

**Catskill Mountainkeeper · Citizen Action of NY · Citizens Campaign for the Environment  
Delaware Riverkeeper Network · Environmental Advocates of New York  
Food & Water Watch · Hudson River Sloop Clearwater, Inc.  
Natural Resources Defense Council · New York League of Conservation Voters  
Riverkeeper, Inc. · Scenic Hudson, Inc. · Water Defense**

May 22, 2018

The Honorable Andrew M. Cuomo  
Governor of New York State  
NYS State Capitol Building  
Albany, NY 12224

***Re: Request to Promptly Establish a Stringent, Enforceable MCL for PFOA and PFOS***

Dear Governor Cuomo:

The undersigned organizations, on behalf of their members across the state and around the nation, are writing to request that you direct the New York State Department of Health (the “Department”) to promptly establish a stringent, enforceable MCL for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

As you have recognized, PFOA and PFOS contamination has become a significant public health threat in communities from coast to coast. Numerous studies have linked these contaminants to serious health risks, including cancer. Blood serum concentrations of PFOA and PFOS have been found to be about ten times the national average in residents living in Hoosick Falls, New York. And elevated levels of PFOA and PFOS have been discovered in New Windsor, Fort Drum, Hempstead, Petersburg, Newburgh, Hampton Bays, Cambridge, and Yaphank, and may well be found in other communities across the state.

We believe that, in the absence of stringent federal safeguards, New York State must act to protect drinking water, reduce risks to the public, and remediate the contaminated drinking water sources. The current situation—the profound effects related to exposure, the very long periods that PFOA and PFOS are present in water absent filtration, and the very long half-lives that result in continued elevated blood serum levels even after exposure ceases—requires swift adoption of a stringent combined MCL for PFOA and PFOS.

Since the 1960s, manufacturers used PFOA or PFOS in a variety of products, including nonstick cookware (e.g., Teflon), stain-resistant repellents used on carpets and fabric (e.g., Scotchgard and Stainmaster), paper and cardboard food packaging (e.g., fast food wrappers), firefighting foam, textiles (e.g., Gore-Tex), toothpaste, shampoos, cosmetics, polishes and waxes, and many products for the aerospace, automotive, construction, and electronic industries.

While PFOA and PFOS do not occur naturally in the environment, due to widespread use of these two chemicals, PFOA and PFOS are now ubiquitous in our environment—present in rivers, soil, air, house dust, food, and drinking water from surface and groundwater sources. PFOA and PFOS are extremely persistent, resistant to environmental degradation. They can move through the soil and into groundwater and remain there for many years. As a result, although American manufacturers have stopped producing PFOA and PFOS, these compounds remain in the environment, seeping into groundwater and staying there.

Both PFOA and PFOS are known to bioaccumulate in the body of people of all ages, even before birth. Once ingested or inhaled, PFOA and PFOS remain in the body for several years. As such, PFOA and PFOS are present in the blood serum of almost every human around the world. Between 1999 and 2012, one or both of the chemicals were detected in 99 percent of the general population.

Drinking water is a major source of exposure to PFOA and PFOS for people living in communities whose water supplies have been contaminated with these chemicals. And even relatively low PFOA and PFOS concentrations in drinking water are associated with substantial increases in blood serum levels. Since the clearance of PFOA and PFOS from the body is slow and these contaminants accumulate in blood, after a long period of exposure, a person's PFOA and PFOS levels in blood serum can be up to 100 times greater than the concentrations of PFOA and PFOS concentration in their drinking water. In addition to several types of cancers, PFOA and PFOS have been linked to an array of other serious health effects, including low birthweight, accelerated puberty, harm to the immune system, lower sperm quality, high cholesterol, obesity, and disorders of the thyroid and liver.

While EPA has taken nominal steps to address PFOA and PFOS, there is no indication that it or any other federal agency now intends to set a stringent, enforceable standard regulating the presence of these chemicals in drinking water. The federal government's obstinacy is affirmed by press accounts that suggest that EPA has sought to block publication of an U.S. Department of Health and Human Services study that found that exposure to PFOA and PFOS at concentrations below 12 ppt could be dangerous to human health.

In the absence of federal regulation, a handful of states are already taking affirmative action to regulate PFOA and PFOS in drinking water, including New Jersey (pending MCL for PFOA at 14 ppt), and Vermont (combined groundwater enforcement standard of 20 ppt).

We have attached to this letter a report prepared by Judith Schreiber, Ph.D., former Chief Scientist at the Environmental Protection Bureau of the New York State Office of the Attorney General and former Section Chief of Environmental Research at the New York State Department of Health. This report, using the same database as EPA and states, provides the basis for our recommended MCL of between 4 and 10 ppt.

Setting an MCL for PFOA and PFOS is long overdue. The serious adverse effects of exposure and the confirmed highly elevated drinking water concentrations cry out for the swift setting of a protective MCL. There will never be a better time than right now for you to once again provide national environmental leadership by setting the toughest standard in the nation for the troublesome unregulated water contaminants PFOA and PFOS. We stand ready to work with you to advance this sensible drinking water protection initiative without delay.

Sincerely,



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Catskill Mountainkeeper



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**PFOA EXPOSURE AND HEALTH RISK SYNOPSIS**

**prepared on behalf of the  
NATURAL RESOURCES DEFENSE COUNCIL\***

By

Judith S. Schreiber

Schreiber Scientific, LLC

February 26, 2018

*\*This report was funded by the Natural Resources Defense Council (NRDC). The views contained herein are those of the author and do not necessarily reflect those of NRDC.*

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## EXECUTIVE SUMMARY

Perfluorooctanoic acid (PFOA) is a member of the class of fluorinated substances called perfluorochemicals (PFCs). PFCs are part of a larger group of chemicals called poly- and perfluoroalkyl substances (PFAS), and includes perfluorooctane sulfonic acid (PFOS). These chemicals do not occur naturally, are resistant to environmental degradation and therefore persist in water, soil, dust, food, and other sources. With half-lives of several years, PFCs also persist in people and are found in the blood serum of almost all U.S. residents and populations worldwide. PFOA is among the most commonly identified of the PFCs, is often used in animal exposure studies, and is used in water analyses as a representative measure for combined PFC exposures.

Widespread use of PFCs has resulted in the ubiquitous presence of these chemicals in the environment including in rivers, soil, air, house dust, food, and in drinking water from both surface and groundwater sources. We are all exposed to small amounts by inhaling house dust from prior uses for water-repellent textiles (for example from treatment on upholstery) and from ingesting small amounts in food, food packaging, and drinking water.

Drinking water becomes the dominant source of exposure to PFCs for people living in communities with drinking water contaminated with these chemicals, far exceeding low levels of exposure from other sources. People exposed to PFOA contaminated drinking water will have higher levels of PFOA in blood serum due to persistence and bioaccumulation. After chronic exposure, blood serum levels will be about 100 times the level of PFOA in drinking water. For infants, PFOA exposure may be further elevated due to the ingestion of PFOA in breastmilk and from infant formula prepared with contaminated drinking water.

In experimental animals, PFCs have been found to cause developmental, immune, neurobehavioral, liver, endocrine, and metabolic toxicity, generally at levels well above human exposures to the general population. However, for people ingesting contaminated drinking water, PFOA concentrations may approach levels that increase risks for adverse effects.

Exposure to PFOA is associated with significant adverse health effects including developmental effects to fetuses during pregnancy, the neonatal period and puberty (low birthweight, skeletal variations, accelerated puberty, mammary gland development), cancer (testicular, kidney), liver effects (tissue damage), immune system effects (antibody production and immunity), thyroid effects and other effects (cholesterol changes). Effects on fetal development and the young have been studied in both humans and animals, which find similar adverse effects. PFOA and PFOS toxicological studies have found increases in tumors in rodents as well as in people. PFOA and PFOS are classified as likely carcinogens (chemicals that cause cancer) by the U.S. Environmental Protection Agency, the Science Advisory Board, the International Agency for Research on Cancer, and the Report of the C8 Scientific Advisory Panel.

Risk assessment for public health protection must account not only for what is known about a chemical's adverse effects, but also what is not known about differences between toxic effects in animals compared to humans; children compared to adults; differences in absorption, metabolism and excretion; and other unknowns. Scientists use uncertainty factors to provide a margin of safety between levels that cause an adverse effect to levels that are deemed acceptable. We don't want people to be exposed to levels that cause effects in animals. Uncertainty factors are applied to account for the adverse effects at a particular level of exposure, as well as incomplete understanding or availability of studies upon which toxicity is appraised.

Using the same database as the U.S. Environmental Protection Agency (USEPA) and the states, using mammary gland and developmental effects as the most sensitive endpoints, and applying a more protective combined uncertainty factor of 1,000 rather than 300, an MCL range of 4 to 10 ppt is derived. This range of MCLs is within the limit of detection for PFOA and PFOS (can be reliably measured), and within the capability of Granular Activated Carbon (GAC) to remove PFOA and PFOS (can be reliably removed), demonstrating the feasibility of an MCL as low as 4 ppt. Analytical testing should be conducted at levels as close to 1 ppt as possible.

New York State should adopt an MCL in the range of 4 ppt to 10 ppt for PFOA and PFOS combined exposure for the protection of public health based on known serious adverse health effects and increased cancer risks. The MCL should be periodically revisited to determine whether newer studies suggest the MCL to become more stringent.

In addition to adopting an MCL, we recommend that NYS conduct a comprehensive survey of drinking water sources, beginning with water sources near potential contributors to contamination such as PFOA/PFOS manufacturing and packaging facilities, fire fighting areas with a history of using PFOA/PFOS, landfills, and airports. We also recommend that comprehensive health surveys be conducted for communities with PFOA contamination. Finally, we recommend that the Drinking Water Quality Council form an Advisory Board to consider infant exposure to PFOA via breastmilk to develop recommendations for mothers and pediatricians.

## INTRODUCTION

Perfluorooctanoic acid (PFOA) is a fluorinated eight carbon chain chemical member of the class of substances called perfluorochemicals (PFCs). PFCs are part of a larger group of chemicals called poly- and perfluoroalkyl substances (PFAS), and includes perfluorooctane sulfonic acid (PFOS). These chemicals do not occur naturally. PFOA and PFOS have been manufactured since the 1960s for use in coatings for clothing, leather, upholstery, and carpets; for fire-fighting foams; in paints, adhesives, waxes and polishes and other products; and industrially as surfactants, emulsifiers, wetting agents, additives and coatings (Ballesteros et al., 2017; Post et al., 2012; USEPA, 2016a).

PFOA and other PFCs including PFOS are resistant to environmental degradation and persist in the environment. They are relatively water-soluble, and have been detected in drinking water sources and in finished (treated) drinking water. Due to their water solubility, after exposure by any route, these chemicals are found in human blood serum rather than in body fat where fat-soluble chemicals such as PCBs reside. With half-lives of several years, PFCs persist in humans and are found in the blood serum of almost all U.S. residents and populations worldwide (CDC, 2015; Post et al., 2012). PFOA is among the most commonly identified of the PFCs, and is often used in animal exposure studies, and in water analyses as a representative measure for combined PFC exposures.

PFOA, PFOS and other PFCs are commonly found together in samples from contaminated water and are identified as co-contaminants in blood serum. These contaminants are structurally similar, and it is reported that the health risks associated with one PFC are expected for other PFCs as well (Lau et al., 2007; Lilienthal et al., 2017; Post et al., 2011). This

report will focus on PFOA, with mention of PFOS and other PFCs, where noted, because PFOA is the most commonly studied chemical of all of the PFCs.

While some scientific uncertainties exist, the human health impacts of exposure to PFOA and related chemicals are acknowledged to have profound effects on the young, are likely carcinogens, are extremely persistent, and are highly bioaccumulative. The weight of scientific evidence is substantial: in experimental animals, in exposed residential populations drinking contaminated water, and in occupational studies, that PFOA and related compounds cause effects on the young and increase cancer risks in exposed populations.

We do not believe that most of New York State's water supplies are contaminated with PFOA; however, the sources that are contaminated are likely to be significantly elevated. Until a comprehensive statewide survey of drinking water sources is conducted, an estimate of the extent to which populations are exposed cannot be determined.

In the absence of federal safeguards, New York State must act to protect drinking water, reduce risks to the public and remediate contaminated drinking water sources. The current situation requires swift adoption of a stringent Maximum Contaminant Level (MCL) for PFOA, due to the serious effects related to exposure, the very long periods that PFOA and related chemicals will be present in water, and the very long half-lives that result in continued elevated blood serum levels in people even after exposure ceases.

This report contains four parts: Part I provides an overview of the presence of PFOA and PFOS in the general public and exposed populations. Part II identifies established health risks associated with exposure. Part III outlines existing PFOA and PFOS health advisories in drinking water and discusses a proposed MCL for New York State. Part IV offers

recommendations as to how New York can protect its residents from the health effects associated with PFOA and PFOS exposure.

**The recommendations in this report are summarized as follows:**

1. Due to increased cancer risk and known serious adverse developmental effects of exposure to PFOA and related chemicals, New York State should set a Maximum Contaminant Level (MCL) in the range of 4 to 10 ppt (parts per trillion) for combined levels of PFOA and PFOS in drinking water.
2. New York should conduct a statewide survey of drinking water sources to ascertain the degree to which public water supplies are contaminated, and the data should be made available to the public. First priority for testing should be public water supplies near former PFOA and PFOS manufacturing facilities, and near fire-fighting areas and airports where these chemicals were used. We understand that such a survey is contemplated and we urge speed and low-detection levels in its conduct. Additionally, the state should offer testing of drinking water from private wells in the vicinity where elevated PFOA and/or PFOS have been identified.
3. New York should carry out a more comprehensive health assessment of exposed residents in communities found to have elevated PFOA or PFOS concentrations in drinking water.
4. Women who are exposed to elevated PFOA in drinking water and are breastfeeding should be advised of the benefits and risks of breastmilk, and provided advice to discuss with their family doctor and pediatrician. The Drinking Water Quality Advisory Council may be in a position to assist in providing such guidance to physicians and families.

## **I. EXPOSURE TO PFOA**

Almost all Americans tested have one or more PFCs in their bodies (Hu et al., 2016; Kato et al., 2011). Widespread use of PFCs has resulted in the ubiquitous presence of these chemicals in the environment including in rivers, soil, air, house dust, food and drinking water from surface and groundwater sources. We are all exposed to small amounts by inhaling house dust from prior uses for water-repellent textiles (for example from treatment on upholstery) and from ingesting small amounts in food and food packaging.

Drinking water becomes the dominant source of exposure to PFCs for people living in communities with drinking water contaminated with these chemicals, far exceeding low levels of exposure from other sources. Other sources of PFC exposure include food, food packaging, consumer products, house dust, indoor and outdoor air, and at workplaces where PFCs are made or used (NJDOH, May 2016; USEPA, 2016a). The national geometric mean for PFOA in drinking water is 4.13 ppt (CDC, 2015). A report by Hu et al., 2016, reported that about 4% of public water supplies in the U.S. (about 200 of 5,000 public water supplies studied), serving 16.5 million Americans in 33 states, 3 territories and an American Indian community, have measurable levels of PFCs.

According to the U.S. Environmental Protection Agency (USEPA), sixty-six public water supplies, serving six million Americans, had at least one sample above that agency's 2016 PFOA health advisory of 70 ppt. PFOA was the most frequently detected PFC in drinking water, followed by PFOS. Drinking water from 13 public water supplies accounted for 75% of PFCs detected in the US. Exceedances of the USEPA's health advisory have been detected in California, New Jersey, North Carolina, Alabama, Florida, Pennsylvania, Ohio, New York,

Georgia, Minnesota, Arizona, Massachusetts and Illinois (Hu et al., 2016). High levels of PFOA and other PFCs in drinking water were strongly associated with proximity to major PFOA industrial sites, civilian airports, and military fire training areas (Hu et al., 2016).

Even relatively low PFOA concentrations in drinking water are associated with substantial increases in blood serum levels. Since the clearance of PFOA is slow and it accumulates in blood, after a long period of exposure, a person's blood serum PFOA level will be about 100 times greater than the PFOA concentration ingested via drinking water (Post et al., 2012).

Vesterfren and Cousins, 2009, evaluated the contribution of water, diet, air and other sources for various exposure scenarios. They found that when drinking water concentrations are in the typical background concentration of 1.3 ppt, dietary exposure is the dominant source of exposure. However, when drinking water concentrations are elevated (they use 40 ppt as an example), the ingestion of contaminated water becomes the predominant exposure. As contamination levels increase, drinking water becomes the overwhelming source of exposure. Drinking water concentrations of 100 ppt and 400 ppt are predicted to contribute 71% and 91%, respectively, of total exposure; and are estimated to increase serum levels, on average, by 250% and 1000%, respectively (Post et al., 2012).

Detection sensitivity of PFOA and PFOS varies, as it is dependent on the method of analysis used to quantify the results. In the United States, the method used to detect PFCs is generally less sensitive than the detection limit in the European Union. Because of this difference in analytical detection methodology, U.S. samples are not detected at very low levels. In U.S. samples, the quantified reporting limit is generally in the range of 4-5 ppt. Generally,

laboratories use USEPA Method 537 or a modified version, as described by Shoemaker et al., 2009. In Europe, the reporting limit is less than 0.85 ppt (Post et al., 2012). If the sample detection limit is lower, it is likely that more samples would be found to contain measurable amounts of PFOA and other PFCs. The relatively high minimum reporting limits in some surveys, some of which were more than 10 ppt (Hu et al., 2012), suggest that more samples would have been detected had the detection level been lower.

Methodology is available that can achieve detection levels of 1 ppt and less.

#### **A. Presence of PFOA and PFOS in People**

Persistent chemicals such as those in the PFC family are characterized by long periods during which the body retains these chemicals after exposure ceases (USEPA, 2016a and b). Both PFOA and PFOS are known to bioaccumulate in people of all ages, even before birth. USEPA estimates that the half-life of PFOA is 2.3 years. (The half-life is the time it takes to reduce the concentration by half.) For PFOS, the half-life is estimated to be more than 8 years.

Because the use PFOA and PFOS in manufacturing has been phased out in the United States, PFOA and PFOS levels in blood serum have decreased in recent years. But because PFOA and PFOS bioaccumulate and are not excreted by the body, and because PFOA and PFOS do not readily degrade and persist in water systems absent filtration, PFOA and PFOS will continue to be present in the general population as well as in exposed populations for many years in the future. The National Health and Nutrition Examination Survey (NHANES) have evaluated blood serum concentrations of PFOA and PFOS in a large representative sample of the U.S. populations age 12 and older. The PFOA geometric mean blood serum concentration for survey years 1999-2000 was 5,210 ppt, with a 95th percentile of 11,900 ppt. For survey years

2007-2008, the PFOA geometric mean was 4,130 ppt, with a 95th percentile level of 9,700 ppt (Kato et al., 2011).

## **B. Fetal and Infant Exposure**

Almost all fetuses and infants will have some degree of exposure (Post et al., 2012; NJDOH, May 2016), including fetal exposure during pregnancy. For infants, PFOA exposure may be further elevated due to ingestion of contaminated breastmilk (a result of the mother's ingestion of contaminated water, and other sources) or infant formula prepared with contaminated drinking water. The mother passes PFOA via her breastmilk, resulting in a reduction of PFOA in the mother and an increase in PFOA in her infant.

There are limited studies of the concentrations of PFOA and PFOS in breastmilk in the general population, finding a range for PFOA of 47 to 210 ppt, and a range of 45 to 360 ppt for PFOS (Man et al., 2006). The levels in breastmilk are much higher than what is typically found in drinking water (about 1 to 4 ppt), due to the mothers' past accumulated exposures and transfer to breastmilk.

PFOA levels (and other PFCs) were measured in blood serum and in breastmilk in a residential population in Ohio exposed to PFOA in drinking water at elevated levels. A mean PFOA blood serum concentration of 28,000 ppt in maternal blood serum resulted in breastmilk PFOA levels of about 700 to 1,000 ppt (2.5% to 3.8% of blood serum level). The geometric mean blood serum concentration for breastfed children in this population was 32,000 ppt (Mondal et al., 2012), higher than the maternal blood serum concentration.

Breastmilk PFOA levels will be higher than drinking water PFOA concentrations ingested by the mother. This is because the PFOA maternal blood serum level is approximately 100 times greater than the drinking water she ingested over time, and 2.5% to 3.8% of the maternal blood serum PFOA concentration will be found in her breastmilk (Post et al., 2011). The State of Minnesota Department of Health estimated a breastmilk transfer factor of 5.2% (Minnesota DOH, 2017a). Therefore, breastmilk is estimated to contain about 2.5 to 5 times the concentration in drinking water. There are many variables regarding transfer of chemicals to breastmilk, and there is a paucity of data upon which to derive these estimates. More comprehensive testing of breastmilk PFOA concentrations, especially for women drinking PFOA contaminated drinking water, will help in determining the degree of exposure via breastmilk.

The degree to which fetuses and nursing infants are exposed via breastmilk is influenced by the mother's past exposures and body burden, as measured by blood serum. Older mothers tend to have higher body burdens due to past cumulative exposures over time. First-born babies receive a higher dose via breastmilk than subsequent infants. (Papadopouou et al., 2016; Post et al., 2012; Wu et al., 2015.)

### **C. PFOA Contamination in Hoosick Falls and Other Locations in New York State**

The Village of Hoosick Falls, New York has been identified as contaminated with PFOA after the New York State Department of Health (NYSDOH) detected the chemical in the public water system at levels ranging from 151 to 662 ppt. Private wells were found to have PFOA levels ranging from 14.4 to 194 ppt (NYSDOH, 2015).

Drinking water samples collected from October 2014 to February 2015 (number of samples, n = 26) from Hoosick Falls public water supply system before treatment ranged from

150 to 540 ppt with a geometric mean of 292 ppt. Additional samples collected from June 2015 to February 2016 (n = 178) found PFOA levels ranging from 2 ppt to 1010 ppt and a geometric mean of 235 ppt. NYSDOH reported an overall geometric mean of 316 ppt for Hoosick Falls drinking water samples (NYSDOH, 2016). Routine water treatment did not result in decreased concentrations; 5 samples analyzed post-treatment ('finished water') found a reported range of 440 to 530 ppt and a geometric mean of 483 ppt. (These samples were not matched pairs.)

These levels far exceed typical PFOA background concentrations in drinking water of about 1 to 5 ppt; with a geometric mean of 4.13 ppt (CDC, 2015).

Hoosick Falls residents' geometric mean blood serum was reported by NYSDOH as 23,500 ppt – about 10 times higher than the U.S. population background for blood serum of 2,080 ppt. Studies have determined that in people long term ingestion of PFOA in drinking water will result in blood serum levels of PFOA about 100 times higher than the concentration in the water. To reach a mean blood serum PFOA concentration of 23,500 ppt, the mean PFOA drinking water concentration is estimated to be 235 ppt – similar to the geometric mean of 300 ppt in drinking water reported by NYSDOH for Hoosick Falls. This suggests that residents' exposure via contaminated drinking water has been on-going because the bioaccumulation in blood serum is nearly 100 times higher than the concentration of PFOA in drinking water.

Other areas in New York State have also found PFOA at elevated concentrations. The City of Newburgh public water supply reported a range of 146 ppt to 155 ppt with a geometric mean PFOA of 150 ppt (n = 4) in March 2016. Subsequently, the water source was changed to a non-contaminated source. ([http://www.cityofnewburgh-ny.gov/sites/newburghny/files/minutes/minutes-file/2016-05-09\\_council\\_minutes.pdf](http://www.cityofnewburgh-ny.gov/sites/newburghny/files/minutes/minutes-file/2016-05-09_council_minutes.pdf)).

Newburgh residents are continuing to receive water from New York City's municipal supply due to the continued risks from PFOA in Newburgh's public water supply.

Well water sampling in Petersburg by the Rensselaer County Department of Health identified many groundwater areas contaminated with PFOA; most were non-detect to 20 ppt, but some water samples exceeded 1,000 ppt (Rensselaer County DOH, 2016). In Suffolk County, the NYS Department of Environmental Conservation found groundwater wells in Westhampton to be contaminated with PFOS and PFOA, likely from firefighting foam used at the Air National Guard Base at the Gabreski Airport in Westhampton (Southampton Press, 2017).

## **II. HEALTH RISKS ASSOCIATED WITH EXPOSURE**

Sufficient information exists to evaluate the adverse health effects and cancer risks of PFCs in humans and in animals. Both human studies and animal studies are used to evaluate adverse effects of chemical exposures. In the case of PFOA and PFOS, the animal and human studies show similar adverse effects and cancer risks, elucidated below. Due to structural similarity and the co-occurrence of PFOA and PFOS in the environment and in people, public health protection and guidance address both PFOA and PFOS.

Several recent comprehensive reviews of the scientific literature have been published (Dong et al., 2017; Post et al., 2012; Lilienthal et al., 2017; Winkens et al., 2017; Ballesteros et al. 2017; Chang et al., 2016; C8 Science Panel Report, 2017). In experimental animals, PFCs have been found to cause developmental, immune, neurobehavioral, liver, endocrine, and metabolic toxicity, generally at levels well above human exposures to the general population.

However, for people ingesting contaminated drinking water, PFOA concentrations may approach levels that increase risks for adverse effects. The most consistent human health findings for PFOA (the most well studied of the PFCs), are increases in serum cholesterol, liver enzymes, and uric acid levels in people exposed to elevated levels found in drinking water (see NJ Department of Health, May 2016).

Exposure to PFOA over certain levels may result in significant adverse health effects including developmental effects to fetuses during pregnancy, the neonatal period and puberty (low birthweight, skeletal variations, accelerated puberty, mammary gland development), cancer (testicular, kidney), liver effects (tissue damage), immune system effects (antibody production and immunity), thyroid effects and other effects (cholesterol changes). (USEPA, 2016c, Grandjean and Budtz-Jorgensen, 2013.) Effects on fetal development and the young have been studied in both humans and animals, which find similar and profound adverse effects, discussed below.

#### **A. Risks Associated with Effects on Fetal Development and the Young**

Since infants and children consume more water per body weight than adults, their exposures may be higher than adults in communities with PFCs in drinking water. Infants may also be exposed via contaminated breastmilk, and/or by infant formula prepared with PFOA contaminated water. In addition, the young also may be more sensitive to the effects of PFCs due to their immature developing immune system, and rapid body growth during development (Apelberg et al., 2007; Ballesteros et al., 2017; Johnson et al., 2014; Rappazzo et al., 2017). In people, exposure to PFCs before birth or in early childhood may result in decreased birthweight, decreased immune responses, and hormonal effects later in life.

Recent literature has identified developmental effects of significance. In particular, prenatal exposure of mice to PFOA found adverse effects on mammary gland development on offspring of treated females. These effects included delayed mammary gland development, fewer terminal end buds, and increased liver weights in the offspring (Macon et al., 2011). This study found that PFOA-induced effects on mammary tissue occur at lower doses than the effects on liver weight, and that adverse effects were observed at all dose levels. Due to the low-dose sensitivity of mammary glands to PFOA in mice, a no-observable adverse effect level for mammary gland developmental delays could not be determined. In other words, all dose levels found adverse effects.

A review of effects on children was published by Rappazzo et al., 2017. Sixty-four studies were evaluated for six categories of health outcome: immunity, infection, asthma, cardio-metabolic, neurodevelopmental/attention, thyroid, renal, and puberty onset. They found evidence of delayed mammary gland development, later age at menarche (menstruation), effects on renal function, and asthma. Adverse effects of PFOA and PFOS on sperm quality in U.S. men (Louis et al., 2017), and endometriosis in U.S. women (Campbell et al., 2017) have been reported. Immunotoxicity was reported in a study of children based on serum concentrations and vaccine antibody responses (Grandjean and Budtz-Jorgensen, 2013).

The USEPA in its Fact Sheet on PFOA and PFOS Drinking Water Health Advisories (USEPA, November 2016c) notes that “exposure to PFOA and PFOS over certain levels may result in adverse effects, including developmental effects to fetuses during pregnancy or to breastfed infants”. These include low birth weight, accelerated puberty, skeletal variations, liver effects, immune effects, thyroid effects, cholesterol changes, and cancer (testicular and kidney).

## **B. Cancer Risks**

PFOA and PFOS toxicological studies have found increases in tumors in rodents as well as in people. The USEPA Science Advisory Board, the International Agency for Research on Cancer, and the report of the C8 scientific advisory panel have identified PFOA and PFOS as likely carcinogens. Carcinogens are chemicals that cause cancer.

Evidence of carcinogenic effects of PFOA in humans is based on studies of kidney and testicular cancer in occupational settings where increased cancer incidence was found (USEPA, 2016a and b). In a New Jersey community significantly exposed to PFOA through drinking water (data not provided), PFOA was associated with higher incidence of kidney and testicular cancers. (NJDOH, 2016; Barry et al., 2013). Blood serum median concentrations of PFOA in this study population was 28,000 ppt, very similar to the residents of Hoosick Falls where blood serum median levels were 23,500 ppt.

Studies of people working with and exposed to PFOA (occupational exposure) have shown associations between PFOA and prostate cancer (Steenland et al., 2015), and bladder cancer (Raleigh et al., 2014). Occupational exposure in 3M and Dupont workers found serum geometric mean PFOA levels ranging from 410,000 to 1,125,000 ppt (NYSDOH, June 2017).

NYSDOH conducted an evaluation of cancer occurrence in the Hoosick Falls population. In that study, no relationship was found between PFOA exposure and testicular cancer, kidney cancer, prostate cancer and bladder cancer. While the investigators did not find evidence for increased cancer risk in this community, studies of community exposures have inherent limitations and are difficult to study in low number populations. As noted by NYSDOH, limitations of this study include small population, incomplete inclusion of the potentially

exposed populations and inclusion of only cancer as endpoints of adverse effects (NYSDOH, May 2017).

### **III. HEALTH ADVISORIES AND DERIVATION OF AN MCL FOR PFOA**

A Maximum Contaminant Level (MCL) is the legal threshold of the amount of a chemical that is allowed in public water systems under the Safe Drinking Water Act. The MCL is an enforceable standard that requires steps to meet the standard for public health protection. An MCL is derived based on three steps: First, the most sensitive endpoint (i.e., the adverse health effect seen at the lowest level of exposure in scientific studies) is identified based on an assessment of the scientific data. Second, to protect the public from the risks associated with exposure, uncertainty factors are applied so people are not exposed to the levels at which adverse effects have been found in animal studies. Third, the MCL should take into account the ability to measure the chemical in water, and the technical feasibility of meeting the standard by using available treatment technology. Based on this assessment, we recommend that the New York State Drinking Water Quality Council set an MCL for the combined concentration of PFOA and PFOS at a level between 4 and 10 ppt.

#### **A. Uncertainty Factors in Risk Assessment**

The use of uncertainty factors has a long history in developing regulatory standards and guidance for chemicals. Uncertainty refers to our inability to know all the adverse effects related to a chemical, often due to incomplete data. When assessing the potential for risks to people, toxicology studies often involve exposing test animals (generally rats and mice) which are used

as a surrogate for humans (USEPA, 2017). A thorough review of the development and use of science-based uncertainty factors can be found in the USEPA document and NAS, 2013a and b.

Risk assessment for public health protection must account not only for what is known about a chemical's adverse effects, but also what is not known about differences between toxic effects in animals compared to humans; children compared to adults; differences in absorption, metabolism and excretion; and other unknowns. The selection of uncertainty factors is designed to account for the incomplete understanding or availability of studies upon which toxicity is appraised.

An uncertainty factor (UF) of 10 is applied for human variation to account for variation in susceptibility across the human population and the possibility that the available data may not be representative of individuals who are most sensitive to the effect (referred to as "UF(H)"). This is a default assumption used in nearly all risk assessments.

An UF of 3 or 10 is applied to account for differences between humans and animals (referred to as "UF(A)"). In estimating an acceptable level of a chemical, scientists determine the appropriate uncertainty factors to apply to animal studies. The determination of whether to apply the full 10, or to apply the modified 3 (less protective) as the appropriate UF to account for animal-human differences is often the matter of much debate. These determinations are made using scientific scrutiny but invariably include subjective assessment of the animal and human studies, and the 'weight-of-evidence' of these studies taken as a whole.

An UF of 3 to 10 can be applied to account for adjustment of studies which have found adverse effects at the lowest dose tested as well as at higher doses (referred to as "UF(LOEL)"). In cases where effects were seen at even the lowest level of exposure, this factor is used to adjust

for the uncertainty of whether these effects would have been observed at lower levels of test dosing ('Low Observed Effect Level' modified to a 'No Observed Effect Level'). An UF of 10 can be applied to account for studies which have a short duration of exposure rather than chronic exposure (referred to as "UF(SC)"). This is used, for example, when test dosing may only be several weeks or months (subchronic) rather than for the full lifetime where other chronic effects may have been found if the study duration were longer.

An UF of 10 can also be applied to account for more sensitive effects that are not otherwise considered (referred to as "UF(Data)"). This can be used to account for a database that does not adequately address organ systems or lifestage at doses that are lower than those that increase risks of other effects, such as liver damage.

The total uncertainty factor combines the UFs that have been applied.

## **B. Existing Advisories and Regulatory Standards**

Current state and federal health advisories and MCLs for PFOA are stringent - with a range from 14 to 70 ppt. For comparison, other chemicals for which there are MCLs regulated by USEPA, such as PCBs, benzene, and mercury, have MCLs which allow substantially more of these chemicals to be present in drinking water because the adverse effects occur at higher levels than for PFOA and PFOS. The MCL for PCBs is 0.0005 parts per million (ppm), equivalent to 500 ppt. The MCL for benzene is 0.005 ppm, equivalent to 5,000 ppt. The MCL for inorganic mercury is 0.002 ppm, equivalent to 2,000 ppt. See National Primary Drinking Water Regulations (USEPA, 2009). This means that the levels of PFOA and PFOS that are considered of public health concern (advisory levels are currently 14 to 70 ppt) are lower than those of most other environmental contaminants, indicating a higher degree of risk.

Although the health advisory concentrations for PFOA vary, the advisories cluster at low ppt levels. The advisories are based on developmental effects and cancer risks, and health authorities uniformly acknowledge the serious concerns related to exposure for the general population consuming PFOA contaminated drinking water. The selection of uncertainty factors is a primary determinant for the variation in the concentrations developed as advisories. None of the federal and state assessments dispute the very serious effects associated with exposure to PFOA and PFOS at very low levels of exposure.

These advisories are summarized in the table below:

**PFOA Summary Table for Advisories**

<b>Author</b>	<b>Advisory, ppt</b>	<b>Study Endpoint</b>	<b>UF Human</b>	<b>UF Animal</b>	<b>UF LOEL</b>	<b>UF Data</b>	<b>TOTAL UFs</b>
<b>USEPA</b>	70	Developmental effects on bone growth and male puberty	10	3	10	not applied	300
<b>New Jersey</b>	14	Mammary gland effects, increased liver weights	10	3	not applied	10	300
<b>Minnesota</b>	35	Developmental effects on bone growth and male puberty, increased liver weights	10	3	3	3	300
<b>Vermont</b>	20	Developmental effects on bone growth and male puberty	10	3	10	not applied	300
<b>NRDC</b>	4 to 10	Mammary gland effects and developmental effects	10	10	not applied	10	1,000

ppt = parts per trillion

UF (Human) to account for variation within the human population

UF (Animal) to account for differences between animals and humans

UF (LOEL) to account for studies where a no effect level was not identified

UF (Data) to account for missing or incomplete data

**a. USEPA Health Advisory**

USEPA has issued drinking water health advisories for PFOA and PFOS of 70 ppt (USEPA, May 2016a and b). In the case of co-occurrence of PFOA and PFOS, the sum of the concentrations is not to exceed 70 ppt. As opposed to MCLs, health advisories are non-enforceable.

The USEPA health advisories were derived from developmental toxicity studies in rodents. USEPA applied combined uncertainty factors of 300 on a low-observed-effect-level (LOEL) of decreased bone development in the fore and hind limbs, in pup mice (both sexes) and accelerated puberty in male mice. These are significant developmental effects.

**b. Standards and Advisories Adopted in Other States**

The Vermont Department of Health published a health advisory based on developmental effects for combined exposure to PFOA and PFOS not to exceed 20 ppt (Vermont Department of Health, 2016). They applied combined uncertainty factors of 300 using USEPA's rationale although they did not explicitly provide an explanation of which uncertainty factors were used to account for which uncertainties.

In New Jersey, the New Jersey Drinking Water Quality Institute (New Jersey Drinking Water Quality Institute, March 2017) derived a recommended MCL in water for PFOA of 14 ppt based on increased liver weight in rodent studies. Previously, the State of New Jersey in 2007 derived an MCL of 40 ppt, which was revised in 2016 to a more stringent level of 14 ppt based on chronic exposure from drinking water for cancer and non-cancer endpoints. Non-cancer endpoints were derived based on delayed mammary gland development as the most sensitive endpoint, and applied uncertainty factors of 300 (10 for intra-human variability, 3 for animal to human toxicodynamic differences, and 10 to protect more sensitive toxicological effects). The

MCL for cancer endpoints was derived from testicular tumor data from chronic dietary exposure in rats. Both cancer and non-cancer endpoints resulted in a MCL of 14 ppt (NJDOH, 2016; see also New Jersey Drinking Water Quality Institute, February 2017 for comprehensive assessment).

The State of Minnesota derived drinking water guidance values of 35 ppt for PFOA, and 27 ppt for PFOS, were developed in 2009, and confirmed in 2017 (Minnesota Department of Health, 2017a). They applied combined uncertainty factors of 300 including: UF of 10 for intraspecies variability, UF of 3 for interspecies differences, UF of 3 for adjustment of a low-effect-level, along with a database uncertainty factor of 3 for the lack of an acceptable 2-generation study. The derivation also included an exposure estimate to account for infant exposure via PFOA in breastmilk, assuming one year of breastfeeding.

Clearly, there are differences in the use and application of uncertainty factors by various agencies and scientific assessments. For example, when considering the developmental effects of PFOA, there was no level at which there were no effects (i.e., all dosing levels showed adverse effects on bone development and accelerated puberty in males). To account for the lack of a no effect level, an uncertainty factor of 10 (UF (LOEL)) was applied by USEPA and the state of Vermont, but the state of Minnesota adjusted this uncertainty factor to a less protective 3.

Additionally, New Jersey and Minnesota applied an uncertainty factor due to the lack of an adequate database to assess possible effects not studied robustly. USEPA and the state of Vermont did not apply this uncertainty factor UF (data), whereas the state of Minnesota applied an uncertainty factor of 3 for incomplete understanding of changes in bone development and puberty, which are poorly understood.

### *c. New York State Advisories*

New York State has not to date developed a specific MCL for PFOA or PFOS, and over the past few years, has relied on a number of different advisory levels for PFOA and PFOS in drinking water. In a Fact Sheet released in 2015, NYSDOH presented the MCL for combined PFOA and PFOS not to exceed 50,000 ppt, based on classification of these chemicals as ‘unspecified organic contaminants’ under state regulations (NYSDOH, 2015). NYSDOH later relied on the USEPA provisional health advisory level for PFOA of 400 ppt. USEPA revised this advisory to 70 ppt in 2016, which NYSDOH then used as an advisory. A water sample in excess of a health advisory indicates a potential threat to public health and initiates actions to reduce exposure and identify the sources of contamination, but does not carry the legal authority of an MCL.

### **C. Proposed MCL for PFOA and PFOS**

New York State should adopt a Maximum Contaminant Level in the range of 4 to 10 ppt for PFOA and PFOS combined for the protection of the public based on available human and animal data. The scientific weight of evidence demonstrating adverse effects at very low levels of exposure is more than adequate to develop this MCL range. Due to increased cancer risk (testicular cancer and kidney cancer), and known serious adverse effects of exposure to PFOA and related chemicals (most sensitive health endpoints are delayed mammary gland development, and delayed bone formation), we propose a drinking water MCL in the range of 4 to 10 ppt for combined exposure to PFOA and PFOS, with a detection testing limit of 1 ppt. As previously discussed, a detection sensitivity of 1 ppt is achievable, and should be required for testing drinking water. The most sensitive detection methods should be employed so that the

lower levels of PFOA in water can be determined. Further, the removal of PFOA has been demonstrated to be effective with granular activated carbon (GAC), showing that the MCL meets technological feasibility.

When comparing derivations of other chemicals of concern, it is clear that PFOA exposure poses a high risk to fetuses, infants, children and pregnant women, as well as the general population. There is particular risk for sensitive members of the population from chemicals of such persistence and clear adverse effects at very low levels of exposure, especially when large data gaps are present.

Delayed mammary gland development is the most sensitive endpoint for PFOA exposure (Macon et al., 2011) and should be used to derive a reference dose for the MCL, to protect infants and children at low doses. This study also identified increased liver weights at about the same level of dosing. The USEPA excluded the results of the mammary gland findings based on their view that the study could not be interpreted, that a susceptible strain of mice was used in the study, and that mammary gland effects had not been previously used for risk assessment. Health advisories of Vermont, New Jersey and Minnesota derived their assessments based on developmental effects (bone growth and male puberty) as the most sensitive adverse effect for PFOA and have used this as the basis of their risk assessments. We believe that these developmental studies showing effects on the mammary gland, male puberty and bone growth in conjunction with other studies in people showing effects such as prostate and testicular cancer, may be hormonally-activated and cannot be dismissed. Grandjean and Budtz-Jorgensen (2013) point out that for PFOA, interference with mammary gland development in mice seems to occur at lower exposures than liver toxicity, and drinking water advisories based on liver toxicity and may not be as protective as intended, despite the use of uncertainty factors. They conclude that

advisories PFOA and other PFCs calculated on the basis of liver toxicity are too permissive and must be decreased substantially to be protective of public health.

An uncertainty factor of 1,000 should be applied to be protective of public health when deriving the MCL for PFOA and PFOS. USEPA and states with an MCL or advisory have inconsistently used a combined uncertainty factor of 300, but for different reasoning. Expert health authorities do not agree on the application of UFs for PFOA. It is clear that the true relationship of exposure to PFOA and effects on the young are largely as yet unknown or poorly characterized. For this reason, careful consideration of uncertainty is critical.

An UF of 10 should be applied to account for variability within people (UF(H)), particularly when accounting for differences in vulnerability based on age. Children's vulnerability to toxic chemicals has received attention because children are far more sensitive than adults to toxic chemicals in the environment. Rather than assessing risk based on the "average adult", they stress the need for evaluating the unique risks of infants, children, and fetuses and other vulnerable groups within the population (Landrigan and Goldman, 2011). There are fundamental and important differences between adults and children. Children have greater exposures to toxic chemicals for their body weight than adults. Their metabolic pathways are immature, and a child's ability to metabolize toxic chemicals is different than adults. In addition, children's early developmental processes are easily disrupted, and can affect multiple systems such as brain, reproductive organs, and hormonal development. Research in pediatrics and developmental toxicology has suggested that "windows of vulnerability" are critical periods in early development when exposures that have no adverse effects on adults can disrupt organ development and cause lifelong functional impairments (Landrigan and Goldman, 2011).

An UF of 10, not the less protective 3, should be applied to provide an adequate margin of safety when extrapolating animal data to humans (UF(A)). There are substantial differences between humans and animals with regard to absorption and retention of PFOA and PFOS. (Post et al., 2017). Blood serum levels in people are much higher, and the half-lives are much longer, than in animals exposed to the same amount (Post et al., 2017). As the Centers for Disease Control's Agency for Toxic Substances and Disease Registry (ATSDR) in their video "PFOA Information for Clinicians," (available on YouTube and the transcript of the November 29, 2017 DWQC meeting, where it was shown) points out that "without a better mechanistic understanding of both the toxicokinetics and toxicodynamics, it is difficult to relate the outcomes in animals to human health effects." In the case of PFOA and PFOS, this introduces uncertainties in data evaluation, which requires an uncertainty factor of 10 rather than 3 be used to account for this unknown.

In addition to variability between animals and people and between people, there is additional uncertainty due to an incomplete database of toxicity studies (UF(Data)). As such, an uncertainty factor of 10 should be applied to account for the fact that the toxicity database is incomplete and that there is no full assessment of potential harm that could be at lower levels. Post et al., 2017 note that an uncertainty factor should be used when "there is concern that future studies may identify a more sensitive effect, target organ, population, or lifestage." The finding of mammary gland effects at the lowest level of exposure tested is another source of uncertainty and supports the use of the full 10-fold factor. (See Macon et al., 2011).

Among the uncertainties are the relationships between hormonal variation, sperm quality, and testicular cancer in men; the relationship between blood serum levels, breastmilk concentrations, infant and child serum levels, and effects later in life such as endometriosis in

women; and many other chronic conditions not yet evaluated. Further, the effects of the combined exposure to PFOA and PFOS are poorly understood. Immunotoxic effects have been identified, but have not been used in risk assessment for development of an MCL. Grandjean and Budtz-Jorgensen (2013) posit that their study shows effects at even lower levels of exposure, suggesting an acceptable level of 1 ppt in drinking water. Noting these same gaps in the database, New Jersey also applied a UF(data) of 10.

#### **D. Summary**

The weight of evidence and uncertainties especially with regard to effects on developing organisms including children indicate that a combined uncertainty factor of 1,000 should be applied (UF(H) of 10; UF(A) of 10; and UF(data) of 10)(Bhat et al., 2017; Dong et al., 2017; Post et al., 2017; Grandjean and Budtz-Jorgensen, 2013; USEPA, 2014).

Using the same database as USEPA and the states have reviewed, using mammary gland and developmental effects as the most sensitive endpoints, and applying the appropriate combined uncertainty factor of 1,000 rather than 300, an MCL range of 4 to 10 ppt is derived. This range of MCLs is at the limit of detection for PFOA and PFOS, and within the capability of Granular Activated Carbon (GAC) to remove PFOA and PFOS. Analytical testing should be conducted at levels as close to 1 ppt as possible.

Therefore, to be protective of human health including fetal and childhood exposures, a combined uncertainty factor of 1,000 should be applied. We urge the New York State Department of Health (NYSDOH) and the Drinking Water Quality Council (DWQC) to rigorously study the choices of uncertainty factors and apply them with the utmost care to protect the citizens of New York.

#### **IV. RECOMMENDATIONS**

##### **A. New York State Should Adopt an MCL for PFOA and PFOS in the range of 4 ppt to 10 ppt**

For the reasons stated earlier, New York State should adopt an MCL in the range of 4 ppt to 10 ppt for PFOA and PFOS combined exposure for the protection of public health based on known serious adverse health effects and increased cancer risks. PFOA and PFOS have been found in public drinking water supplies as well as in private water supplies at elevated levels across New York State. There is overwhelming evidence of adverse effects of exposure which is not in dispute. The MCL should be periodically revisited to determine whether newer studies suggest the MCL to become more stringent.

##### **B. New York State Should Conduct a Statewide Comprehensive Survey of Drinking Water for PFOA**

A statewide survey of drinking water sources should be conducted by NYSDOH to ascertain the degree to which potable water supplies are affected. The analyses should be conducted using the most sensitive detection methods for a comprehensive assessment. First priority for testing should be public water supplies where sources of water (ground and/or surface) are near former PFOA manufacturing or processing facilities; near fire-fighting areas where PFOA were used; and near airports which may have used PFOA. Drinking water supplies near landfills should also be given priority. We understand that such a survey is contemplated and we urge speed and low-detection levels in its conduct. In areas where public water supplies have been found to have elevated PFOA and/or PFOS, the state should offer testing of private drinking water wells in the vicinity.

Data on PFOA and other PFCs in water supplies already tested by the NYSDOH and other entities should be provided for evaluation by scientists and the public. Where available, blood serum levels of PFOA and related chemicals that have been analyzed should be provided as matched pairs with water samples, where available, without individual identification so that confidentiality will be protected.

**C. New York State Should Conduct a Comprehensive Health Survey for Communities with PFOA Contamination**

The New York State Department of Health should conduct a more comprehensive health assessment of exposed residents in Hoosick Falls and other communities found to have elevated drinking water PFOA concentrations. These studies should consider health endpoints in addition to cancer, such as effects on children's health, pregnancy and birth outcomes, and other effects not evaluated. If other communities are found to have contaminated water supplies after the statewide drinking water survey is conducted, studies should be conducted for these populations as well.

**D. New York State Should Create an Advisory Board to Consider Breastmilk and Infant Formula to Develop Recommendations to Mothers and Pediatricians**

Given the evidence that PFOA and related chemicals are expected to be present in breastmilk of mothers exposed to PFOA contaminated drinking water, it is likely that there will be questions about whether it is advisable to provide breastmilk or infant formula to babies. The presence of PFOA in infant formula is of concern if it is prepared using PFOA contaminated water. However, that can be avoided, whereas breastmilk contamination will almost certainly be present due to the mother's' past cumulative exposures. These are important personal decisions best made between the mother and the child's pediatrician. It would be helpful for the Drinking

Water Quality Council to form an Advisory Board to consider options and to advise mothers and doctors so informed decisions can be made.

Breastmilk analysis should be offered to women who are nursing their infants if they are in an area known to have PFOA contamination in drinking water.

## UNITS AND DEFINITIONS

ppb = parts per billion = nanogram per milliliter (ng/ml) (usually used to express blood serum concentration)

ppt = parts per trillion = nanograms per liter (ng/L) (usually used to express water concentration)

ng/ml = 1,000 ppt

1 ppb = 1,000 ppt

UF = Uncertainty Factor

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