on interim RfD values for PFOA and PFOS that have changed in the final 2016 HA documentation.

Therefore, the RSL values were re-calculated using the final RfD values. Soil levels are presented for residents and for worker populations; these values differ by an order of magnitude as a result of differing exposure assumptions.

Table 1. PFOA and PFOS Risk Based Concentrations

	Compound	
	PFOA	**PFOS**
RfD µg/kg/day	0.02	0.02
Lifetime HA µg/l	0.07	0.07
RSL Residential Soil mg/kg soil	1.6	1.6
RSL Composite Worker mg/kg soil	23	23

REFERENCES

1. EPA Office of Water, EPA 822-R-16-005. 2016. Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA).

2. Memorandum, EPA Office of Solid Waste and Emergency Response,. dated 28 October 2009, Subject: The Toxicity of Perfluorooctanic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS).

3. Memorandum, EPA Region 4, dated 2009, Subject: Soil Screening Levels for Perfluorooctanoic Acid (PFOA) and Perfluorooctyl Sulfonate (PFOS).

4. EPA Office of Water, EPA 822-R-16-004. 2016. Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS).

5. EPA Region 9, Regional Screening Levels online calculator. http://www.epa.gov/region9/superfund/prg