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#### PFAS Chemicals: The Bad News, The Worse News, Then Perhaps Some Hope.

**Prepared by: Rex Tennant** 

The story of PFAS chemicals and their effects is disturbing, on many levels. Like so many "helpful" things that turn out to be evil, PFAS chemicals are now apparently the bane of our existence. In the past, smoking was thought to be healthy, until it wasn't. Chloroform was the constituent of many medicines, until it was found to be deadly. Children once played with liquid mercury. Now, if a single drop of that element escapes a broken thermometer, it is a cause for alarm. It is the same for PFAS chemicals.

One of the attributes of PFAS chemicals is their fire-retardant properties. Over a half-century ago, it was relatively common for children and adults to be burned to death or scarred for life simply because they got too close to an open flame and their cotton clothing ignited. There were other flame-retardant treatments, like boron salts. However, the protection wore off after a few laundry cycles. Then fabric treatments, like ScotchGard, were developed. This product, and many others, made cotton clothing resistant to rapid combustion, saving countless lives. It also made clothing water- and stain-resistant. Moreover, the protection didn't disappear after the clothing was washed. We didn't know, however, that a tiny amount of the PFAS chemicals were leached from the clothing and ended up in the wastewater. PFAS passed, unaltered, through the sewage treatment plant and ended up in the river. Downstream, the chemical was taken in by the drinking water treatment plant, to be consumed by all of the users of the tap water. Meanwhile, the sludge from the upstream sewage treatment plant, which also contained traces of PFAS from the fabric treatment, was hauled to a farm for land-application. The hay growing in the farm's fertilized fields was harvested and eaten by beef cattle or milk cows. The livestock absorbed the PFAS from the hay, which has picked up the contaminant from the sewage sludge. People who ate the beef or drank the milk now consumed PFAS. All this from one can of flame retardant chemical.

We are now told that levels of PFAS chemicals in the part-per-trillion range can cause severe health problems, including cancer. Can it be that the person who, in innocence, used a single can of fabric protector is ultimately responsible for the sickness and deaths of scores to hundreds of people? PFAS chemicals, the so-called "forever chemicals", have been found in water, air, fish, and soil at locations around the globe. How do we determine guilt and assess punishment if we are all offenders? A nightmare situation is that, in the near future, every person in the world will be both a plaintiff and a defendant in a myriad of class-action suits. The result will be the Galaxy's greatest Jarndyce v Jarndyce situation, and we will all dwell in a truly Bleak House.



PFAS chemicals are naturally stable. (Note: They are "stable", but certainly not "inert"). Traditionally, the best way to remove PFAS from water is concentration of the chemical in activated carbon filters. Similar filters are able to trap air-borne PFAS. However, carbon filters have a finite capacity to adsorb PFAS, then they must be replaced. Since PFAS can be found in virtually all waters everywhere, then all water on the planet must be filtered before it can be deemed safe for consumption.

The question is, what to do with the PFAS-laden spent carbon filters? The answer is high-temperature incineration. The temperature must be high enough to destroy the carbon-fluorine bonds. Otherwise, the process just releases PFAS into the atmosphere. Solar and wind power will not be effective in generating the necessary heat to destroy the PFAS chemicals. We may be forced to decide between heating our homes or fueling the PFAS incinerators. However, incineration not only destroys the offending chemicals, but also the carbon filters, releasing enormous quantities of carbon dioxide. We will be trading one peril for another.

There is one glimmer of hope: back in the 1940's and 1950's PCB's were thought to be "forever" chemicals. They too are chemically stable, but not inert. The health effects from PCBs are virtually the same as those from PFAS chemicals. In the 1980's scientists noticed PCB levels in sediments were decreasing. They realized certain soil bacteria were effectively breaking the carbon-chlorine bonds in PCBs and turning the toxic chemicals into benign hydrocarbons. Researchers are experimenting with different microbes in the hope that bacteria can be cultured to degrade PFAS chemicals, rendering them likewise benign. Scientists have had some success with a limited number of PFAS chemicals. This is one area where gain-of-function research might yield beneficial results. In time, contaminated soil will be treated with a bacteria culture and "land-farmed" until the PFAS has been consumed. Likewise, spent carbon filters will be flushed with bacteria suspensions, incubated, and after a few days, be re-used. We will solve one vexing problem without creating another.



#### **Forever Chemicals in the Courts**

#### Prepared by: Dallas F. Kratzer III

Forever chemicals are featured in litigation of all shapes and sizes. There are individual state actions, and there are MDLs.<sup>1</sup> The cases may involve shareholder claims, or claims against the government, or torts. Detailing all the litigation across the country would be no less than a Herculean feat. Yet a few cases stand out for their potential impact on forever chemical litigation in general.

### 1. Federal district court rules that a jury should resolve factual questions regarding government contractor defense.

The U.S. District Court for the District of South Carolina oversees an MDL concerning PFAS in aqueous film forming foams, or AFFF, "used at airports, military bases, or certain industrial locations." The foam manufacturers asked the district court to determine whether they were entitled to immunity under the government contractor defense. Last September, the district court denied the manufacturers' motion for summary judgment, observing that the jury should resolve factual issues surrounding the availability of the defense.

First, the district court ruled that the foam manufacturers could not rely on military standards to show that "the United States approved reasonably precise specifications." It explained that the military standards did not require the use of a "particular formula" and were "far less detailed than the specifications at issue" in other cases. Additionally, the court noted that the manufacturers did not support their contentions with evidence of "extensive collaboration with the government" and that the standards were not so stringent that "the government dictated—implicitly—that either PFOS or PFOA be present."

Second, the district court also ruled that factual disputes prevented it from using the "continued use" doctrine to shield either 3M or the so-called Telomer Manufacturers from liability at the summary judgment stage. In short, the "continued use" doctrine affords immunity to a contractor upon a showing that "the government's continuous use of the product was with full

<sup>&</sup>lt;sup>1</sup> As briefly as possible, an MDL, or multi-district litigation, is a collection of individual federal lawsuits from district courts across the country that are consolidated based on their shared characteristics for pre-trial proceedings before a single district court.

<sup>&</sup>lt;sup>2</sup> In re Aqueous Film-Forming Foams Prods. Liab. Litig. (In re AFFF), 2022 WL 4291357, at \*2 (D.S.C. Sept. 16).

<sup>&</sup>lt;sup>3</sup> That defense insulates a party from "liability for design defects in military equipment" if "the United States approved reasonably precise specifications," "the equipment conformed to those specifications," and "the supplier warned the United States about the dangers in the use of the equipment that were known to the supplied but not to the United States." *Boyle v. United Techs. Corp.*, 487 U.S. 500, 512 (1988) (cleaned up). The defense has expanded to also cover instances where "the government continued to use the product after acquiring full knowledge of its defects and risks." *In re AFFF*, *supra*, at \*4.

<sup>&</sup>lt;sup>4</sup> In re AFFF, supra, at \*15.

<sup>&</sup>lt;sup>5</sup> *Boyle*, 487 U.S. at 512.

<sup>&</sup>lt;sup>6</sup> In re AFFF, supra, at \*6.

<sup>&</sup>lt;sup>7</sup> *Id.* at \*7.

knowledge of its defects and risks and that the contractor warned the government of defects and risks known to it and not the government." For both 3M and the Telomer Manufacturers, the court detailed the information both possessed as compared to the information they disclosed. As to 3M, the court found factual disputes remained with respect to whether 3M's delayed disclosure "retarded the government's knowledge" or "constituted a failure of its duty to warn." And as for the Telomer Manufacturers, the court noted several factual issues, including their "knowledge about the propensity of their products to degrade over time" and whether the government knew about the products' "properties and danger," among other things. 11

Although they failed to secure a favorable decision on the government contractor defense on summary judgment, the foam manufacturers may yet prevail because the jury could resolve the factual disputes in their favor. The foam manufacturers can also challenge the district court's ruling, but they will have to wait for a final order.<sup>12</sup>

#### 2. Federal court of appeals affirms decision prohibiting re-litigation of causation issues.

The U.S. District Court for the Southern District of Ohio has been the home of an MDL concerning drinking water contamination claims stemming from C-8 discharges from the Washington Works Plant near Parkersburg, West Virginia, where E.I. du Pont de Nemours & Co. (DuPont) manufactured Teflon products. A 2017 global settlement largely resolved the MDL, but additional parties filed cases after the settlement.

Of those additional cases, Travis and Julie Abbot's case resulted in a \$50 million jury verdict for the plaintiffs. DuPont appealed, challenging in relevant part the district court's decision that DuPont could not relitigate issues of duty, breach, and foreseeability. The Sixth Circuit disagreed with DuPont and affirmed. In doing so, it explained that the juries in prior cases from the MDL had already decided that "DuPont owed a duty to the class member, breached that duty, and should have foreseen that injury would result." Since the focus of those inquiries was on

<sup>9</sup> See generally id. at \*8-15.

<sup>&</sup>lt;sup>17</sup> In re E.I. du Pont de Nemours & Co., 54 F.4th at 924.



<sup>8</sup> *Id.* at \*8.

<sup>&</sup>lt;sup>10</sup> *Id.* at \*12.

<sup>&</sup>lt;sup>11</sup> *Id.* at \*15.

<sup>&</sup>lt;sup>12</sup> A denial of the government contractor defense "is not immediately appealable." *Al Shimari v. CACI Int'l Inc.*, 679 F.3d 205, 218 (4th Cir. 2012) (en banc).

<sup>&</sup>lt;sup>13</sup> U.S. Dist. Ct. S. D. Ohio, MDL 2433: MDL & Case Information, http://bit.ly/3IIQ89a (last visited Mar. 1, 2023).

<sup>&</sup>lt;sup>14</sup> See In re E.I. du Pont de Nemours & Co., 54 F.4th 912, 920 (6th Cir. 2022).

<sup>&</sup>lt;sup>15</sup> The jury awarded \$40 million to Travis and \$10 million to Julie, but the district court reduced Julie's award to \$250,000 upon application of the Ohio Tort Reform Act. *Id.* at 921. Another case went to trial, resulting in a hung jury. The parties settled the remaining cases filed after the global settlement. *See* ECF No. 5387 (Motion to Terminate), at PageID 132178, *In re E.I. du Pont de Nemours & Co.*, No. 2:13-md-2433 (S.D. Ohio Apr. 29, 2021).

<sup>&</sup>lt;sup>16</sup> DuPont also challenged evidentiary rulings relating to specific causation and the directed verdict concerning its statute of limitations defense. The Sixth Circuit rejected both, affirming the district court's decisions. *In re E.I. du Pont de Nemours & Co.*, 54 F.4th at 917, 921. Judge Batchelder disagreed with the majority's decision on the statute of limitations issue. *Id.* at 936, 946–47 (Batchelder, J., dissenting).

DuPont's conduct—and not issues specific to the particular plaintiffs—DuPont could not revisit those questions. 18

Nevertheless, the Sixth Circuit has not provided the last word. DuPont can still pursue an appeal to the Supreme Court of the United States.

#### 3. Federal district court largely denies motions to dismiss and various defenses.

The U.S. District Court for the Northern District of Georgia is currently handling a putative class action concerning PFAS in carpet production.<sup>19</sup> The class representative alleged that chemical suppliers, carpet manufacturers, and utilities—among others—"contributed to or caused the discharge of these chemicals into North Georgia waterways around Dalton."<sup>20</sup> In a 180-page order, the district court resolved twelve motions to dismiss, concluding that nearly all of the representative's claims could proceed.<sup>21</sup>

In all, the motions to dismiss took issue with the Clean Water Act claims and myriad state law claims (e.g., negligence and nuisance) and raised several defenses (e.g., economic loss rule, free public services doctrine, and sovereign immunity).<sup>22</sup> A few facets of the "odyssey of an order"—which navigated "more than 900 pages of briefing"—are notable.<sup>23</sup>

*First*, the district court dismissed a few select nuisance and negligence claims. For one, the court dismissed certain negligence and negligence per se claims against specific defendants for want of allegations that those defendants discharged wastewater, noting the lack of authority "establishing a duty on the part of a chemical supplier to protect an unknown third-party." For another, the court dismissed public nuisance claims against a utility based on the class representative's concession. <sup>25</sup>

Second, the district court rejected several defenses. For example, it rejected a utility's request for sovereign immunity under "both longstanding and current Georgia legal authority" removing "municipal immunity for nuisance claims involving personal injury." The court also determined that the economic loss rule—which prevents recovery in tort for damages properly obtained for breach of contract—did not bar any claims due to allegations of personal and property injuries and the common law (i.e., non-contractual) duties owed. Additionally, the

<sup>21</sup> *Id.* at 1269.

<sup>&</sup>lt;sup>28</sup> *Johnson*, 563 F. Supp. 2d at 1310.



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<sup>&</sup>lt;sup>18</sup> See id. at 925. The Sixth Circuit also noted that DuPont's prior agreement "not to contest general causation" also "informs the application of collateral estoppel here." *Id.* at 926.

<sup>&</sup>lt;sup>19</sup> Johnson v. 3M, 563 F. Supp. 3d 1253, 1268 (N.D. Ga. 2021).

<sup>&</sup>lt;sup>20</sup> *Id*.

<sup>&</sup>lt;sup>22</sup> Id. at 1268.

<sup>23</sup> Id

<sup>&</sup>lt;sup>24</sup> *Id.* at 1325; *see also id.* at 1356. The district court also dismissed a negligence per se claim against a defendant that was "improperly and inadvertently named." *Id.* at 1345.

<sup>&</sup>lt;sup>25</sup> *Id.* at 1311 n.13.

<sup>&</sup>lt;sup>26</sup> This ruling was affirmed on an interlocutory appeal. See Johnson v. 3M Co., 55 F.4th 1304 (11th Cir. 2022).

<sup>&</sup>lt;sup>27</sup> *Id.* at 1312.

court found the free public services doctrine—which prohibits a county from recovering costs incurred to provide public services necessitated by another's conduct—did not apply to a private citizen's claims.<sup>29</sup>

Since its ruling on the legion of motions to dismiss, the parties proceeded to discovery because, with one exception, an appeal must wait for a final order.<sup>30</sup> Any appeal is not, however, in the near future, as expert depositions are ongoing, class certification briefing has not closed, and summary judgment and *Daubert* motions are not due until May 2023.<sup>31</sup>

\* \* \*

So, what can we take away from these cases? To start, although one federal district court has limited the government contractor defense, it remains available to a certain extent (and an appeal may undo any limitations). Additionally, considering the decision of one federal court of appeals, the first round of litigation on causation may be the most important, as it may prevent revisiting that issue (but again, an appeal may change this). Lastly, as another federal district court has concluded, important defenses (e.g., economic loss rule and sovereign immunity) may not be available in forever chemical cases.

<sup>&</sup>lt;sup>31</sup> See ECF No. 1077 (Order), Johnson v. 3M Company, No. 4:20-cv-8 (N.D. Ga. Jan. 23, 2023).



<sup>&</sup>lt;sup>29</sup> *Id.* at 1311.

<sup>&</sup>lt;sup>30</sup> See note 26, supra.

#### Sinclair, DC. 2023. Evaluating the Epidemiological Evidence in Toxic Tort Litigation<sup>32</sup>

#### 1.0 The Role of Epidemiology in the Courtroom

Epidemiology is populations-based; however, a substantial body of legal precedent establishes that epidemiologic evidence is critical to prove causation for individual litigants through probabilistic means. Courts frequently have recognized the utility of epidemiological studies as evidence of general and specific causation.<sup>33</sup>

In Amorgianos v. Nat'l R.R. Passenger Corp., <sup>34</sup> the court addressed the vital role of epidemiology in the determination of causation of occupational diseases in medicolegal actions. Observing that "[t]he fundamental principles of epidemiology, which are now becoming well known to the courts, provide additional guidance," the court described the relative evidentiary weight accorded to epidemiologic studies:

There are several different forms that epidemiological studies take in the areas of occupational medicine . . .. These various research designs differ in the evidentiary weight they lend to a hypothesis that exposure to a given substance [physical, chemical, or biological factors] causes a given condition. An uncontrolled case study, or cases-series report, is not actually a formal epidemiologic investigation but simply the identification of an unusual occurrence or disease. In an occupational cross-sectional study, a survey is conducted to determine and compare the prevalence of disease or health status between groups of workers classified with respect to exposure status.

Because of their inherent limitations, these two study designs "usually represent preliminary or pilot investigations used to screen for possible workplace hazards or to generate hypotheses for testing in more complex designs." In contrast, cohort studies, which test for the incidence of a health condition in a randomly selected group of exposed workers and a randomly selected group of unexposed workers over time [citation omitted], and case-control studies, which compare the exposure histories of a group of workers who exhibit a particular health condition with a group of workers who do not exhibit the health condition but who are comparable in characteristics

<sup>&</sup>lt;sup>34</sup> Amorgianos v. Nat'l R.R. Passenger Corp., 137 F. Supp. 2d 147 (E.D. N.Y. 2001).



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<sup>&</sup>lt;sup>32</sup> Adapted from Sinclair, DC. 2024. Medical Expert Witness Testimony – Principles and Practice. In: Effective Management of Occupational and Environmental Health and Safety – A Practical Guide, Ch. 24, 4th Ed., Hegmann, KT and Hughes, M, Eds., OEM Press, Beverly Farms, Mass. (In press).

<sup>&</sup>lt;sup>33</sup> Green, MD, Freedman, M, Gordis, L. *Reference Guide on Epidemiology. In Reference Manual on Scientific Evidence*. 3d Ed., Federal Judicial Center & National Research Council, National Academies Press, Washington, DC (2011).

other than exposure . . . are "the most informative investigations used to test specific etiological hypotheses and to confirm and quantify degrees of health risk related to causal exposures . . ."<sup>35</sup>

#### 2.0 Inferring Causal Associations

The Amorgianos court observed, "[e]ven when an appropriately designed study yields evidence of a statistical association between a given substance and a given health outcome, epidemiologists generally do not accept such an association by itself as proof of a causal relationship [association] between the exposure and the outcome. [Internal citations omitted]. Epidemiologists generally look to several additional criteria to determine whether a statistical association is indeed causal. [Internal citation omitted]. These criteria are sometimes referred to as the Bradford Hill criteria, after the author of a leading statement of the principles." The Hill guidelines for inference of causation are:

- 1. **Strength of the association** [What is the magnitude of the association between the suspected risk factor and the observed health effect?];
- Consistency of the association [Have different investigators consistently observed an association among different groups under different conditions of exposure?];
- 3. **Specificity of the association** [Is the specific exposure factor uniquely associated one or more adverse health outcomes?];
- Temporality of the association [Does exposure to the putative risk factor always precede, never follow, the onset of the adverse health outcome?];
- Biological gradient [Does the occurrence or severity of the adverse health outcome increase or decrease in relative proportion to the magnitude of the exposure – a so-called doseresponse relationship?];

<sup>&</sup>lt;sup>36</sup> *Id.* at 168; see Hill, A. B., *The environment and disease: Association or causation?* Proc. Royal Soc. Med. 58:295-300 (1965); **importantly**, see also Susser, M.W., *Judgment and causal inference*, Am. J. Epid., 105:1-15 (1977); *Causal Inference*, Rothman, K.J., Ed., Epidemiological Resources Inc., Chestnut Hill, MA, (1988); Savitz, D.A., *Interpreting Epidemiological Evidence: Strategies for study design and analysis*, Oxford U. Press, NY, NY (2003); *A Dictionary of Epid.*, Porta, M., Ed., 5<sup>th</sup> Ed., Oxford U. Press, NY, NY (2008), discussing the Hill guidelines and their modern permutations.



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<sup>&</sup>lt;sup>35</sup> *Id.* at 168 (citing *Environmental & Occupational Medicine*, Rom, W., Ed., 3d Ed., (1998); *Casarett & Doull's Toxicology*, Klaassen, C., Ed., 5<sup>th</sup> Ed., (1996)).

- 6. **Biological plausibility** [Is the observed association logical, given contemporary knowledge of physiological responses to the exposure of interest?];
- 7. **Coherence** [Is the association consistent (*i.e.*, does not conflict) with contemporary knowledge concerning the natural history of disease?];
- 8. **Experimental evidence** [Has observation of the association led to an intervention that has prevented or diminished the prevalence of the disease?]; and
- 9. **Analogy** [Is there a reasonable analogy between an exposure of interest and an adverse health consequence on one organ or bodily system and an exposure-effect relationship involving another organ or bodily system?].37

Except for "analogy," which has been largely abrogated from modern notions of causality, the Amorgianos court adopted these criteria, but articulated them as adapted in authoritative references on epidemiology, toxicology, and scientific evidence.<sup>38</sup>

#### 3.0 Assessing the Quality of Individual Epidemiological Studies

The AMA Guides to the Evaluation of Disease and Injury Causation describe the hierarchy of evidentiary weight to be accorded to the various epidemiological study designs. Absent randomized controlled trials, the highest quality study is the prospective cohort study. Higher quality studies are accorded greater evidentiary weight provided that they have no major flaws.<sup>39</sup>

<sup>&</sup>lt;sup>39</sup> Hegmann, KT, Thiese, MS, Oostema, Melhorn, JM, Causal Associations and Determination of Work-Relatedness. Ch. 3. In Guides to the Evaluation of Disease and Injury Causation, 2<sup>nd</sup> Ed., Melhorn, JM, Talmage, JB, Akerman, WB, Hyman MH, Eds., American Medical Association Press, Chicago, III. (2014).



<sup>&</sup>lt;sup>37</sup> Bracketed explanations from: Sinclair, DC. 2010. Epidemiology in the Courtroom: An Evidence Based Paradigm for the Determination of Causation in Compensation Environments. JOEM, 52(4): 1-6.

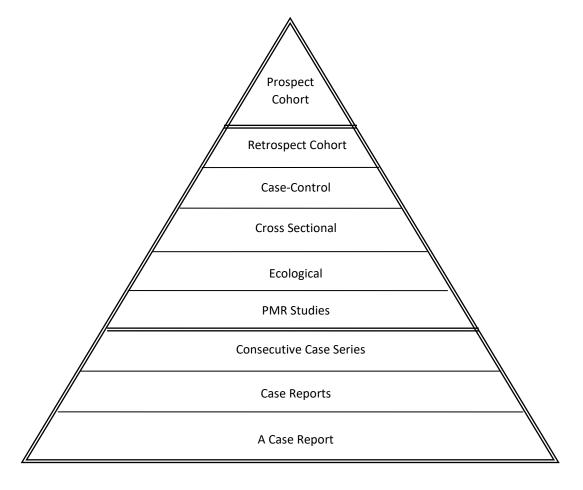


Figure 1. Hierarchy of Study Design Evidentiary Weight

**Adapted** from Hegmann KT, Oostema SJ. 2008. *Causal Associations and Determination of Work-Relatedness*. Ch. 3. In: Melhorn JM, Ackermann WE, Eds., *Guides to the Evaluation of Disease and Injury Causation*. AMA, Chicago, III.

It is important to perform a balanced review of the literature, rather than relying upon a single study or studies that support a predetermined conclusion favorable to a party's retained expert witness. 40 Greater credence should be accorded to well-designed and executed studies of higher hierarchical quality: the quality of an individual study may be so deficient that it may be dismissed from analysis. The following factors should be considered to evaluate the quality of individual research articles:

- 1. What is the volume of epidemiological research examining the association between the adverse health outcome of interest and the exposure of interest? (Generally, one cannot reasonably rely on one or a few studies, particularly if the studies are of inferior design and/or execution.)
- 2. Is the study reasonably contemporary?
- 3. Is the study descriptive or observational? (Anecdotal reports case reports and case series – are **not** epidemiological studies; rather, they are hypothesis generating only. Almost never can they be relied upon to provide inferences re causal association.)
- 4. What is the quality of the study design (e.g., randomized clinical trial, prospective cohort study, retrospective cohort study, or cross-sectional study)?
- 5. Are the study population subjects and the control population subjects matched for all attributes except exposure ... to preclude selection bias (or stratified and/or statistically adjusted)?
- 6. Are case definitions sufficiently rigorous (i.e., described in accordance with generally accepted diagnostic criteria)? Are case definitions consistent among studies (i.e., sufficiently homogenous to provide for meaningful comparison among multiple studies)?
- 7. Were potential sources of information bias (recall bias, reporting bias, healthy worker effect (survival/attrition rates), volunteer bias, selection bias, etc.) recognized and accounted for?
- 8. Were exposures to the agent of interest (physical, chemical, or biological) objectively measured and quantitated in accordance with valid and reliable methodologies (or were exposures self-reported or a surrogate exposure metric [e.g., occupational title] utilized)?
- 9. Were potentially confounding variables recognized and accounted for (i.e., exclusion, stratification, or statistical adjustment)?

<sup>&</sup>lt;sup>40</sup> Greaves, WW, Das, R, Green-McKenzie, J, Sinclair, DC, Hegmann, KT. 2018. Work-Relatedness. JOEM 60(12): e640-646; Greaves, WW, Das, R, Green-McKenzie, J, Sinclair, DC. 2018. Work-Relatedness. MDGuidelines®. Web, Hegmann, KT, Ed., www.mdguidelines.com. Reed Group, Ltd., acc'd Jan. 12, 2018.



- 10. Is an exposure-response relationship evident (*i.e.*, does a manifestation or magnitude of symptoms or the prevalence/incidence and severity of disease modulated by a decrease/increase in the frequency, intensity, duration, temporal pattern of exposure, or body burden)?
- 11. What is the statistical rigor of the study? (What statistical methods were employed in the conduct of the study? Are the statistical methods appropriate for the study design? Are the identified associations statistically significant? What is the *p* value at which statistically significant associations were observed? What is the confidence interval around significant associations? Is the study powered adequately to detect subtle, but important, associations between the exposure and the adverse health outcome of interest?)
- 12. Are the conclusions of the researchers consistent with the reported data?<sup>41</sup>

These factors *may* also be relied upon to determine – in the absence of formal pooled data analysis or meta-analysis – whether the body of epidemiological literature is sufficiently homogenous to provide meaningful synthesis of multiple studies.

#### 4.0 The Role of Epidemiology in Proof of General and Specific Causation

In a toxic tort action [and any action involving an occupation or environmental exposure to physical, chemical, or biological agents] a litigant must establish both general and specific causation through evidence that the toxic agent is not only generally capable of causing, but also did cause (*i.e.*, was the "cause-in-fact") the litigant's alleged injury: "[t]he plaintiff must show that he was exposed to the toxic substance and that the level of exposure was sufficient to induce the complained-of medical condition (commonly called a 'dose-response relationship').<sup>42</sup>

Litigants must establish that "'the individual [was] exposed to a sufficient amount of the substance in question to elicit the health effect in question,' and that 'the chronological relationship between exposure and effect [is] biologically plausible'; as well as that the expert considered the likelihood that the chemical caused the disease or injury in the context of other known causes." Absent expert testimony that establishes both general **and** specific causation a litigant's action will fail. 44

"[T]he issue of causation is not merely a question of science, but a question of law." Evidence proffered by plaintiff's experts may have demonstrated that the defendants were responsible for

<sup>44</sup> See Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 677 (6th Cir. 2011).



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<sup>&</sup>lt;sup>41</sup> Adapted, reordered, and revised by the author from Greaves, et al. (2018) fn 9.

<sup>&</sup>lt;sup>42</sup> Amorgianos 137 F. Supp. at 168 fn 3.

<sup>&</sup>lt;sup>43</sup> Adams v. Cooper Indus., 2012 U.S. Dist. LEXIS 85492 at \*5 (E.D. Ky.) (citing David L. Eaton, Scientific Judgment and Toxic Torts – A Primer in Toxicology for Judges and Lawyers, 12 J.L. & Pol'y 5, 38-40 (2003); *Downs v. Perstorp Components, Inc.*, 126 F.Supp.2d 1090, 1095 (E.D. Tenn. 1999)).

an inadvertent release of chemicals, and the testimony may have demonstrated a causal association between such chemicals and disease; however, "[s]uch evidence did not prove that the defendants were legally culpable for . . . decedent's death, because . . . it did not establish that the decedent was exposed to a sufficient quantity of the chemical to have caused his injury, and further, because it failed to exclude other possible [biologically plausible] causes." This latter consideration requires an evaluation of independent and dependent causes.

#### 5.0 Synthesizing the Epidemiological Evidence

The American College of Occupational and Environmental Medicine Work-Relatedness guideline adopts an algorithm for evaluating the epidemiological evidence, which is apropos for synthesizing the epidemiological literature in medicolegal proceedings. 46

Remainder of page intentionally left blank: a table follows.

<sup>&</sup>lt;sup>46</sup> Greaves, *et al.* (2018) fn 6.



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<sup>&</sup>lt;sup>45</sup> *Id.* fn 12. (Emphasis added).

Table 1. Steps for Evaluating Epidemiological Evidence of a Causal Association

- 1. Collect all epidemiological literature reported on that disorder
- 2. Identify the design of each study
- 3. Assess each study's methods
  - a. Exposure assessment methods and potential biases
  - b. Disease ascertainment methods and potential biases
  - c. Absence of significant uncontrolled confounders; consideration of residual confounding
  - d. Addressing of other potential biases
  - e. Adequacy of biostatistical methods and analytical techniques
- 4. Ascertainment of statistical significance degree to which chance may have produced those results
- 5. Assess the studies using the Updated Hill's Criteria, both applied to individual studies (especially 5a-d) and in aggregate (all)
  - a. Temporality
  - b. Strength of Association
  - c. Dose-Response
  - d. Consistency
  - e. Coherence
  - f. Specificity
  - g. Plausibility
  - h. Reversibility
  - i. Prevention/Elimination
  - i. Experiment
  - k. Predictive Performance
- 6. Conclusion regarding the degree to which such a causal association is/is not met

**Adapted** from Hegmann KT, Oostema SJ. 2014. *Causal Associations and Determination of Work-Relatedness*. Ch.3, In: Melhorn JM, Ackermann WE, Eds., *Guides to the Evaluation of Disease and Injury Causation*. AMA, Chicago, III.

The ACOEM guideline summarizes collation of the epidemiological evidence, evaluation of individual study quality, synthesis of the quality epidemiological literature to determine whether there is sufficient evidence to infer a causal association between an occupational or environmental exposure and adverse health consequences in community populations.



#### State Legislatures Likely to Address PFAS in 2023

Prepared by: Skipp Kropp

A recent legislative analysis indicates that numerous state legislatures are focusing on PFAS issues in 2023. The analysis by Safer States, which is "an alliance of diverse environmental health coalitions and organizations from across the nation committed to building a healthier world," (<a href="www.saferstates.org">www.saferstates.org</a>) reviewed state policies nationwide and found that twenty-eight (28) state legislatures, including AK, CA, CT, DE, IA, IL, IN, MA, MD, ME, MI, MN, NC, NH, NJ, NV, NY, OK, OR, PA, RI, SC, TN, VA, VT, WA, WI, and WV as well as the District of Columbia will consider some type of legislation addressing various PFAS issues.

Stateline, an initiative of The Pew Charitable Trusts, reports (<a href="https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2023/02/14/a-slew-of-state-proposals-shows-the-threat-of-forever-chemicals">https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2023/02/14/a-slew-of-state-proposals-shows-the-threat-of-forever-chemicals</a>) that "[s]tate lawmakers across the country want to tackle the growing problem. Several states have passed landmark laws in recent years, and now dozens of legislatures are considering hundreds of bills to crack down on using such compounds. The legislation would strengthen product disclosure laws, increase liability for polluters, bolster testing plans and enact water quality standards."

Sarah Doll, national director of Safer States, is quoted in the February 14 issue of Stateline, as saying "[t]here's a lot of urgency. I'm seeing more states try to take really big bites at managing the PFAS crisis."

It appears that the fear of PFAS exposure is driving many state legislatures to consider various issues related to PFAS. Safer States reports that the states of AK, CT, IA, MA, MN, MI, NV, NJ, NY, RI, and VT are expected to consider banning PFAS chemicals from multiple source categories, and some will consider requiring disclosure of PFAS chemicals in products. CO, ME, and WA have already adopted some form of these policies.

The states of MA, NH, NJ, NV, NY, RI, VT, and VA are expected to consider policies to eliminate PFAS from textiles for product categories including carpets, rugs, upholstery, aftermarket textile treatments, juvenile products, outdoor gear and apparel. CA and WA have identified these types of products as significant sources of human and ecological exposures to PFAS and are attempting to find safer alternatives.

At least six (6) states, including CT, IA, MN, NJ, PA, and RI will consider policies to eliminate PFAS from firefighting foam, including bans, restrictions, and/or take-back programs since firefighting foam is a major source of PFAS drinking water contamination. Many states have already passed bans on PFAS in firefighting foams and Congress is now requiring the military and the FAA to stop using PFAS-based firefighting foams. Several states now require disclosure of PFAS in personal protective equipment.



At least eleven (11) states, including CT, HI, IA,MA, MI, NH, NJ, NV, OR, RI, and VT, will consider policies to eliminate PFAS chemicals from food contact materials, including packaging and cookware because of the concern that PFAS chemicals can leach into food from packages and cookware, which may result in PFAS exposure when the food is consumed. Studies also show that when PFAS-coated food packaging is composted or landfilled, the chemicals can migrate into the environment. Indeed, a 2020 study reported in Environ. Sci.: Water Res. Technol., 2020, 6, 1300-1311 (<a href="https://pubs.rsc.org/en/journals/journal/ew">https://pubs.rsc.org/en/journals/journal/ew</a>) concluded that landfill leachate contributes per-/poly-fluoroalkyl substances (PFAS) and pharmaceuticals to municipal wastewater, finding that PFAS were detected more frequently in leachate (92%) than in influent (55%), and that total PFAS concentrations in leachate were more than ten (10) times higher than in influent.

In 2021, the NY Times reported that EPA approved in 2011 use of chemicals that, "under some conditions...'degrade in the environment' into substances akin to PFOA, a kind of PFAS chemical, and could 'persist in the environment...' As a result of this and other reports of fracking chemicals forming PFAS in the environment, the state of MA in 2023 will be considering restrictions for PFAS in fracking fluid. Other fears have caused legislatures to consider bans on PFAS in products such as artificial turf (MA, RI, VT), paint (NY), pesticides (MA, MN, VT), ski wax (MN, RI) and antifogging spray (NY).

In summary, as a result of a combination of inaccurate or no data and public pressure on legislative representatives, it is highly likely that many states will pass legislation that is premature and may result in costly, ineffective action in response to the growing concern over the fate of PFAS chemicals in the environment and PFAS exposure of the voting public.



#### Acquisition and Evaluation of PFAS Contaminated Properties

#### **Prepared by Kathy Beckett**

All Appropriate Inquiries. The All Appropriate Inquiries ("AAI") Rule sets the Federal standards for conducting and meeting the standards and practices necessary for fulfilling the requirements of CERCLA §101(35)(B) to obtain CERCLA liability protection and for conducting site characterizations and assessments with the use of brownfields grants. 40 CFR Part 312. The premise of AAI is that bona fide prospective purchasers and contiguous property owners may qualify for limited liability under Sections 107 and 101(35) of CERCLA.

Every Phase I environmental site assessment conducted with EPA Brownfields Assessment Grant funds must be conducted in compliance with AAI Final Rule at 40 CFR Part 312. The recently modified AAI Final Rule provides that ASTM International Standard E1527-21 ("Standard Practice for Environmental Site Assessment Process") and E2247-16 ("Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process for Forestland or Rural Property") are consistent with the requirements of the final rule and can be used to satisfy the statutory requirements for conducting AAI. AAI may be conducted in compliance with either of these standards to obtain protection from potential liability under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) as an innocent landowner, a contiguous property owner, or a bona fide prospective purchaser.

<u>Substances</u>. USEPA's updated due diligence rule was published in the Federal Register on December 15, 2022 and can be found at 87 Fed. Reg 76578. The final rule became effective on February 13, 2023. This new rule provides for the optional utilization of the ASTM E1527-21 standard practice to comply with the all appropriate inquiries requirements of CERCLA.<sup>47</sup> The new standard may also be used by an entity conducting a site characterization or assessment of a property with funding from a brownfields grant awarded under CERCLA 104(k)(2)(B)(ii). This includes State, local and tribal governments that receive brownfields site assessment grants.

EPA provides that there are no legally significant differences between the regulatory requirements at 40 CFR part 312 and the ASTM E1527-21 standard. EPA has generated a "Comparison of All Appropriate Inquiries Regulation, the ASTM E1527-13 Phase I Environmental Site Assessment Process, and the ASTM E1527-21 Phase I Environmental Site Assessment Process". This resource is found at: <a href="https://www.regulations.gov/document/EPA-HQ-OLEM-">https://www.regulations.gov/document/EPA-HQ-OLEM-</a>

<sup>&</sup>lt;sup>47</sup> The new due diligence rule phases out the use of ASTM E1527-13 which is slated for sunset by ASTM. The phase out is designed to accommodate ongoing investigations using this standard. One year after December 15, 2022 utilization of ASTM E1527-13 will no longer be compliant with this program. "A Phase I Environmental Site Assessment completed before that date using ASTM E1527-13 will be recognized as compliant with the AAI rule."



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<u>2021-0946-0002</u> Key to understanding the applicability of this new standard to emerging contaminants like PFAS is the statement by EPA as follows:

Another significant difference of this new updated standard is the discussion around emerging contaminants. ASTM E1527-21 notes in Sections 13.1.5.15 and X6.10 that **substances not defined as hazardous substance under CERCLA**, including some substances generally referred to as emerging contaminants because human understanding is evolving (e.g., per- and polyfluoroalkyl substances, or PFAS), **are not included in the scope of a Phase I report.** However, emerging contaminants may want to be assessed in connection with commercial real estate, because once these contaminants are defined as a hazardous substance under CERCLA, then these substances must be evaluated within the scope of E1527-21.48

What are the options for assessing PFAS in the interim where EPA has yet to list PFAS as a Hazardous Substance under CERCLA and AAI and bona fide purchaser protections are not applicable? Without a listing of PFAS or other Emerging Contaminants as a regulated hazardous substance, what legal options are available to an entity seeking ways to limit liability for PFAS contaminants?

- EPA Audit Policy. This policy encourages the use of environmental auditing by regulated entities to help achieve and maintain compliance with environmental laws and regulations, as well as to help identify and correct unregulated environmental hazards. The policy strives to protect and promote environmental auditing. As a matter of policy, EPA will not routinely request environmental audit reports.
- State Law Audit Privilege. States have established certain statutory laws
  governing the conduct and disclosure of internal audits. Assessment of those laws
  can be helpful in understanding the ability to assert privilege from disclosure of
  such self-critical analyses and under what circumstances.
- Audit conducted at the request of counsel. Work product privilege applies if the
  audit is conducted at the request of counsel, as opposed to audits conducted in
  the ordinary course of business. All written communications must be clearly
  labeled as "attorney-client privileged/attorney work product" and must be
  communication between the client and the attorney, rather than individuals or
  entities not included in the attorney-client relationship.

<sup>&</sup>lt;sup>48</sup> In the E1527-21 standard, ASTM provides a footnote that suggests including PFAS or other emerging contaminants in the assessments if states define them as hazardous substances and users want to obtain state liability defenses.



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What happens relative to liability under CERCLA when EPA lists PFAS as a Hazardous Substance? Persons may be held strictly liable for cleaning up hazardous substances at properties that they either currently own or operate, or owned or operated in the past. Strict liability under CERCLA means that liability for environmental contamination may be assigned based solely on property ownership. The AAI due diligence protocol can assist in protecting bona fide prospective purchasers and contiguous property owners to qualify for protection from CERCLA liability. It also can be used during site characterization or assessment of a property with funding from a brownfields grant.

<sup>&</sup>lt;sup>49</sup> On February 10, 2023 the Office of Information and Regulatory Affairs received the USEPA proposed rule, "PFAS-Related Designations as CERCLA Hazardous Substances." The draft rule is pending review.



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#### **PFAS Sampling and Analytical Methods**

#### Prepared by: Joyce Gentry, PE

Analytical methods and sampling techniques are changing as new information comes available. Below is the current information as of March 2023.

#### **Drinking Water**

- Method 537.1: Determination of Selected PFAS in Drinking Water by SPE and LC/MS/MS (2018/2020) EPA method for the determination of 18 PFAS in drinking water, including HFPO-DA (one component of the GenX processing aid technology). First published in 2009 for the determination of 14 PFAS, this method was updated as more PFAS, that have the potential to contaminate drinking water, have been identified or introduced as PFOA/PFOS alternatives in manufacturing. Notes: This method replaced Method 537 originally developed in 2009. The updated 2020 version 2.0 of 537.1 contained only editorial changes and no technical changes.
- Method 533: Determination of PFAS in Drinking Water by Isotope Dilution Anion Exchange SPE and LC/MS/MS (2019) - EPA isotope dilution method developed to support measurements for the Fifth Proposed Unregulated Contaminant Monitoring Rule (UCMR) sampling effort. This method targets "short chain" PFAS (none greater than C12), including perfluorinated acids, sulfonates, fluorotelomers, and poly/perfluorinated ether carboxylic acids. Method 533 measures a total of 25 PFAS.

#### Non-Potable Water and Other Environmental Media

- Method 8327: PFAS Using External Standard Calibration and MRM LC/MS/MS (2019): Direct injection method for non-drinking water aqueous (groundwater, surface water, and wastewater) samples. Validated for 24 analytes.
- Draft Method 1633 Draft, single-laboratory validated, direct injection EPA method for 40 PFAS in wastewater, surface water, groundwater, soil, biosolids, sediment, landfill leachate, and fish tissue. Note: EPA and the Department of Defense are collaborating on the development of this method. A multi-laboratory validation study will be conducted by DoD, in collaboration with EPA.

#### Source Air Emissions

 Other Test Method (OTM)-45 - EPA method that measures PFAS air emissions from stationary sources. This method will help other federal agencies, states, tribes, and



communities have a consistent way to measure PFAS released into the air. Currently, OTM-45 can be used to test for 50 specific PFAS compounds. In addition to testing for these 50 specific PFAS, the method can also be used to help identify other PFAS that may be present in the air sample, which will help improve emissions characterizations and inform the need for further testing. EPA intends for the scientific community to provide feedback on OTM-45. EPA will consider and incorporate feedback to keep improving the method. Scientists and stakeholders can learn more about the process for submitting feedback in the introduction text of the method document.

- SW-846 Test Method 0010: Modified Method 5 Sampling Train For semi/non-volatiles. A performance-based, Modified Method 5 that uses an isotope dilution train approach for GC/MS targeted and non-targeted analysis.
- Modified Method TO-15: For volatiles. Uses SUMMA canisters for GC/MS targeted and non-targeted analysis.

#### **Ambient Air**

- Ambient/Near-Source (coming soon) Field deployable Time of Flight/Chemical Ionization Mass Spectrometer for real time detection and measurement.
- Semi-volatile PFAS (coming soon) A performance-based method guide by EPA TO-13a.
- Volatile PFAS (coming soon) Uses SUMMA canisters and sorbent traps for GC/MS targeted and non-targeted analysis.

#### Total

- Total Organic Fluorine (TOF) (coming soon) EPA is developing a potential rapid screening tool to identify total PFAS presence and absence. This eventual standard operating procedure will be used to quantify TOF. Note: EPA is working to develop this method in 2021.
- Total Organic Precursors (TOP) (coming soon) EPA is considering the development of a method, based on existing protocols, to identify PFAS precursors that may transform to more persistent PFAS. Note: TOP methods are commercially available. EPA will consider the need for a thorough multi-laboratory validation study in 2021.

#### Sampling Dos and Don'ts

#### Dos

- Develop a Quality Assurance Project Plan (QAPP) the analyte list, method of analysis, environmental matrices, and reporting limits.
- Develop a sampling plan and coordinate with the laboratory conducting the analysis.
- Wash hands and use new nitrile gloves for each sample collected.



- Collect the PFAS sample first, prior to collecting samples for any other parameters into any other containers. This avoids contact with any other type of sample containers, bottles, or package materials.
- When the labeled sample is collected, place the samples in an individual sealed plastic bag separate from all other sample parameter bottles.
- Samples must be chilled during shipment and should arrive at the lab at <6 C +/-2.</li>
- Use field blanks, trip blanks, equipment blanks, and duplicate samples to identify possible cross-contamination.

#### Don'ts

- Utilize any item containing one or more of the following compounds: Teflon®, Hostaflon®, Kynar®, Neoflon®, Tefzel®, Teflon® FEP and Hostaflon® FEP.
- No food should be consumed in the staging or sampling areas, including pre-packaged food or snacks.
- Clothing: new or unwashed clothing; Anything made of or with Gore-Tex<sup>™</sup> or other water-resistant synthetics, fabric softener, anything applied to the clothing
- Application of personal care products (PCPs)<sup>50</sup> such as sunscreen and insect repellant in the staging or sampling area.
- Decontamination Decon 90® and PFAS treated paper towels.
- Sampling: Teflon® lined bottles or caps.

<sup>&</sup>lt;sup>50</sup> The following products have been tested by Michigan EGLE and allowable if used outside of the staging and sampling area. Sunscreens: Banana Boat® - for Men Triple Defense Continuous Spray Sunscreen SPF 30, Sport Performance Coolzone Broad Spectrum SPF 30, Sport Performance Sunscreen Lotion Broad Spectrum SPF 30, and Sport Performance Suncreen Stick SPF 50; Coppertone® Sunscreen Lotion Ultra Guard Broad Spectrum SPF 50, Sport High Performance AccuSpray Sunscreen SPF 50, Sunscreen Stick Kids SPF 55; L'Oreal® Silky Sheer Face Lotion 50; Meijer® - Clear Zinc Sunscreen Lotion Broad Spectrum SPF 50, Sunscreen Continuous Spray Broad Spectrum 30, Clear Zinc Sunscreen Lotion Broad Spectrum SPF 15, 30 and 50, and Wet Skin Kids Sunscreen Continuous Spray Broad Spectrum SPF 70; Neutrogena® - Beach Defense Water + Sun Barrier Lotion SPF 70, Beach Defense Water + Sun Barrier Spray Broad Spectrum SPF 30, Pure & Free Baby Sunscreen Broad Spectrum SPF 60+, and UltraSheer Dry-Touch Sunscreen Broad Spectrum SPF 30 Insect Repellents: OFF® Deep Woods and Sawyer® Permethrin



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#### **Publicly Owned Treatment Works and PFAS:**

#### Managing Industrial Users in a Pre-Regulation World

Prepared by: Marissa G. Nortz

By now, you are likely aware that many states and the U.S. Environmental Protection Agency ("EPA") are actively preparing to roll out a litany of regulations aimed at the use and introduction of per-and polyfluoroalkyl substances ("PFAS") into both commerce and the environment.<sup>51</sup> Yet, if your organization is set to be impacted by these regulations, what do you do in the interim, especially when civil actions related to the impacts of these substances are being filed almost daily?<sup>52</sup> For publicly owned treatment works ("POTWs"), the impending regulations are even more daunting, as POTWs are considered a primary source of PFAS in the environment yet are passive receivers of these substances because they neither generate these substances within their operations nor profit from their use.<sup>53</sup> For POTWs across the country, one proactive step in the management of these substances is the evaluation and regulation of industrial users whose operations actively contribute wastewater containing PFAS to the wastewater system.

For POTWs in West Virginia, and likely many others across the country, the West Virginia Public Service Commission ("PSC") mandates that POTWs provide wastewater services to those users, including industrial users,<sup>54</sup> that properly apply for such service.<sup>55</sup> While the PSC mandates that such service be provided, the West Virginia Department of Environmental Protection ("WVDEP") is charged with regulating these users within a POTW's national pollutant discharge elimination system ("NPDES") permit in compliance with the pretreatment requirements of the federal Clean Water Act.<sup>56</sup> Depending on the size of the POTW,<sup>57</sup> WVDEP retains enforcement authority over

<sup>&</sup>lt;sup>57</sup> See W. Va. Code R. § 47-10-14.4.



<sup>&</sup>lt;sup>51</sup> See EPA PFAS Strategic Roadmap, <a href="https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024">https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024</a> (last updated Feb. 13, 2023); see also U.S. State Resources about PFAS, <a href="https://www.epa.gov/pfas/us-state-resources-about-pfas">https://www.epa.gov/pfas/us-state-resources-about-pfas</a> (last updated Jan. 9, 2023).

See A Brief Primer on PFAS Litigation: Trends and Future Disputes, https://www.thompsoncoburn.com/insights/publications/item/2022-08-25/a-brief-primer-on-pfas-litigation-trends-and-future-disputes (Aug. 25, 2022).

<sup>&</sup>lt;sup>53</sup> See Utah Department of Environmental Quality: Sources of PFAS, <a href="https://deq.utah.gov/pollutants/sources-of-pfas">https://deq.utah.gov/pollutants/sources-of-pfas</a> (last updated Feb. 17, 2022).

<sup>&</sup>lt;sup>54</sup> Industrial users are simply nondomestic dischargers introducing pollutants to a POTW.

<sup>&</sup>lt;sup>55</sup> W. Va. Code R. § 150-5-5.5.a ("A sewer utility, whether publicly or privately owned, is under a public service obligation to extend its mains, and its plant an facilities to serve new customers within its service area who may apply for service."),

<sup>&</sup>lt;sup>56</sup> W. Va. Code R. § 47-10-14.3.

a POTW's industrial users, which limits the POTWs ability to enforce or restrict the type of actions and discharges these users are taking.

While a POTWs hands may be tied through the enforcement of its NPDES permit, there are still actions a POTW can take to regulate its industrial users and to ensure that the POTW maintains control of the pollutants, including PFAS, that these users may be introducing to the wastewater system. It is recommended that POTWs consider the following actions for their industrial users:

- Determine whether any of your industrial users are introducing PFAS into the wastewater system.
  - You may review safety data sheets, discuss the presence of PFAS with a representative of the user, or sample the user's influent for PFAS prior to its discharge to your system.
  - There may be options for financing this research through the Clean Water State Revolving Fund.
- If you determine that a user is introducing PFAS into your system, request that your NPDES permit be modified to require the user to monitor for these substances so that you can actively monitor what and how much of the PFAS is being introduced.
- Actively develop and use Sewer Use Agreements
  - These agreements serve as a contract between the POTW and industrial user, and so long as they comply with the requirements of the PSC or other state regulatory agencies, can be enforced as such.
  - Within these Agreements, specifically detail the authority the POTW will have over the user as it relates to PFAS. Examples include:
    - Require the user to notify the POTW of the introduction of any PFAS into the system.
    - Require the user to implement pretreatment for the PFAS prior to discharge into the POTW system.
    - Ability to conduct inspections of the user's system and to conduct sampling of their discharge before it enters the POTW.
    - Ability to engage in enforcement actions for violations of the Sewer Use Agreement and/or relevant provisions of the NPDES permit.
    - Ability to require the industrial user to pay for any treatment upgrades the POTW is required to implement as a result of the PFAS present in the industrial user's discharge.



- Ability to require the industrial user to bear the burden of any enforcement, either administrative or civil, that the POTW may face as a result of accepting the industrial user's discharge.
- Ability to require an industrial user to cease the discharge of wastewater to the POTW when it is determined that the presence of PFAS within this discharge is likely to cause harm to: (1) human health; (2) the environment; and/or (3) the POTW's treatment system.<sup>58</sup>

While POTWs may be passive receivers of PFAS, they can be proactive in how they manage the introduction of these substances into their system prior to the enactment of final regulations. One such action is to evaluate a system's industrial users and take advantage of Sewer Use Agreements and existing regulations to ensure that these users bear most of the responsibility for the management of these substances.

<sup>&</sup>lt;sup>58</sup> Note, there are specific requirements a POTW will need to follow in order cease the acceptance of wastewater from an industrial user, as such an order can lead to human health and environmental concerns should the waste not be properly managed. A POTW should evaluate these requirements prior to requiring an industrial user to cease the discharge of wastewater to its system.



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# EPA's Long Awaited Safe Drinking Water Act MCLs For PFAS Are Here What's Next for Public Water Systems?

**Prepared by: Marissa Nortz** 

On March 14, 2023, the United States Environmental Protection Agency ("EPA") <u>announced</u> its much anticipated per-and polyfluoroalkyl substances ("PFAS") National Primary Drinking Water Regulation. This draft proposal extends to six (6) PFAS: perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorononanoic acid ("PFNA"), hexafluoropropylene oxide dimer acid ("HFPO-DA," commonly known as GenX Chemicals), perfluorohexane sulfonic acid ("PFHxS"), and perfluorobutane sulfonic acid ("PFBS"). This proposal comes after EPA's 2021 determination that PFOA and PFOS, the two most well known PFAS, required regulation under the Safe Drinking Water Act ("SDWA"), and used additional regulatory authority to develop a regulation for the four additional PFAS.

EPA's proposal establishes both legally enforceable Maximum Contaminant Levels ("MCL") as well as non-enforceable Maximum Contaminant Level Goals ("MCLG") for these PFAS in drinking water. The breakdown of limits and requirements in the proposal are as follows:

Compound	Proposed MCLG	Proposed MCL (enforceable levels)
PFOA	Zero	4.0 parts per trillion (also expressed as ng/L)
PFOS	Zero	4.0 ppt
PFNA		
PFHxS	1.0 (unitless)	1.0 (unitless)
PFBS	Hazard Index	Hazard Index
HFPO-DA (commonly referred to as GenX		
Chemicals)		

Further, EPA's proposal would require public water systems ("PWSs") to monitor for these PFAS, notify the public of the results of these monitoring efforts if the MCL is exceeded, and reduce the levels of these PFAS in drinking water if the MCL is exceeded through the implementation of treatment technologies or other control techniques.



EPA's proposal raises questions critical to a PWS, particularly as to the roles and responsibilities EPA purports to allocate to a PWS, should this rule be finalized. The proposal purports to require a PWS to pay for both the required monitoring and required treatment, which could be no small task for more rural systems. While EPA does reference the availability of outside funding options, there is currently little detail provided on how those funds will be distributed at either the state or federal level. Clarification of the funding portion is critical to ensure that PWSs will not carry an unfair and undue burden, which in many cases will be distributed to a PWS's customers, without promise of aid from outside resources. Further, this proposal still fails to detail how and when EPA will address the primary source of these substances in the environment, as a reduction of these substances in our nation's waters must begin at the source, and not solely with passive receivers such as PWSs.

PWSs should participate in the public comment period for this proposal to ensure that their concerns are heard by EPA. While the public comment period will be set out in the official Federal Register publication of this proposal once published, PWSs should start preparing their comments now.



# Current Treatment Practices and Disposal for Per and Poly Fluoroalkyl Substances Prepared by John Keeling

Introduction - Per and Poly Fluoroalkyl Substances otherwise known as the general category acronym of PFAS are manmade substances which, when released to water or soil, do not degrade naturally. These substances do however accumulate in water, soil, vegetation, and other living creatures due to their durability. There are several thousand PFAS compounds which have been produced since the substances were first created in the 1930's. Some of the original PFAS substances are no longer produced but many others, which are currently considered to be of less risk, are still produced and used in a variety of products. Firefighting foams which are designated as aqueous film forming foams (AFFF) were used (firefighting, practice, and spills) at public, private, and defense department airports are typically the largest source of PFAS in the environment, but manufacturing facilities which produced the materials were/are also significant sources. Some airport facilities still have the AFFF of concern while many have converted to foams with similar capabilities but not forever in nature. Almost all airports have some soils/groundwater contamination associated with PFAS. PFAS environmental contamination is present worldwide.

While there are treatment and disposal options for removal of PFAS substances use of such is expensive and results in other environmental concerns. This paper discusses current treatment technology and waste disposal.

<u>Water and drinking water treatment</u> – PFAS contamination of surface water and groundwater is most prevalent on property and downstream of PFAS manufacturing facilities and airports. USEPA has established maximum concentrations for PFAS in drinking water which requires potable water suppliers to treat the raw intake water for PFAS removal if such contamination is present.

Ex-situ sorption and/or concentration technologies have been used for a few years and remain the most reliable method for water treatment. These technologies include:

- Granular activated carbon tried and true, but PFAS will breakthrough.
- Ion-exchange resins shows improving promise for select ability.
- Reverse osmosis effective but expensive.
- Colloidal activated carbon use is increasing for groundwater.

The most common treatment method currently used is filtration of water through activated carbon. Since activated carbon absorption of PFAS is limited, the systems have to be monitored to ensure breakthrough has not occurred. Once the carbon is spent, reactivation or disposal is expensive for the activated carbon.



<u>Soil, Sludge, and Sediment Treatment Technologies</u> – PFAS in soil, sludge, sediment, of other solid media can be treated (stabilized), solidified, or destroyed. The following is a brief listing of these technologies:

- Stabilization (Rembind, Flourosorb, biochar, bentonite)
- Solidification (Portland Cement, fly ash)
- Soil Washing (PFAS transfer from soil to water)
- Thermal Desorption/Thermal Oxidation (TD/TO)
- Chemical Oxidation (in-situ)
- Incineration

Solidification with cement is currently the most common method used for PFAS containing solids. This method can be cost effective if the PFAS concentrations are high enough. The final disposal method for solidified solids is landfilling.

<u>PFAS Contaminated Water Disposal</u> – Disposal of higher concentrated PFAS water currently has limited options which are listed below:

- Deep Well Injection
  - 1. Republic, Romulus, MI,
  - 2. Texas Molecular, Deer Park, TX
  - 3. Buckeye Brine, Coshocton, OH
- Landfill Solidification
- Incineration
  - 1. Clean Harbors
  - 2. Heritage

<u>Waste Management and Remediation Challenges</u> – The current treatment and disposal options for PFAS contaminated media offer some significant challenges and considerations as listed below:

- Costs to transport and dispose PFAS containing soil and water differ across US.
- Inconsistencies and confusion for which facilities are receiving PFAS containing soil/sediment.
- Project specific approvals.
- Reliable and consistent opportunities for waste disposal from remedial activities.
- On-site Soil treatment Hesitancy to perform treatment as regulatory clean-up standards decreasing as toxicological research continues.

Many states have not promulgated final clean up criteria or may be changing to lower concentrations as EPA publishes new limits for PFAS in soil and water. Some states have clean-up criteria but are not sure how to use them to regulate remediation.



#### **APPENDIX**

#### **AUTHOR BIOGRAPHICAL & CONTACT INFORMATION**



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Joyce M. Gentry – Joyce McCune Gentry, MS, a member of the PFAS Team, has more than twenty-five years of experience in the environmental arena. Joyce received a B.S. degree in Civil Engineering and a M.S degree.in Civil/Environmental Engineering. She works with industrial and commercial clients, providing technical consulting services, including water and air permitting, pollution prevention planning, the development and implementation of waste management programs, as well as advice on client-specific environmental issues. In addition to providing support for industrial and commercial clients, she has provided litigation support, such as environmental data analysis and data management.

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John J. Keeling, PE, CIH, CSP, QEP, is a Senior Environmental, Safety, and Occupational Health Consultant and member of the PFAS Team, with more than 40 years of experience in Environmental and Occupational Safety/Health issues. Keeling has a BS Degree in Civil Engineering from the University of Kentucky and a variety of Professional Certifications/Licenses. As Senior Environmental, Safety, and Occupational Health Consultant he routinely provides services for environmental assessment and remediation projects, environmental due diligence associated with property transactions, NSR and Title V air emissions permitting/compliance, above ground storage tank compliance, NPDES related compliance (Process and Stormwater), Process Safety Management, workplace indoor air quality and working

conditions assessments, IH Monitoring Program development, ISO Environmental Management Assessments, and litigation support. He has managed multiple WV Voluntary Remediation Program (VRP) projects. He has served as an Expert Witness in multiple Federal and State Court Cases over the past two decades.

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Dallas Kratzer, a member of the PFAS Team, joined Steptoe & Johnson after spending more than five years working in the United States Courts. His legal practice is focused on litigation, and his experiences in federal trial and appellate courts—including the Fourth Circuit, Sixth Circuit, and the Supreme Court of the United States —help him advise clients in any situation. As a high school lacrosse coach, he has a unique perspective on the teamwork needed when working with clients in high stakes litigation. Whether in the courtroom or on the lacrosse field, Dallas also recognizes how important it is to understand and predict an opponent's behavior to succeed. Clients appreciate that Dallas can simplify a complex and nuanced situation and present a logical solution to their problem. He believes that it's best to approach everything with a purpose—and that includes defending his clients and advising fellow attorneys.

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Edward "Skipp" Kropp, a member of the PFAS Team, was born and raised in central Indiana and, after having spent a number of years in Ohio and West Virginia, where he is also licensed, relocated to Indianapolis in 2010 to continue his practice. He represents a number of Indiana clients, including the largest wastewater treatment operator in the state. Skipp's passion other than law includes singing barbershop harmony. In fact, he is so passionate about the barbershop harmony art form that he has served on the Board of Directors of the 15,000 member Barbershop Harmony Society for 7 years, including serving as its International President in 2017 and 2018. When you dig deeper, however, you quickly realize that while Skipp likes to joke, he has deep and broad environmental experience in the areas of air, water, and waste. As the former Chief of the WV DEP Office of Air Quality and former Deputy Director of the WV DEP.

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Marissa Nortz, a member of the PFAS Team, focuses her practice in the often complex and ever-changing landscape of federal and state environmental regulations. Her clients, often municipalities and industrial, chemical and manufacturing companies, regularly call on Marissa for assistance with permitting, compliance, operational, and litigation needs, stemming from issues such as water and wastewater discharges, solid and hazardous waste disposal, air emissions, and other environmental and regulatory needs.

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An experienced litigator and member of the PFAS Team, Mr. Sinclair concentrates his practice on occupational and environmental litigation in the energy and transportation sectors, including water, air, and soil quality; industrial noise and vibration; occupational diseases; toxic torts; toxic and traumatic encephalopathies, seizures, and syncope; the evidence-based determination of medicolegal causation; and the admissibility of novel and complex scientific evidence.

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Rex Tennant, a member of the PFAS Team, is the Environmental Chemist for Steptoe & Johnson PLLC with more than 22 years' experience. Rex has experience in regulatory interaction, remediation, RCRA waste units, and water/wastewater treatment. He also has significant experience in preparation of NPDES permit applications and renewals (individual and general) for manufacturing and commercial clients; Spill Prevention Control and Countermeasure plans preparation; Best Management Practices/Storm Water Pollution Prevention plan preparation; Groundwater Protection Plan preparation; performance of Phase I Environmental Site Assessments; preparation of SARA Toxic Release Inventories and Tier II Reporting; and preparation of reports for above ground storage tank installation and closure.

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