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Update on PFAS legal developments, including EPA's newly proposed Safe Drinking Water Act limits

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On March 14, 2023, the U.S. EPA for the first time proposed public drinking water limits on six types of PFAS – a ubiquitous group of chemicals found in a broad array of products and industrial applications that may be linked to adverse health issues. This client update provides an overview of the proposed rule and its potential impacts, discusses other key PFAS developments in the United States and the EU and provides our key takeaways.

Background

On March 14, 2023, the U.S. Environmental Protection Agency (EPA) announced a <u>proposed National Primary Drinking</u> <u>Water Regulation</u> (Proposed Rule) for six types of per- and polyfluoroalkyl substances (PFAS). Pursuant to its authority under the Safe Drinking Water Act (SDWA), EPA's Proposed Rule sets stringent limits known as Maximum Contaminant Levels (MCLs) for these six PFAS in public drinking water supplies and will require water utilities to comply with additional monitoring, reporting and treatment obligations. Though the Proposed Rule directly affects water utilities, its impact is also expected to be felt by businesses that manufacture or otherwise use PFAS or are involved in cleanups of PFAS contamination.

PFAS are a group of synthetic chemicals that are used in a wide variety of products and applications due to their durability and persistence in the environment. PFAS are or have historically been used in nonstick cookware, stain resistant fabrics, firefighting foam, industrial coatings and personal care products, among other uses. Because PFAS may be linked to adverse health impacts such as birth defects and certain cancers, they have come under increasing scrutiny from governmental authorities over the past two decades. The Proposed Rule is a significant element of the Biden administration's PFAS regulatory agenda, known as the 2021 PFAS Strategic Roadmap, and is the first national standard targeting PFAS contamination in drinking water. While the Proposed Rule has not yet been published in the Federal Register, EPA notes that a public hearing has been scheduled on May 4, 2023. The rule is expected to be finalized in late 2023 or early 2024 and will likely be subject to legal challenges questioning the scientific basis of the MCLs.

Proposed rule

Key provisions

The Proposed Rule would set limits and obligations related to six types of PFAS compounds, and would establish stringent and legally enforceable MCLs of 4 parts per trillion each for two of the oldest and most widely studied PFAS

(known as PFOA and PFOS). This is the lowest contamination level that is reliably detectable by laboratories, and is lower than the limits set by any U.S. state regulations to date. The Proposed Rule would also regulate four other PFAS compounds (PFNA, PFHxS, PFBS and HFPO-DA) as a mixture through a hazard index calculator, which will allow EPA to regulate these four compounds according to an MCL based on a defined hazard index of 1.0 (calculated based on a formula established by EPA), rather than an MCL threshold based on parts per trillion. Pursuant to the Proposed Rule, public water systems would be required to monitor all six PFAS compounds and take remedial action if any exceedances of the MCLs are observed. Additionally, the Proposed Rule has set non-enforceable MCL goals for all six PFAS compounds, which more generally indicate EPA's health objectives and are not enforceable as a regulatory standard.

Though the Proposed Rule would directly target water utilities, any company that uses these six PFAS compounds or is involved in site cleanups where they are implicated could be impacted in several ways:

- Expanded cleanup standards pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA and state regulators can use MCLs under the SDWA as cleanup standards under CERCLA. If EPA designates any of these six PFAS compounds as a "hazardous substance" under CERCLA,¹ the Proposed Rule may be used to establish cleanup standards and design remedial actions to protect current or potential sources of drinking water. If this were to occur, any potentially responsible parties at CERCLA sites where any hazardous-substance-designated PFAS have been released could potentially be subject to increased investigation and remediation obligations to meet the MCLs under the Proposed Rule. EPA may also seek to relitigate Superfund sites that have been settled on the basis that any newly discovered PFAS contamination, or the growing body of scientific evidence regarding their health impact, constitute new conditions or information triggering standard "reopener" clauses included in CERCLA consent decrees. Given the technological challenges in remediating PFAS, the incorporation of the MCLs under the Proposed Rule into cleanup standards can be expected to dramatically increase site remediation costs.
- Stricter wastewater discharge permit limits. Once finalized, state permitting authorities may use the MCLs as a basis for setting effluent limits for facilities that discharge regulated PFAS to ground or surface water under wastewater discharge permits. For example, New York recently issued guidance for effluent limits for PFOS and PFOA based on that state's MCL of 10 ppt. If the MCL is lowered to 4 ppt, New York might be expected to lower its guidance accordingly.
- Increased exposure to litigation. Water utilities that are tasked with complying with the Proposed Rule may initiate litigation to recover compliance costs from industries that contaminate public drinking water supplies with PFAS. Contamination can occur when industries discharge effluents into interconnected waterways, contribute PFAS-containing waste to landfills or otherwise release PFAS that leach into local waterways and drinking water sources.

Other federal legislative and regulatory initiatives

In addition to the Proposed Rule, EPA has initiated other actions related to PFAS pursuant to the 2021 PFAS Strategic Roadmap:

Toxic Substances Control Act (TSCA). Pursuant to its authority under TSCA, EPA has (i) required manufacturers to develop new information to evaluate PFAS risks; (ii) worked with U.S. manufacturers to voluntarily phase out PFOS, PFOA and related substances; (iii) issued Significant New Use Rules for PFAS (e.g., requiring EPA review and approval before parties manufacture, process or import products containing certain long-chain PFAS); (iv) issued orders requiring various groups of companies (e.g., chemical manufacturers) to conduct and submit testing on PFAS; and (v) issued penalties for violations of Section 15 of TSCA (e.g., use of a chemical for commercial purposes that violates certain provisions of TSCA and failure or refusal to establish or maintain records, submit reports, notices or other information, or permit access to or copying of records). Additionally, EPA intends to further regulate

PFAS under TSCA. For instance, the Office of Management and Budget's Regulatory Agenda indicates that a final PFAS reporting rule under TSCA may be issued, which would require reporting by manufacturers of PFAS twelve months after the effective date of the rule (likely by mid-2024).

- Clean Water Act. Pursuant to its authority under the Clean Water Act, EPA and state-level permitting authorities have issued permits containing requirements related to PFAS (e.g., effluent limitations and monitoring requirements). EPA has been developing technology-based PFAS wastewater discharge limits for industrial facilities known as Effluent Limitation Guidelines (ELGs) for a number of industries, including organic chemicals, plastics, synthetic fibers, pulp and paper, textiles, electroplating, metal finishing and paint formulating. In its 2021 PFAS Strategic Roadmap, EPA noted that it plans to make "significant progress in its ELG regulatory work" by the end of 2024. Additionally, EPA published draft water quality criteria for aquatic life in April 2022 for PFOA and PFOS and announced a plan to publish final recommended water quality criteria for PFAS for human health in the fall of 2024.
- CERCLA. On August 26, 2022, EPA proposed a rule to designate PFOA and PFOS as "hazardous substances" under CERCLA. If the designation is finalized, EPA will have the authority to order parties to remediate contamination or pay the costs of remediation. EPA may also subject parties to additional reporting requirements. EPA's 2021 PFAS Strategic Roadmap indicates a plan to finalize this rule by the summer of 2023.
- Toxic Release Inventory (TRI). In December 2020, pursuant to the National Defense Authorization Act, EPA added 172 PFAS to the list of chemicals subject to TRI reporting, which requires facilities that manufacture, process or otherwise use listed-chemicals, and are subject to reporting obligations under the Emergency Planning and Community Right-to-Know Act, to submit annual reports to EPA. In December 2022, EPA proposed a rule that would remove the *de minimis* exemption for reporting obligations, which would have the effect of significantly expanding the scope of the reporting obligations.

State legislative and regulatory initiatives

Many states have already promulgated PFAS legal requirements, especially those related to drinking water. As of February 2023, 23 states had promulgated their own drinking water regulations related to PFAS. Additionally, some states have added significant phase-outs and general bans on PFAS in consumer products. For instance, in 2021, Maine enacted a law which banned intentionally adding PFAS to any product sold in the state, subject to various timelines for compliance. In January 2023, Maine began to phase out PFAS in rugs, carpets and fabric treatments. Additionally, California enacted measures to prohibit misleading claims that products are free of certain PFAS compounds such as PFOA.

European legislative and regulatory initiatives

In February 2023, EU regulators proposed a general ban on PFAS (subject to certain exemptions, including those related to concentration limits). The proposed ban expands the EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, and would ban the manufacture, placing on the market and import or use of approximately 10,000 types of PFAS compounds. The restriction is currently being considered by EU regulators.

Once the restriction under REACH is finalized, manufacturers, importers and users of PFAS will have between 18 months and 12 years to introduce alternative substances. The time period for introducing alternatives will depend on their availability. Although some products may be exempt from the restrictions due to the fact that they are already subject to more stringent regulations, products such as electronics, textiles, cosmetics, food packaging and medical devices will likely be affected. Companies who may be affected by the regulation, including non-EU-based companies, may face disruptions in their value chains as a result of this proposed ban.

The EU will begin public consultation to hear comments regarding this proposed ban on March 22, 2023, and this

Landscape for PFAS-related litigation

PFAS have also been the subject of an enormous amount of litigation, resulting in more than 6,400 federal lawsuits since 2005. In 2019, it was estimated that the chemical manufacturing industry alone could face potential costs ranging from \$25 billion to \$40 billion related to PFAS litigation. In a pattern reminiscent of other toxic torts, claims initially focused on a small group of manufacturers of PFAS, but have recently targeted companies that manufactured or sold products that contained PFAS, or that used PFAS materials in their operations.

These claims vary by category:

- Environmental contamination: Claims brought by state authorities, water utilities or private parties alleging that PFAS have contaminated soil, groundwater, and surface water. These claims are brought under various environmental laws, such as CERCLA and state equivalents, as well as common law claims of negligence and trespass.
- Personal injury: Claims brought by individuals alleging that exposure to PFAS resulted in personal injury, including cancer, thyroid disease and other health effects.
- Consumer fraud: Claims brought by consumers against companies that have sold products containing PFAS, alleging that these companies misled them regarding the safety of their products through statements in their marketing materials, websites or sustainability reports.

The regulatory efforts outlined above will likely accelerate these trends. The stringent MCLs contained in the Proposed Rule as well as a designation that certain types of PFAS are "hazardous substances" under CERCLA will provide regulators and private parties with more tools to pursue cleanup claims against businesses that made or used certain types of PFAS. Additionally, plaintiffs in personal injury litigation are likely to rely on increasingly stringent regulatory standards to bolster their arguments regarding the health impacts associated with PFAS.

Key takeaways

Though the Proposed Rule would apply directly to water utilities, the impact will likely be felt by companies whose operations involve the six PFAS addressed by the rule. As regulations continue to evolve, and more types of PFAS become subject to more stringent regulation, more companies may be exposed to an increased regulatory burden and litigation risk. Given these trends, companies should take steps to understand what kinds of PFAS may be included in the products they sell or manufacture and the materials used in their operations so they can assess the risks posed by PFAS regulation and litigation.

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If you have any questions regarding the matters covered in this publication, please reach out to any of the lawyers listed below or your usual Davis Polk contact.

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¹ As noted above, EPA has already proposed such a designation for PFOS and PFOA.