

Perfluorocarbons (PFCs) in Drinking Water

Technical Memo Supporting Information and Toxicology Summary for Health Care Providers



Background

This technical memo supporting information and toxicology summary has been developed as an additional resource to help Navy Medicine health care providers prepare for health related questions from stakeholders concerned about their potential exposures to perfluorochemicals (PFCs) in drinking water. This information provides the current (as of the publication date) status of the science, and the actions taken by federal, state and international governments so far in response to that emerging science. The approaches of these standards-producing entities differ in some respects to each other, but their work may provide you better understanding of the effects of PFCs as we know them, and give you a broader base of information by which to advise your patients.

History

On 8 January 2009, the EPA's Office of Water released a Provisional Health Advisory (PHA) establishing health-based screening levels for PFOS and PFOA. They reflect health-based concentrations above which action should be taken to reduce exposure to these unregulated contaminants in drinking water. The PHA for PFOS is 0.2 micrograms per liter ($\mu\text{g/L}$) and the PHA for PFOA is 0.4 $\mu\text{g/L}$.

The Navy and Marine Corps have begun testing for PFCs in drinking water systems at certain installations CONUS, followed by all installations OCONUS.

As per attached BUMED Memo 6280 Ser M3B7/15UM30462 of 24 Dec 2015, in preparation for addressing potential high PFOS/PFOA sampling results, Navy Medicine Regions and medical treatment facilities (MTFs) must take the following steps:

Ahead of drinking water sampling, Regions must ensure each MTF identifies a POC who is knowledgeable of this program, is experienced in risk communication, and can answer questions regarding health risks and significance of testing results. The POC should coordinate with the regional or installation Drinking Water Manager prior to initiation of sampling and testing. Navy Medicine Regions should also identify a regional POC.

If PFOS or PFOA sampling results are above the EPA PHA, then MTFs should anticipate medical inquiries. The medical POC should also prepare to visit the affected facilities to address any concerns.

The medical POCs should be prepared to discuss the potential health risks due to PFOS/PFOA exposure, reasons why PFOS/PFOA blood testing is not recommended, as well as how to obtain a medical evaluation.



Blood testing for PFOS/PFOA is not medically necessary. While PFC blood tests can measure the level of PFCs in person’s body at the time of the test, and one can compare those levels to those found through other U.S. testing programs, they cannot:

- (1) Tell a person where or how they were exposed to PFCs since there are many other sources of PFC exposure in a person’s living and working environment.
- (2) Tell a person what, if any, health problems might occur, or have occurred, because of PFC exposure.
- (3) Be used by a health care provider to guide individual treatment decisions or additional medical tests. There are no medically approved “treatments” or ways to remove PFCs from a person’s body other than to decrease total exposure in order to reduce body burden over time.

Healthcare providers should perform any routine diagnostic or screening tests as medically indicated, based on their patients’ history, physical examination, and assessment, and not based on PFOS/PFOA levels.

The NMCPHC can provide assistance in the areas of toxicology, risk assessment, risk communication, preventive medicine, and occupational and environmental medicine. NMCPHC POC is Dr. Paul Gillooly, Environmental Programs, at (757) 953-0664 or DSN (312) 377- 0664 or paul.b.gillooly.civ@mail.mil.

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FEDERAL GUIDANCE LEVELS for PFCs

EPA Provisional Health Advisory (2009)

PFOA Provisional Health Advisory = 0.4 µg/L

PFOS Provisional Health Advisory = 0.2 µg/L

Using a 10-kg child consuming 1 L/day. A default relative source contribution (RSC) of 20% was used to allow for exposure from other sources such as food, dust and soil. The relevant period of exposure is a **short-term** exposure. The value should be protective of all population subgroup and lifestages.

EPA DRAFT Health Effects Document for Perfluorooctane Sulfonate (PFOS) (Feb 2014) Office of Water; Health and Ecological Criteria Division; EPA Document Number: 822R14002

DRAFT RfD for PFOS = 0.00003 mg/kg/day Based on rat developmental neurotoxicity and supported by the increases in liver weight and other developmental effects.

There are no data available on dermal absorption of PFOS. In humans, PFOS has been found to distribute mostly to the liver and blood, but has also been identified in umbilical cord blood and breast milk. In humans, the ratio of PFOS identified in the serum and liver tissue are similar, while in animals the amount in the liver is higher than the serum.

The **weight of evidence for the carcinogenic potential** to humans of these tumors was judged to be **too limited to support a quantitative cancer assessment**.

EPA DRAFT Health Effects Document for Perfluorooctanoic Acid (PFOA) (Feb 2014) Office of Water; Health and Ecological Criteria Division; EPA Document Number: 822R14001

Draft RfD for PFOA = 0.00002 mg/kg/day Based on loss of homeostasis and protection against co-occurring adverse effects.

There is evidence that PFOA is absorbed following dermal exposure. In vitro, percutaneous absorption studies of PFOA through rat and human skin result in permeability coefficients for PFOA: **rat**= $3.25 \pm 1.51 \times 10^{-5}$ cm/h **human** = $9.49 \pm 2.86 \times 10^{-7}$ cm/h.



Draft Cancer Slope Factor (CSF) = 0.07 (mg/kg/day)⁻¹ Should not be used at doses greater than 0.58 mg/kg/day (The human equivalent dose corresponding to the point of departure for the 4% incidence of Leydig Cell tumors following lifetime exposure to PFOA.)

Centers for Disease Control and Prevention (CDC) PFOA Fact Sheet (2009)

<http://www.cdc.gov/biomonitoring/PFOAFactSheet.html>

How PFOA Affects People's Health

The human health effects from exposure to low environmental levels of PFOA are unknown. PFOA can remain in the body for long periods of time. In laboratory animals given large amounts, PFOA affected growth and development, reproduction, and injured the liver. More research is needed to assess the human health effects of exposure to PFOA.

STATE GUIDELINES for PFCs

New Jersey Department of Health (DOH) (Accessed Dec 2015)

http://www.state.nj.us/health/eohs/pfc_in_drinkingwater.shtml

Chronic (lifetime) exposure to **PFOA = 40 ppt (ng/L)**.

New Jersey Department of Environmental Protection

DRAFT interim specific ground water criterion for PFNA of 20 ppt (ng/L) – see

<http://www.state.nj.us/dep/dsr/pfna>

Note: A subcommittee of the Drinking Water Quality Institute recommended that the upper limit for perfluorononanoic acid (PFNA) in drinking water should be **no higher than 0.013 parts per billion (ppb) (13 ppt)** in order to safeguard public health.

California State Water Control Board (Revised June 2010)

<http://www.waterboards.ca.gov/gama/docs/pfoa.pdf>

Cites **West Virginia**, where residents must be provided with alternative drinking water when PFOA levels exceed **0.5 parts per billion (ppb, or 0.5 µg/L)** and **North Carolina** where a regulatory standard of **1.6 µg/L** has been proposed, but not adopted.

Minnesota Department of Health

<http://www.health.state.mn.us/divs/eh/hazardous/topics/pfcshealth.html>



MDH has developed drinking water criteria, known as Health Risk Limits (HRLs) for PFOA, PFOS, PFBA, and PFBS. HRLs represent levels of chemicals in drinking water that MDH considers safe for people, including sensitive populations.

PFOA: 0.3 micrograms per liter (µg/L)

PFOS: 0.3 (µg/L)

PFBS: 7 (µg/L)

PFBA: 7 (µg/L)

Delaware Health and Social Services, Division of Public Health (June 2014)

<https://dhss.delaware.gov/dph/hsp/alerts/artesianwatercopfos061214.html>

Studies of broad negative impact on humans are inconclusive. Given its common use, the Centers for Disease Control and Prevention, estimates that perfluorinated chemicals, like PFOS and PFOA, are present in the blood of 98% of the United States population.

In laboratory animals, studies indicate that PFOA and PFOS can cause developmental, reproductive, and other adverse effects, including tumors. There is **no conclusive evidence** that PFOA or PFOS causes cancer in humans. Some increases in prostate and bladder cancer have been seen in workers with significant exposure through their job but the actual cause of the cancers is unknown. Based upon the differences between animals and humans, scientists have not determined a direct link between the chemicals and cancer in humans.

A few studies of pregnant women found higher levels of PFOA and PFOS to be associated with slightly lower weight babies, meaning it may or may not have been the cause of the slightly lower birth weights. The **most consistent findings from studies** are elevated blood cholesterol levels among exposed populations.

Massachusetts Department of Environmental Protection (May 2015)

<http://www.mass.gov/eea/docs/dep/water/drinking/standards/pfos-fs.pdf>

In laboratory studies, animals exposed to levels of PFOS far above the US EPA's Provisional Health Advisories exhibited low birth weight and slow growth, increased liver weights, and effects on thyroid hormones. Some studies have suggested that PFOS may cause certain types of cancer but the evidence is limited. The levels at which PFOS may cause health effects due to long-term exposures are a matter of ongoing research.

If your water is at or below the provisional health advisory, you can use it to drink, cook, and make ice and infant formula. If it is above, the answer to these questions will depend upon the level of PFOS in the water and must be considered on a case-by-case basis. If the level exceeds the US EPA Provisional Health Advisory, as a precaution, you may choose to use bottled water (see more on this below) or water from another clean source for these uses, in particular to make infant formula or other infant foods or beverages.



Maine Center for Disease control and Prevention (March 2014)

<https://www1.maine.gov/dhhs/mecdc/environmental-health/eoph/wells/documents/pfoameg.pdf>

Maximum Exposure Guideline (MEG) = 0.1µg/L

Overall, the MECDC MEG for PFOA in drinking water of 0.1µg/L was developed using methods largely in line with USEPA guidelines for developing drinking water equivalent levels (USEPA, 2000). The MECDC PFOA MEG is within the range (0.04 – 1µg/L) of other health-based drinking water values for PFOA developed by the USEPA, New Jersey, Minnesota and North Carolina. In comparison to PFOA serum levels and estimated drinking water levels that have been associated with adverse health effects from epidemiological studies involving PFOA, the MEG is within the range of some serum levels associated with adverse human health effects. The MEG is slightly above serum levels associated with immune suppression in children. However, these immunological studies involved exposures to PFOA and PFOS, additional PFCs and possibly other immunosuppressive contaminants. Consequently, it is difficult to fully assess the sole impact of PFOA on immune responses in these studies due to the presence of other immunosuppressive contaminants.

It will be important to stay up to date with emerging epidemiological studies to better assess the relevance of the MECDC PFOA MEG. The MEG was developed using the available risk assessments and primary peer-reviewed literature. The USEPA is in the process of developing a RfD for lifetime exposures and subsequent maximum contaminant level for PFOA in drinking water and have recently released a draft PFOA risk assessment for public comment and peer-review⁷. The MECDC may consider revision of the current PFOA MEG once the USEPA draft PFOA risk assessment and RfD have gone through public and peer-review and a final PFOA RfD published.

INTERNATIONAL GUIDELINES for PFCs

DENMARK: Danish EPA (Accessed Dec 2015)

<http://www2.mst.dk/Udgiv/publications/2015/04/978-87-93283-01-5.pdf>

Quality Criteria (QC)_{dw} = 0.3 µg/L for daily intake of drinking water

This report also cites other countries' drinking water standards including:

Germany: German Minstry of Health (2006)



PFOS (health based level) = 0.3 µg/L

PFOA (health based level) = 0.3 µg/L

United Kingdom: (2007)

PFOA Maximum Acceptable Concentration (in drinking water) = 10 µg/L

Tier 1 level > 0.3 µg/L: at this level the local health professionals should be consulted and increased monitoring established.

Tier 2 level > 10 µg/L: further to put in place measures to reduce concentrations to below 10 µg/l as soon as is practicable.

Tier 3 level >90 µg/L: ensure consultation with local health professionals takes place as soon as possible; take action to reduce exposure from drinking water within 7 days. (DEFRA, 2008)

PFOS Maximum Acceptable Concentration (in drinking water) = 0.3 µg/L

Tier 1 level > 0.3 µg/L: at this level the local health professionals should be consulted and increased monitoring established.

Tier 2 level > 1.0 µg/L: further to put in place measures to reduce concentrations to below 1.0 µg/l as soon as is practicable.

Tier 3 level >9 µg/L: ensure consultation with local health professionals takes place as soon as possible; take action to reduce exposure from drinking water within 7 days.

Netherlands: (RIVM 2011)

Drinking Water Maximum Tolerable Level PFOS = 0.53 µg/L

Sweden: (Livsmedelsverket 2014)

Drinking Water Maximum Tolerable Level PFOS = 0.09 µg/L

(Based on a Tolerable Daily Intake (TDI) of 0.15 µg/kg bw/d derived by EFSA (2008) and considering an exposure scenario where 10% of this value was allocated to the consumption of infant formula based on drinking water.)



TOXICOLOGY and RISK ASSESSMENT SUMMARY for PFCs

EPA Provisional Health Advisory (2009)

Toxicity (Noncancer)

The subchronic toxicity study in Cynomolgus monkeys (Seacat et al., 2002) was selected by the OW as the critical study for the derivation of the Provisional Health Advisory value for **PFOS**. A NOAEL of 0.03 mg/kg/day was identified in this study.

A developmental toxicity study in mice was selected as the critical study for the derivation of the provisional Health Advisory for **PFOA** (Lau et al., 2006). The lowest BMDL₁₀ was 0.46 mg/kg/day for increase in maternal liver weight at term.

Toxicity (Cancer)

Data are not sufficient to make an evaluation.

Risk Calculations

The following Provisional Health Advisory is obtained: **PFOA = 0.4 µg/L**
PFOS = 0.2 µg/L

EPA DRAFT Health Effects Document for PERFLUOROCTANE SULONATE (PFOS): Office of Water; Health and Ecological Criteria Division (Feb 2014)

Toxicity (Cancer)

Based on the available evidence, the data are inadequate to support a PPAR α -linked MOA for the liver and thyroid adenoma's observed by Thomford (2002) in the chronic two year bioassay in Crl:CD(SD)IGS BR rats. A dose-response pattern was not observed although the test for trend was positive (P=0.03) for the liver tumors. The classification for of PFOS under the U.S. EPA Guidelines for Carcinogen Risk Assessment is currently consistent with the ***suggestive evidence of carcinogenic potential descriptor***.

EPA DRAFT Health Effects Document for PERFLUOROCTANIC ACID (PFOA): Office of Water; Health and Ecological Criteria Division (Feb 2014)

Toxicity (Cancer)

Despite the limitations in the data for the Leydig cell and pancreatic tumors, a finding of ***suggested evidence of carcinogenicity*** is justified and quantification of the dose response is not recommended. The tumor dose-response data are not indicative of a high potency, and the



dose-response information from the noncancer studies indicate that protecting for several of the noncancer effects will result in an RfD that will be protective for any tumorigenic effects.

New Jersey Department of Health (Accessed DEC 2015)

http://www.state.nj.us/health/eohs/pfc_in_drinkingwater.shtml

Toxicity (Noncancer)

In humans, exposure to PFCs before birth or in early childhood may result in decreased birth weight, decreased immune responses, and hormonal effects later in life.

Toxicity (Cancer)

In a community significantly exposed to PFOA through drinking water, PFOA exposure was associated with higher incidence of kidney and testicular cancers

Michigan (September 2014)

Selection of PFOS Fish Consumption Screening Values (FCSVs)

Risk Calculations

The human equivalent dose (4.1×10^{-4} mg/kg/d) associated with the NOAEL was divided by a total uncertainty factor of 30 resulting in an ***Interim RfD of 1.4×10^{-5} mg/kg/d.***

