

TOXIC AND HAZARDOUS SUBSTANCES LITIGATION

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IN THIS ISSUE

This article explains how the development of PFAS standards for drinking water and the environment may affect ongoing PFAS personal injury and environmental damage claims.

Which Came First, the Standard or the Suit?

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Introduction

Lawsuits claiming damages from the class of chemicals known as per- and poly-fluorinated alkyl substances (“PFAS”), just as the substances themselves, are everywhere. Many of these suits, filed by states, municipalities, and individuals, target the primary chemical producers or the second-line manufacturers that utilized PFAS-containing materials in their products, and claim that exposure has put them at higher risk for illness or caused environmental damage. For many years PFAS chemicals were considered safe and effective for firefighting, stain-proofing, and many other applications. Even though now portrayed as a certain and significant health hazard by PFAS plaintiffs, the reality is that science has not yet determined how much or how often exposure to PFAS may cause negative impacts to human health and the environment and precisely what those impacts might be.

Amid this uncertainty, the United States Environmental Protection Agency (“EPA”) in 2016 issued a non-regulatory Health Advisory Level of a combined 70 parts per trillion (“ppt”) for perflouroctanoic acid (“PFOA”) and perfluorooctane sulfonate (“PFOS”) for drinking water.¹ PFOA and PFOS are two of the most-studied among the thousands of different PFAS that exist. Many

states followed by issuing their own versions of standards and non-regulatory guidelines for various types of PFAS. This article will explore how such federal and state-issued PFAS advisories and standards have been treated by courts and may affect the ongoing PFAS litigation.

The Science of PFAS Standards and Causal Links to Injury

By virtue of their design, PFAS chemicals persist in the environment and can be absorbed and accumulate in the human body. While EPA says that people exposed to high levels of PFAS “may suffer adverse health effects,”² little else is known for certain. Investigations of the possible health effects of PFAS are based on two kinds of studies: epidemiological studies of exposed populations and laboratory animal studies. Each has its own shortcomings. Epidemiological studies are influenced by confounding factors such as diet, lifestyle, and exposure to other environmental contaminants. Laboratory studies require scientists to extrapolate the results of animal studies to humans using a complex set of assumptions. The Agency for Toxic Substances and Disease Registry (“ASDTR”) says that more research is needed for the extrapolation process “[b]ecause animals and humans process these chemicals

¹ EPA Fact Sheet, PFOA & PFOS Drinking Water Health Advisories, EPA 800-F-16-003 (Nov. 2016), available at [https://www.epa.gov/sites/production/files/2016-](https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf)

[06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf](https://www.epa.gov/sites/production/files/2016-06/documents/drinkingwaterhealthadvisories_pfoa_pfos_updated_5.31.16.pdf).

² EPA, Basic Information on PFAS, <https://epa.gov/pfas/basic-information-pfas> (last visited March 30, 2020).

differently.”³ For this and other reasons, there are not yet federal Maximum Contaminant Levels (“MCLs”), enforceable standards that set limits for PFAS in drinking water. Though EPA issued non-regulatory cleanup guidance for groundwater in 2019 as part of its PFAS Action Plan, there are no national guidelines for other media such as surface water, soil, and ambient air. Separately, states have used a variety of toxicology criteria and scientific methodologies to develop standards, guidelines, and advisories that are often inconsistent.

However, while a lack of scientific certainty has not deterred plaintiffs from filing suits, it is likely to limit litigation outcomes. To show a causal link between exposure to a toxic substance and injury, a personal injury plaintiff must be able to prove both general causation (that the toxin is capable of causing a particular injury) and specific causation (that the plaintiff was actually exposed to levels sufficient to cause the plaintiff’s harm).⁴ To date scientific research has not answered the dose-response question of “how much is too much?”.

Without this, plaintiffs may find it hard to establish even general causation.

Today’s pace of litigation is ahead of standards development, and courts have begun asking questions to both sides. Reflecting on this during a recent Science Day, U.S. District Judge Richard Gergel of South Carolina, who presides over the expansive MDL for PFAS-containing firefighting foams, remarked that “in a ‘perfect world’ the lawsuits over the firefighting foam wouldn’t be litigated until the science was settled. But that’s not how the country’s judicial system works.”⁵

The Dilemma of Emerging Contaminants

Emerging contaminants present unique challenges in toxic tort litigation. They are often found in personal care products, pharmaceuticals, and industrial chemicals. As EPA defines them, emerging contaminants often carry a perceived or real threat to human health or the environment but lack published health standards. PFAS present special concern because of their characteristics: they are extremely slow to

³ Agency for Toxic Substances and Disease Registry, Per- and Polyfluoroalkyl Substances (PFAS) and Your Health, What are the Health Effects? <https://www.atsdr.cdc.gov/pfas/health-effects.html> <https://www.atsdr.cdc.gov/pfas/health-effects.html> (last updated Jan. 21, 2020).

⁴ *E.g., McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241 (11th Cir. 2005) (“[T]o carry the burden in a toxic tort case, a plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff’s actual level

of exposure to the defendant’s toxic substance before he or she may recover.”) (internal quotation marks omitted).

⁵ Andrew Brown, Federal Judge in SC Wades through Lawsuits About Toxic Firefighting Foam Used at Military Sites (Oct. 17, 2019), https://www.postandcourier.com/business/federal-judge-in-sc-wades-through-lawsuits-about-toxic-firefighting/article_b5af995c-ef4c-11e9-813c-1b75b5cceb94.html.

break down and they have the potential to bioaccumulate.⁶

An early PFAS case in Escambia County, Florida highlights the difficulties posed by emerging contaminant litigation. This case, brought by a water utility against Aqueous Film-Forming Foam (“AFFF”) manufacturers claimed that PFOA and PFAS in the foam contaminated its wells after it was used for training exercises at the Pensacola Regional Airport.⁷ At the time there were no state standards and EPA had issued a non-regulatory action level for PFOA and PFOS of 0.5 parts per billion.⁸ Critical to the outcome was the fact that the Authority had no need to take actions (such as installing filters or using additional treatments) since levels were below the EPA’s action level. Because the Authority was unable to show that it had incurred any monitoring or remediation expenses due to the presence of PFOA and PFOS in the wells, the court granted summary judgment for the defendants.⁹ The court ruled that the Authority’s claim that “the chemicals are ‘unwelcome’ must be accompanied by some evidence of a concrete and particularized harm to ECUA as a result of the chemicals’ presence in its water supply.”¹⁰

In contrast to *Emerald Coast*, courts have awarded damages to water utility plaintiffs

that show they have expended resources to sample and treat contamination consistent with their responsibility to provide a pure water supply to customers even if the levels are below the applicable regulatory standard.¹¹ In a case involving contamination of groundwater with perchloroethylene, the court determined that “[w]hile the MCL may be helpful in determining whether an injury has occurred, the MCL does not set a bar below which an injury cannot have occurred.”¹² There, since the affected water district showed that it had expended resources to sample and treat contamination, the court found it had suffered a cognizable injury regardless of the level of contamination.

The issues raised in today’s PFAS cases are comparable to prior litigation involving methyl tertiary butyl ether (“MTBE”) and trichloroethylene (“TCE”), both emerging contaminants that tend to migrate through groundwater. Like PFAS, the EPA had not set an MCL for MTBE, a gasoline additive, at the time plaintiffs began filing cases against gasoline manufacturers in earnest. In the early 2000’s, cases filed by municipal water providers and regulators included claims for product liability, public nuisance, negligence, and natural resource damages claims for groundwater contamination. Many of these cases were consolidated into an MDL in the

⁶ Center for Disease Control, Per- and Polyfluorinated Substances (PFAS) Factsheet (April 7, 2017).

⁷ *Emerald Coast Utilities Auth. v. 3M Co.*, 746 F. Supp. 2d 1216, 1219 (N.D. Fla. 2010).

⁸ *Id.* at 1220.

⁹ *Id.* at 1231-32.

¹⁰ *Id.* at 1232.

¹¹ *Suffolk Cty. Water Auth. v. Dow Chem. Co.*, 121 A.D. 3d 50, 56 (N.Y. 2014).

¹² *Id.* (citing *In re Methyl Tertiary Butyl Ether [MTBE] Prods. Liab. Litig.*, 458 F. Supp. 2d 149, 154–158 (S.D.N.Y. 2006)).

Southern District of New York. At the summary judgment stage, the court discussed the MCL for MTBE established by the New York State Department of Health and other states.¹³ The MTBE levels measured in most of the wells at issue were below New York's MCL. Regardless, the court refused to dismiss the claims, holding that compliance with the MCL "does not define *whether* an injury has occurred."¹⁴

Instead of a determinative value that can prove or disprove an injury, the court saw the MCL as a "convenient guidepost" useful for determining the likelihood of injury.¹⁵ The MTBE court went on to endorse a two-part analysis in which comparison to the MCL would be followed by the second step of determining whether the contamination had actually caused injury to the plaintiffs.¹⁶ The court concluded by saying that "[w]hile it may eventually be determined that some levels of contamination below the applicable MCLs do not injure plaintiffs' protected interests, plaintiffs have presented sufficient evidence for purposes of standing to show that they may have been injured," and the question should be resolved by the jury.¹⁷

A number of courts reached a different conclusion in litigation involving TCE, finding that levels below regulatory levels did not constitute injury.¹⁸ In a case that considered TCE screening levels in indoor air, the United States District Court for New Jersey dismissed a case because measurements of airborne contaminants were below screening levels.¹⁹ Without evidence that the low levels of contaminants detected at plaintiffs' properties posed a threat to human health or the environment, the case did not survive summary judgment.²⁰

The State of PFAS Suits

In PFAS litigation to date, few courts have had the chance to directly address questions about dose-response and the possible toxic effects of PFAS, as the majority of cases have ended in settlements without making findings of general and specific causation. In one highly-publicized example, the Michigan Department of Environmental Quality filed suit against Wolverine World Wide, Inc. on January 10, 2018, the same day that the state issued its own enforceable drinking water standard of 70 ppt (combined) PFOA plus PFOS, a level equal to EPA's current Health Advisory Level. The claims included

¹³ *In re Methyl Tertiary Butyl Ether*, 458 F. Supp. 2d at 158 (S.D.N.Y. 2006).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.* at 157 (citing *Rose v. Union Oil Co. of California*, No. C 97-3808 FMS, 1999 WL 51819, at *7 (N.D. Cal. Feb. 1, 1999)).

¹⁷ *Id.* at 158.

¹⁸ See e.g., *In re Wildewood Litig.*, 52 F.3d 499, 503 (4th Cir. 1995) (TCE levels below "the level of

toxicological concern" as defined by the MCL, did not unreasonably interfere with the plaintiffs' use and enjoyment of their property); *Brooks v. E.I. Du Pont de Nemours & Co.*, 944 F. Supp. 448, 449 (E.D.N.C. 1996) (contamination below the MCL does not constitute an injury, "rather, such levels pose an acceptable risk").

¹⁹ *Leese v. Lockheed Martin Corp.*, No. CIV.A. 11-5091 JBS, 2014 WL 3925510, at *6 (D.N.J. Aug. 12, 2014).

²⁰ *Id.* at *14.

“imminent and substantial endangerment” under the Resource Conservation and Recovery Act, violations of the state’s newly established drinking water standard, and common law nuisance.²¹ Wolverine filed a third-party complaint against the PFAS manufacturer 3M, asking that it contribute to the cleanup.²² Both parties ultimately settled in February 2020. Wolverine agreed to pay Michigan \$69.5 million, continue to monitor groundwater contamination, and maintain filters in areas served by private wells where PFOA plus PFOS levels exceed 10 ppt (a value 7 times lower than EPA’s Health Advisory Level).²³ 3M agreed to pay Wolverine \$55 million to support the cleanup.²⁴

The *Wolverine* settlement was preceded by several other settlements between states and PFAS manufacturers including a February 2018 settlement with the state of Minnesota for \$850 million, an amount significantly lower than the \$5 billion originally sought.²⁵ Authors have noted that scientific studies that questioned the causal link between exposure and certain illnesses played a role in both the timing and amount

of the Minnesota settlement.²⁶ Within the last two years, state attorneys general have filed similar suits against PFAS and AFFF manufacturers in New York, New Jersey, Ohio, New Hampshire, and Vermont. This list continues to grow.

Another large class action suit is pending in Ohio, where former firefighter Kevin Hardwick claims to represent all United States residents that have detectable levels of PFAS in their blood. Mr. Hardwick has asked a group of defendant manufacturers to fund a scientific panel to study health impacts. By implicating only detectable blood levels instead of particular levels and dose-response relationships between exposure and toxic effects, Mr. Hardwick’s suit avoids the unsettled causation questions. This case survived a motion to dismiss in September 2019 after the court found that the remedy Mr. Hardwick requested was available under Ohio law.²⁷ At this early stage, the court made a limited finding that the allegation that PFAS were present in class members’ blood or bodies, without specifying that any level of a

²¹ Complaint for Declaratory and Injunctive Relief, *Michigan Dept of Environmental Quality v. Wolverine World Wide*, No. 1:18-cv-00039-JTN-ESC (W.D. Mich. filed Jan. 10, 2018).

²² *Wolverine World Wide, Inc.’s Third-Party Complaint and Demand for a Jury Trial*, Case 1:18-cv-00039-JTN-ESC (W.D. Mich. Filed Dec. 18, 2018).

²³ Consent Decree at 28, *Michigan Dept of Environmental Quality v. Wolverine World Wide* Case 1:18-cv-00039-JTN-SJB, ECF No. 151 (W.D. Mich. Filed Feb. 20, 2020).

²⁴ Hailey Konnath, 3M To Pay Wolverine \$55M for Cleanup of “Forever Chemicals” Law 360 (Feb. 20, 2020).

²⁵ Minnesota 3M PFC Settlement, <https://3msettlement.state.mn.us/>.

²⁶ See e.g., Jeffrey Karp et al., PFAS Update: Evolving Science and Liability, IADC Committee Newsletter, Toxic and Hazardous Substances Litigation (October 2019).

²⁷ *Hardwick v. 3M Co.*, No. 2:18-CV-1185, 2019 WL 4757134, at *8 (S.D. Ohio Sept. 30, 2019) (citing *Hirsch v. CSX Transp., Inc.*, 656 F.3d 359, 363 (6th Cir. 2011))

particular PFAS is present, was enough to demonstrate a plausible harm.²⁸

Recently the National Rural Water Association filed a class action complaint against PFAS manufacturers the U.S. District Court for the District of Columbia.²⁹ The complaint seeks court-supervised PFAS testing of water wells and other relief on behalf of the City of Millington in Shelby County, Tennessee and other water association members whose wells are located in close proximity to sites where fire-fighting foams containing PFAS have been used. The complaint cites EPA's Lifetime Health Advisory Level for PFOA and PFOS of 70 ppt but does not allege that any water wells have levels in excess of the level.³⁰ Instead the complaint states that there is a "likelihood" that wells are contaminated.³¹

At the same time, approximately 500 cases filed by local governments, water districts, and individuals alleging that widespread use of aqueous film-forming foams ("AFFF") released PFAS to groundwater have been consolidated into a multi-district litigation before the District of South Carolina.³² Plaintiffs in these cases seek damages for personal injury and property damage, medical monitoring, and compensation for

other economic losses. The outcome of the AFFF MDL is likely to inform other PFAS cases on how PFAS standards and science are treated going forward. During pretrial proceedings Judge Gergel held a Science Day on PFAS. Science Day included presentations from six experts on issues requested by the court including: (1) the scientific basis for EPA's Health Advisory Level and the reasons for differences between this level and others set by the CDC, states, and other health agencies; (2) the validity and costs of evaluating groundwater for potential toxic effects; and (3) the diseases and conditions that are caused or associated with exposure to PFOA and PFOS and methods for establishing exposure as a proximate cause.³³ The experts on both sides testified that there are "associations" between PFAS exposure and some diseases, there is no consensus on a definite dose to establish causation. The most recent status report for this case indicates that discovery is ongoing.³⁴

The State of PFAS Standards

Simply measuring PFAS can be problematic because samples are easily contaminated by PFAS contained in sampling equipment itself, as well as personal care products a

²⁸ *Id.* at *18.

²⁹ Class Action Complaint and Demand for a Jury Trial, *City of Millington; National Rural Water Association v. 3M Company et al.*, U.S. District Court for the District of Columbia, No. 1:20-cv-00546 (Feb. 25, 2020).

³⁰ *Id.* at ¶ 156.

³¹ *Id.* at ¶ 188.

³² *In Re: Aqueous Film-Forming Foams Products Liability Litigation*, MDL No. 2-18-mm-2873-RMG.

³³ Order at ¶4, *In Re: Aqueous Film-Forming Foams Products Liability Litigation*, MDL No. 2-18-mm-2873-RMG (July 24, 2019).

³⁴ *Aqueous Film-Forming Foams (AFFF) Products Liability Litigation*, Current Developments, <https://www.scd.uscourts.gov/mdl-2873/current.asp>.

technician might use. EPA certified laboratory methods apply only to drinking water (not surface water, soil, or other media that contain elevated levels of suspended solids).³⁵ Due to high demand and a limited number of certified labs, processing PFAS samples may take months. But most perplexing of all are the extremely low levels at which PFAS must be detected for comparison to advisories and standards—in the parts per trillion range. In most toxic tort cases up to now, courts have considered results in the range of parts per million or billion. But the presence of PFAS chemicals must be quantified down to parts per trillion. To visualize this, a part per million is the equivalent of one drop of chemical in 10 gallons of water, while a part per trillion is equivalent to one drop in 20 Olympic-sized pools.

The EPA has made definite steps toward developing a Maximum Contaminant Level (“MCL”) under the Safe Drinking Water Act. In March 2020, EPA announced its positive regulatory determination that it would begin the process of establishing a National Primary Drinking Water Regulation

(“NPDWR”) for PFOA and PFOS; two of the most highly studied PFAS compounds.³⁶ This announcement signals the start of a years-long process. As a first step, EPA will develop a non-enforceable Maximum Contaminant Level Goal (“MCLG”). This may be followed with an enforceable NPDWR if EPA determines that it is appropriate to regulate the contaminant in drinking water.³⁷ Regulations require EPA to develop the MCLG within two years of the positive regulatory determination. After this, the EPA has 18 additional months to publish a final regulation or NPDWR. A common misconception is that a decision to develop a NPDWR means that the EPA must set a MCL.³⁸ However, this is not always true, as the agency has the choice either to set an MCL or to establish treatment technique rules. When the contaminant meets certain criteria, EPA may choose the option to set treatment rules instead of an MCL “if the Agency determines it is not ecologically or technologically feasible to ascertain the level of the contaminant.”³⁹ In other words, the EPA may consider the feasibility of setting the standard and is not required to set a drinking water standard that is not feasible.

³⁵ EPA methods 533 and 537.1 can be used to measure 29 types of PFAS in drinking water. Labs analyzing non-drinking water samples often present results under “modified method 537” which has not been validated by EPA. EPA PFAS Drinking Water Laboratory Methods, <https://www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods>. New methods are in development, but not yet fully vetted and approved.

³⁶ Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. 14098, 14120 (March 10, 2020).

³⁷ *Id.* at 14100. An MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. The MCL is the highest level of a contaminant that is allowed in drinking water. EPA sets the MCL as close to the MCLG as feasible using the best available treatment technology and taking cost into consideration.

³⁸ *Id.*

³⁹ *Id.* at 14122.

Although states often rely on the federal government to regulate potentially toxic chemicals, many have taken actions to develop their own advisories or standards ahead of the EPA process. These are now in various stages of development and implementation and may vary significantly from EPA's current Lifetime Health Advisory Level.⁴⁰ The processes used by states include a variety of endpoints and exposure modeling approaches and have yielded a large range of results. Thus, it is critical for environmental practitioners to scrutinize the details of how advisories and standards were developed when these values are used in toxic tort litigation.

At least one state that has established its own MCLs for PFAS has been sued for doing so. New Hampshire set PFAS levels for several types of PFAS at levels ranging from 11 to 18 ppt to be "protective for the most sensitive populations over a lifetime of exposure."⁴¹ This rulemaking exercise was met with a complaint filed by a water supply district, a biosolids management company, a citizen, and industry. The state court complaint alleged that the New Hampshire Department of Environmental Services did

not follow proper procedure when promulgating MCLs and groundwater standards for six types of PFAS.⁴² After acknowledging that the "legal issues raised by the Plaintiffs' challenge are complex, the importance of public health is paramount and the expense imposed by the proposed rule is significant," the Superior Court preliminary enjoined implementation of the standards and the case is now on interlocutory appeal to the New Hampshire Supreme Court.⁴³

Conclusion

Time will tell if courts will treat PFAS standards as "convenient guideposts" or determinative values that can prove or disprove an injury. Regardless of the outcome, today's lack of scientific consensus has done nothing to slow filing of new PFAS suits. New scientific studies will undoubtedly inform cases in progress and shape those to come. As more advisories and standards are released, it remains important that attorneys learn all they can about the highly technical field of toxicology and scrutinize regulatory developments. Both the standards and the suits are here to stay.

⁴⁰ The Environmental Council of States ("ECOS") has published an informative white paper compiling information on state PFAS guidelines and discussing the differences among them. Sarah Grace Longworth, Processes & Considerations for Setting State PFAS Standards (Feb. 13, 2020), available at <https://www.ecos.org/documents/ecos-white-paper-processes-and-considerations-for-setting-state-pfas-standards/>.

⁴¹ NHDES Proposes New PFAS Drinking Water Standards, Final Rulemaking Proposal for PFOA,

PFOS, PFHxS and PFNA (June 28, 2019), <https://www.des.nh.gov/media/pr/2019/20190628-pfas-standards.htm>.

⁴² Complaint, *Plymouth Village Water & Sewer District, et al. v. Robert R. Scott*, No. 217-2019-CV-00650 (Sept. 30, 2019).

⁴³ Order, *Plymouth Village Water & Sewer District, et al. v. Robert R. Scott*, No. 217-2019-CV-00650 (Nov. 26, 2019).

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