A Fork in the Road? EPA's PFAS Roadmap After Two Years

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In response to the perceived threat per- and polyfluoroalkyl substances (PFAS) pose to public health and the environment, Environmental Protection Agency (EPA) administrator Michael Regan established the Executive Council on PFAS in 2021. The Council created the PFAS Strategic Roadmap, which outlines an aggressive approach to regulate these chemicals. EPA, through its PFAS Strategic Roadmap, promised, among other things, to ensure science-based decision-making and to hold polluters accountable. Over the past two years, EPA has taken a number of rulemaking actions to regulate the use, discharge and reporting of PFAS. Some maintain that a number of these actions are not based on sound science, but no one disputes that EPA's actions have all been intended to hold polluters accountable. That will continue in 2024, as EPA finalized its National Enforcement and Compliance Initiatives for 2024-2027, including "Addressing Exposure to PFAS." That initiative will "focus on implementing EPA's PFAS Strategic Roadmap and hold responsible those who manufactured PFAS and/or used PFAS in the manufacturing process, federal facilities that released PFAS, and other industrial parties who significantly contributed to the release of PFAS into the environment."[1]

In 2023, EPA finalized reporting rules and proposed a number of other rules, none of which came without controversy. In October 2023, EPA published a final rule, under the Toxic Substances Control Act (TSCA), that establishes reporting requirements for any company that manufactures or has manufactured PFAS (including imports), or even articles that contain PFAS, in any year since January 1, 2011. The rule requires these manufacturers (or importers) to submit within 18 months of the effective date to EPA information regarding PFAS uses, production volumes, byproducts, disposal, exposures and existing information on environmental or health effects. Some small businesses have an additional six months to meet the reporting requirements under the rule.

Notably, the final rule utilizes a structural classification, as found in 40 CFR 705.3, to define covered PFAS, rather than identifying the particular PFAS substances subject to reporting. That structural definition of PFAS utilized by EPA is incredibly broad and will likely include approximately 1,462 PFAS,[2] the vast majority of which have not yet been studied. In stark contrast, federal and state legislators and regulators, to date, have largely focused on only a handful of PFAS chemicals for which there is some evidence that the chemicals may cause adverse environmental or health effects. EPA's final reporting rule will ultimately require manufacturers and importers to provide EPA with a list of every product they have manufactured and/or imported since 2011 that contains PFAS. That will provide EPA with a roadmap of companies to target for regulatory enforcement actions, particularly if EPA finalizes its proposed rule to designate certain PFAS as hazardous substances under CERCLA. This rule is particularly problematic following EPA's recent warning that the top priority of its Office of Enforcement and Compliance Assurance (OECA) will be the investigation and prosecution of PFAS manufacturers. It will also likely provide a roadmap to plaintiffs' attorneys for civil litigation targets.

EPA also expanded the list of chemicals covered under the Toxics Release Inventory (TRI) via inclusion of seven additional PFAS. These particular substances joined an ever-expanding list of PFAS that both public and private facilities in designated industry sectors must report their use of in respective manufacturing processes. No longer subject to the de minimus exception enjoyed by other TRI-listed substances, approximately 196 PFAS substances are now subject to mandatory reporting, regardless of the amount utilized in mixtures or products. This reporting is also inclusive of incidental environmental releases or other waste management.

In 2023, EPA also proposed national drinking water standards for six PFAS. EPA has proposed Maximum Contaminant Levels (MCLs) for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) at four parts per trillion (ppt), the lowest level that current technology can reliably detect. The proposed rule would also regulate perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO-DA) (commonly known as GenX chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS) through the use of a Hazard Index calculation to determine if the combined levels of these PFAS pose a potential risk to human health. The rule is expected to be finalized in the early part of 2024 and will apply to all public water systems. The MCLs proposed by EPA are not only as low as can be reliably detected; they are lower than those enacted by every state that has regulated PFAS in drinking water. As a result, if finalized, the proposed regulation will require public water systems to immediately monitor for these six chemicals and, if levels exceed the proposed regulatory standards: (1) notify the public within thirty (30) days; and (2) reduce the levels of these PFAS below the regulatory standards. It is anticipated that the vast majority of water systems in the United States will require costly remediation in order to meet the EPA's proposed standards, potentially costing ratepayers and/or taxpayers billions of dollars. In fact, the American Water Works Association estimates the cost of compliance will be approximately $37 billion initially, and another $650 million annually.

The proposed rule has come under fire from a number of industry groups, who argue that the proposed rule is not based on sound science and realistic economic data. This is not surprising considering that the science behind PFAS is still emerging and at least one other federal agency, the Agency for Toxic Substances and Disease Registry, could not conclude that a cause-and-effect relationship exists between PFAS and human health problems despite reviewing more than 600 studies. Moreover, due to the uncertainty concerning the science, no other regulatory entity worldwide has proposed or implemented MCLs at levels this low. Canada has proposed MCLs of 30 ppt, while the World Health Organization has recommended 100 ppt, and Australia has implemented MCLs as high as 560 ppt. As a result, we expect legal challenges to any final rulemaking, particularly as there continues to be little to no scientific support for MCLs at the levels proposed by EPA, while the costs of compliance are estimated to range in the billions of dollars.

Finally, we expect EPA will publish a final rule to designate PFOS and PFOA as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), also known as “Superfund.” On June 13, 2023, EPA's Spring 2023 Unified Agenda extended the deadline for a final rule from August 2023 to February 2024 for the designation of PFOA and PFOS as hazardous substances. It is possible, however, that the final rule may also include other PFAS, as EPA previously released an Advanced Notice of Proposed Rulemaking (ANPRM) in which it sought public input concerning whether, in addition to PFOA and PFOS, it should also designate PFBS, PFHxS, PFNA, HFPO-DA (sometimes referred to as GenX), PFBA, PFHxA and PFDA as hazardous substances pursuant to CERCLA. EPA's delay in promulgating the final rule may signal its intent to include these other PFAS chemicals as hazardous substances. A CERCLA designation would authorize the federal government and private citizens to use of various enforcement tools to require “Potentially Responsible Parties” (PRPs), such as private businesses, recycling and waste management companies, and governments to clean up contaminated sites.

The primary critique of this rule relates to the charge that EPA severely underestimated the costs associated with the implementation of the rule, and thus failed to conduct a formal regulatory impact analysis (RIA). EPA has asserted that the costs associated with designating PFOS and PFOA as hazardous substances would not have an annual effect on the economy of $100 million, which is the threshold beyond which regulations are considered “economically significant” and subject to more thorough analysis and internal review. By not designating the rule as economically significant, EPA avoided undertaking a formal RIA of PFAS cleanup costs triggered by a CERCLA designation. The United States Chamber of Commerce (USCC) published the results of economic modeling and analysis of the financial liabilities associated with cleanup of sites contaminated with PFOA and/or PFOS. This study estimated that the costs associated with the proposed hazardous substance designation of PFOA and PFOS are between $700

million and $800 million in annualized costs (or a total of approximately $11.1 billion to $22 billion, far in excess of the $100 million annual effect threshold requiring an RIA. As such, we also expect industry challenges when EPA promulgates its final rule.

While EPA has made significant progress on its PFAS Strategic Roadmap, a number of legal challenges are expected to delay the implementation of a number of proposed rules unless EPA begins to take seriously its promise to follow a science-based approach to PFAS regulation.

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[1] EPA Key Actions to Address PFAS

[2] In an effort to clear up confusion, on January 26, 2024, EPA published a list of 1,224 PFAS that trigger reporting requirements under this TSCA rule. Unfortunately, this publication fails to eliminate all confusion, as EPA explicitly stated that this is not an exhaustive list and chemicals not on the list may trigger reporting requirements.

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