May 21, 2008

Water Docket (2822T)
Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, DC 20460


To Whom It May Concern:

The Environmental Working Group (EWG) is a non-profit public health and environmental research and advocacy organization based in Washington, DC. EWG research addresses toxic industrial chemicals that pollute the environment and may be present in everyday consumer products. With this letter, we provide detailed comments and recommendations to the EPA regarding its draft Drinking Water Contaminant Candidate List 3 (CCL3), especially highlighting the urgent need for the inclusion of pharmaceuticals and perfluorochemicals (PFCs) on the final CCL3, and the promulgation of drinking water standards for these widespread pollutants that pose health risks to millions of Americans.

EWG analysis of water utilities’ tap water test results shows that nationwide, water contaminated with 260 chemicals, including 166 industrial pollutants, such as plasticizers, solvents, pharmaceutical production ingredients, and propellants, are served to 210,528,000 people in 42 states (EWG 2005b). Fifty six percent of those people drink water with one or more industrial contaminants present at levels above non-enforceable EPA guidelines. In fact, more than 140 of the chemical contaminants detected in tap water are unregulated, without an enforceable, health-based limit in tap water. Due to the lack of federal oversight and the absence of monitoring and health standards, vulnerable populations, especially pregnant women and children, are not protected from this multitude of toxic chemicals in drinking water.

As highlighted by the recent national investigation by the Associated Press (Mendoza 2008), in addition to industrial chemicals, a wide range of pharmaceuticals that include antibiotics, sex hormones, and drugs used to treat epilepsy and depression, contaminate drinking water supplies of at least 41 million Americans. With every refreshing glass of water, millions of Americans are also drinking low-level mixtures of highly potent pharmaceuticals. The health effect of this cocktail of chemicals and drugs has not been studied, but there are many reasons to be concerned about risks for infants and others who are vulnerable. Pharmaceuticals, hormones, pesticides, and
anti-microbial ingredients from personal care products contaminate many streams around the entire United States (Kolpin 2002). Chemical pollution of ambient waters contributes to the load of chemicals in tap water. EPA needs to show leadership and act with utmost dedication to protecting public health by mandating monitoring and setting enforceable health standards for these hazardous contaminants.

We especially urge the EPA to include perfluorinated compounds on the final CCL3 list. PFCs are persistent, long-lasting industrial chemicals that have been utilized in a variety of manufacturing applications such as production of non-stick Teflon cookware, stain-proof Scotchgard products, grease-resistant food packaging and other types of paper materials, as well as carpets, water-proof textiles, and fire-fighting foam. In addition to the major fluorochemical producers (DuPont and 3M in the United States), many secondary manufacturers have used PFCs for decades in their products. Industrial wastewater discharges and air emissions of PFCs from businesses that produce stain- and grease-resistant paper, carpets, textiles, and furniture likely contributed to the PFC pollution of drinking water supplies across the country. Due to their extraordinary stability, PFCs last in the environment for thousands of years. PFCs accumulate in bodies of both wildlife and humans, recirculating through groundwater, lakes, rivers, and oceans, and coming back to people with water, food, air and dust. As a result of decades of environmental discharges of PFCs, these toxic chemicals are now found in many areas of the country, in many bodies of water, and in bodies of more than 98% of all Americans (Calafat, Kuklenyik 2007; Calafat, Wong 2007). At least 11 different states have documented drinking or ambient water contamination with PFCs and a national survey is critically needed to reveal the full extent of PFC water contamination.

PFCs such as perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS) and related chemicals, bioaccumulate and remain in blood, liver, and other tissues for years. This persistence in the human body distinguishes PFCs from other contaminants and significantly elevates the level of health concern, making monitoring and the establishment of tap water standards critical for PFC compounds. Contamination of drinking water with PFCs creates a constant source of exposure and has been associated with some of the highest blood levels of these toxic compounds ever measured. Some residents of communities in Ohio and West Virginia drinking PFOA contaminated tap water had blood levels of PFOA 250 times the national average. These individuals experienced PFOA exposures equivalent to occupational levels and in amounts associated with serious adverse health effects, as demonstrated by initial data obtained in a major ongoing epidemiological study in the region (West Virginia University School of Medicine 2008). It is thus reasonable to feel concerned that other communities in other states drinking PFOA contaminated water would face similarly elevated exposures and health problems.

PFCs have a broad spectrum of adverse health effects. PFOA exposure has been associated with impaired fetal and neonatal development, changes in reproductive and thyroid hormones, compromised immune and liver function, increased blood cholesterol levels, and potential
predisposition to chronic diseases later in life. Gestational period, newborn babies and young children are the most sensitive developmental stages that should be especially protected from PFC contaminants in drinking water. During pregnancy, PFCs move to the body of the fetus through the placenta (Apelberg, Goldman 2007; Inoue 2004; Midasch 2007; Tittlemier 2004); a newborn child also gets a large dose of PFCs with breast milk (Arcaro 2008; Karrman 2007; Kuklenyik 2004; So 2006; Tao 2008; Volkel 2007). Tap water standards for PFOA and other PFC will go a long way in protecting the health of this vulnerable population from adverse effects both in early development and in later life.

The Safe Drinking Water Act (SDWA) requires EPA to publish an updated list every five years which details currently unregulated drinking water contaminants that may pose human health risks. From this list, EPA must make determinations on whether to establish tap water standards for at least five contaminants with a national primary drinking water regulation. EPA originally considered three candidate perfluorochemicals for inclusion into the Contaminant Candidate List 3: PFOA, a processing aid for manufacturing of Teflon non-stick and water-resistant chemicals, PFOS, the primary ingredient in the furniture stain-proofing coating Scotchgard that was phased out in 2000, and perfluorobutanoic acid (PFBA), a replacement chemical that manufacturers are increasingly using instead of longer-chain PFCs.

Of the three PFCs nominated for CCL3, only PFOA was included in the current draft of CCL3. While we support the EPA decision to place PFOA on the list, we urge the agency to add other perfluorochemicals including, but not limited to PFOS and PFBA, as potential water contaminants that ought to be regulated under the Safe Drinking Water Act. Given the widespread use of PFCs in industrial applications and consumer goods ranging from food packaging to carpets and textiles, as well as detection of multiple PFCs in bodies of 98% of Americans, PFC contamination of drinking water requires thorough scrutiny in order to meet current scientific and regulatory standards for safety.

Specifically, we urge EPA to:

- List a full range of perfluorochemicals on the CCL3, including, but not limited to, PFOA, PFOS, PFBA, and other PFCs that have been found in the environment and in people and that are likely to contaminate both finished and ambient water sources;
- Establish regulatory standards for PFOA in drinking water;
- Include in the final CCL3 a broader list of contaminants found by water utilities in tap water, especially focusing on antibiotics and other pharmaceuticals.

Details and our rationale for these recommendations are provided below.

1. List a full range of perfluorochemicals on the CCL3, including PFOA, PFOS, PFBA, and other PFCs found in the environment and in people.
We support the EPA decision to place PFOA on the Draft Drinking Water Contaminant Candidate List 3. However, we disagree with the Agency’s decision to exclude PFOS and PFBA from consideration as hazardous water contaminants. The stability of PFCs in the environment makes these chemicals distinct from many other classes of chemical water pollutants that have been previously regulated by the EPA (Conder 2008). Biomonitoring studies carried out by the Center for Disease Control found PFOS, PFOA, perfluorohexane sulfonic acid (PFHxS) and perfluorononanoic acid (PFNA) in more than 98% of 2,094 people tested. For some of these chemicals, children younger than 12 years of age have higher levels than adults (Olsen, Church 2004). PFCs enter human bodies from different sources, such as food, chemical-laden dust and water (Emmett 2006; Frisbee 2008). Various PFCs have been detected in finished and/or ambient water sampled in various locations in 11 states (Table below). PFOA has been found in tested water samples from all of these 11 states, PFOS has been found in 7 states, and PFBA appears poised to become an emergent water contaminant (MDH 2008).

We urge the Agency to add PFOS and PFBA to the CCL3. Even though production of PFOS has been banned by the EPA (US EPA 2002), this persistent and bioaccumulative compound is still present in many water sources in the US (MDH 2008). PFOS negatively affects early development in animals and humans (Apelberg, Witter 2007; Lau 2004); it interferes with the function of the nervous system and causes neurobehavioural defects (Johansson 2008), kills immune cells and weakens body’s capacity to resist infection (Keil 2008; Peden-Adams 2008), and affects thyroid hormones that are critical for normal growth and maturation in children (Lau 2003; Luebker 2005). Considering how common is PFOS contamination of water sources, we believe EPA needs to set a regulatory standard to protect the health of people, especially young children, from PFOS.

In the absence of EPA guidance, states need to carry out their own risk assessments and set water contamination levels for PFCs. For example, the Minnesota Department of Health issued advisory guidelines of 1.0 µg/L for PFBA and set the limits for other PFCs chemicals in drinking water as well (MDH 2008). The presence of PFBA and other PFCs in groundwater at the fluorochemical manufacturing sites points to the potential of these replacement PFC chemicals to become new, emergent water contaminants whose health consequences will be directly tested on people exposed through drinking water. Now that the human health effects of PFC contamination in drinking water are becoming widely known from the C8 (PFOA) Health Project (West Virginia University School of Medicine 2008), it is imperative to protect vulnerable populations from future exposures to PFCs.

EPA needs to assess cumulative risks associated with multiple PFCs in finished and ambient water sources for children and other vulnerable populations. New data are constantly coming to light that demonstrate the extent of water contamination with PFCs (Fuchs 2008; Fuquay 2008; Hawthorne 2008; Konwick 2008; United Steelworkers Union 2006). Already, drinking and ambient water in 11 states is contaminated with PFCs and the full scope of this problem might be
even larger since businesses using fluorochemical products are found all around the country. This gap in our knowledge should be filled with a national survey of PFCs in water and a full range of PFCs should be included in the Unregulated Contaminant Monitoring Program.

In summary, we urge the EPA to list perfluorochemicals on the final CCL3, including, but not limited to, PFOA, PFOS and PFBA, and other PFCs that are commonly detected in people and the environment, so that the agency can mitigate the human health risks posed by these chemicals.

2. Establish regulatory standards for PFOA in drinking water.

We support the EPA in including PFOA on the Contaminant Candidate List 3 and we urge the agency to take the next, urgently needed step for public health protection by issuing national regulatory standards for PFOA levels in drinking water. In order to help the individual states that look to EPA for guidance and protect the health of all Americans, the agency should proceed with this step immediately, even while the data on other PFC water contaminants are collected.

Unquestionably, PFOA meets all the criteria for a contaminant that requires regulation by the EPA. Together with other PFCs, PFOA is now found in bodies of 98% of Americans (Calafat, Wong 2007); often, children younger than 6 years of age have higher PFOA levels compared to adults (Emmett 2006; Olsen, Church 2004). PFOA can cross the placenta and transfer from the mother’s body to the fetus (Apelberg, Goldman 2007; Inoue 2004; Midasch 2007; Tittlemier 2004). PFOA contaminates the milk of breast-feeding mothers (Karrman 2007; Kuklenyik 2004; So 2006; Tao 2008; Volkel 2007). Once ingested with food or water, PFOA accumulates in the human body to 100-fold greater levels and persists for many years (Emmett 2006; Olsen, Burris 2007). This means that trace levels of PFOA in tap water can produce much higher long term exposures in people. For example, drinking water from the Little Hocking water system in Ohio was contaminated with PFOA at about 3.5 parts per billion (ppb), but some individuals drinking this water, who had no other unique exposures to PFOA, had blood levels of PFOA as high as 1,000 ppb (Emmett 2006).

As demonstrated by numerous studies in people and in animals, PFOA has an adverse effect on many health parameters, such as fetal and neonatal development (Lau 2004), immune function (DeWitt 2008; Yang 2002), reproductive and thyroid hormones (Lau 2007), liver function (Frisbee 2008; Son 2007), and blood levels of cholesterol and other lipids (Frisbee 2008; Olsen and Zobel 2007; Sakr, Kreckmann 2007; Sakr, Leonard 2007). In two studies of newborn babies, higher PFOA levels correlated with smaller weight and size at birth (Apelberg, Witter 2007; Fei 2007, 2008). PFOA exposure increases predisposition to obesity, heart disease, diabetes, and stroke (European Congress on Obesity 2008; Leonard 2007; Lundin 2007). PFOA causes liver, pancreatic, testicular, and mammary cancer in animals (Sibinski 1987). In epidemiological studies, PFOA has been shown to increase the risk of various cancers, especially prostate cancer, as well as liver, kidney, and bladder cancers (Leonard 2007; Lundin 2007; Olsen, Burlew 2004).
Despite extensive denial of PFOA health effects by the chemical industry, toxic effects of this chemical have been revealed by the chilling initial results from the C8 Health Project (West Virginia University School of Medicine 2008), a major epidemiological survey of residents in Ohio and West Virginia whose drinking water supply has been contaminated by PFOA. Sixty nine thousand people have been enrolled in the project, making it by far the largest study ever of PFC health effects in people (Frisbee 2008). The health effects observed in the study population are strong indicators of health problems that might be caused by PFOA in average Americans. Toxic effects from PFOA were observed in study participants with blood levels of the chemical equal to those found in the more highly exposed individuals in the US population. It is reasonable to expect that people in other states with contaminated drinking water may reach the same levels of exposure associated with significant adverse health effects in this study. As reported by the scientific team from the West Virginia University:

- Higher levels of PFOA in people correlate with lower levels of liver-produced C-reactive protein that helps the body fight bacteria, viruses, and other pathogens.
- PFOA exposure is associated with higher serum levels of two enzymes that can indicate liver damage; the same findings as have been found in occupational studies (Olsen and Zobel 2007; Sakr, Kreckmann 2007). These two findings indicate powerful liver toxicity of PFOA.
- Elevated PFOA levels in children are associated with high cholesterol levels, predisposing children to future weight problems and accompanying risk of heart disease.
- PFOA-exposed people have abnormal levels of thyroid hormones.

The multitude of PFOA health effects is especially worrisome because both PFOA and other PFCs are known to occur in public water systems with a frequency and at levels of public health concern. PFOA has been detected in public water supplies in many localities in West Virginia and Ohio (Emmett 2006; WVDEP 2005), 78% of drinking water systems tested by the New Jersey Department of Environmental Protection (NJDEP 2007), and in multiple townships in Washington County, Minnesota (MDH 2008). Additionally, drinking water supplies in some localities in Georgia may potentially be contaminated with PFOA (United Steelworkers Union 2006), where surface waters have been shown to be polluted with high levels of various PFCs (Konwick 2008). Other affected states include North Carolina (NCDENP 2008a), where groundwater contamination with PFOA in the vicinity of DuPont’s Fayetteville Works plant doubled between 2006 and 2007 (Fuquay 2008), Alabama, where the Tennessee River is contaminated with PFOA and PFOS emitted by the 3M fluorochemical plant (Decatur) (Hansen 2002), Illinois, where both PFOA and PFOS have been detected in Chicago drinking water supply (Hawthorne 2008) as well as New York and Virginia (Clean Water Action Alliance of Minnesota 2008). All of these data are presented in the Table below:
All together, various PFCs have been detected in finished and/or ambient water sampled in various locations in 11 states. PFOA has been found in tested water samples from all of these 11 states; PFOS has been found in 7 states. Most worrisome, groundwater levels of PFBA, a replacement chemical for some of the older PFC applications, appear to be on the rise (MDH 2008).

Without federal health standards for PFOA, individual states are forced to set their own standards so as to protect their citizens. For example, PFOA standards or risk-based levels have been established by North Carolina (2 µg/L) (NCDENP 2008b), Minnesota (0.5 µg/L) (MDH 2008), and New York (2 µg/L) (Sinclair 2006).
2007) and New Jersey (0.04 µg/L) (NJDEP 2007). The 2006 consent order between EPA and DuPont required the company to offer alternative drinking water source or treatment for both public and private water users living near the Washington Works plant in Parkersburg, West Virginia whenever PFOA levels in their drinking water exceed 0.5 µg/L (US EPA 2006).

When confronted with such regulatory patchwork and the lack of guidance from the EPA, many states do not know how best to proceed, leaving the health of Americans at jeopardy (Hawthorne 2008; Sohn 2008). Many other states do not have the resources or expertise to establish and enforce drinking water standards for PFCs. Most states and the people who live in them depend on the EPA to protect them from drinking water contaminants. A failure to act will leave the residents in those states drinking tap water contaminated with highly toxic and persistent PFC pollutants for many years to come.

EPA regulation of PFOA and other PFCs that are commonly detected in people and the environment presents a meaningful opportunity for reduction of health risk due to these industrial chemical pollutants in drinking water. We urge the EPA to take much-needed action on PFOA and set a health-protective standard for PFOA in drinking water that will rely on the best available science and safeguard the health of millions of people.

3. Include in the final CCL3 a broader list of contaminants found by water utilities in tap water, especially focusing on antibiotics and other pharmaceuticals.

Pharmaceutical residues contaminate drinking water supplies when people take various prescribed and over the counter medications. While their bodies absorb and metabolize some of the chemicals, the rest is flushed out of the body and down the drain. Drinking water treatment plants are not designed to remove these residues, and the Associated Press (AP) National Investigative Team uncovered data showing these same chemicals in treated tap water and water supplies in 24 major metropolitan areas around the US (Mendoza 2008). Together with earlier publications by the US Geological Survey that identified pharmaceuticals and personal care product chemicals in waters bodies and streams around the United States (Kolpin 2002), the results of the AP investigation point to the potential health dangers presented by pharmaceuticals in drinking water.

All of the pharmaceuticals reported in drinking water supplies are unregulated in treated tap water—any level is legal. So far, the federal agencies have failed to set standards for pharmaceuticals which are generally exempted by the FDA from any environmental assessment (FDA 2008). Moreover, the EPA has not even required water utilities to test for these chemicals. Drug residues in tap water join hundreds of other synthetic chemicals Americans are exposed to daily, as contaminants in food, water, and air, or in common consumer products. EWG found an average of 200 industrial chemicals, pesticides and other pollutants in umbilical cord blood from 10 babies born in the U.S., indicating that our exposures to toxic chemicals begin in the womb, when risks are greatest (EWG 2005a). EWG analysis shows that of the top 200 drugs commonly
prescribed in the U.S., 13 percent are known to have serious side effects at levels less than 100 parts-per-billion (ppb) in human blood, with some causing potential health risks in the parts-per-trillion range. These levels are dangerously close to the ones found in drinking and ambient water sources (Kolpin 2002; Mendoza 2008).

We now call on the EPA to take swift action by setting standards for antibiotics and pharmaceuticals in tap water that will protect the health of all Americans, especially children. By the very nature of their design, pharmaceuticals can have effects on human body even at low doses. We urge the EPA to include in the final CCL3 a broad range of pharmaceutical residues and other contaminants found in tap water. This action will serve as the first, much needed step for ensuring the long-term health of our tap water – and the people who drink it.

In conclusion, presence of pharmaceuticals and perfluorochemicals in all states where water samples have been tested for these compounds, and their effects on the environment and on human health makes these chemicals very important candidates for federal regulation under the Safe Drinking Water Act. Federal drinking water policies and regulations should be set to ensure that vulnerable populations, including pregnant women and children, are protected from chemical contaminants in drinking water. Ingestion of drugs and PFCs with drinking water presents a significant hazard for human health, especially during sensitive times in life, such as in utero. Most states do not have the resources to establish or enforce drinking water standards, and people in these states depend on strong protections from the EPA. Regulation of these pollutants will assure equitable and uniform protection for the health of all Americans. Thus, we urge the EPA to follow up on the draft CCL3 by setting regulatory standards for both pharmaceuticals and PFCs in drinking water.

Sincerely,

Olga V. Naidenko, Ph.D.
Senior Scientist
Environmental Working Group
1436 U street NW Suite 100
Washington, DC 20009
202-939-9157
olga@ewg.org

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References


