As TSCA's Amendments Turn Five, EPA Chemical Policy Changes Signal Volatility: What Companies Need to Know

July 2 2021

The U.S. Environmental Protection Agency ("EPA") recently announced several significant policy changes affecting the first ten (10) existing chemical risk evaluations completed under the Toxic Substances Control Act ("TSCA"). Under these shifts EPA will reopen the evaluations to apply assumptions that could result in increased compliance and risk mitigation costs for chemical manufacturers and downstream users. EPA's policy changes will not only affect the 10 evaluations, but also the next 20 ongoing chemical evaluations and their manufacturers. Involving counsel with eyes on the EPA chemical regulation landscape can assist companies make chemical manufacturing and use decisions during these volatile times.

Under the TSCA 2016 Amendments, EPA is required to evaluate existing chemical uses and to determine whether those uses are "not likely to present an unreasonable risk of injury to health or the environment, including to potentially exposed or susceptible subpopulations." EPA completed the first 10 existing chemical risk evaluations in 2020-21 after several public comment opportunities and review by the TSCA Scientific Advisory Committee on Chemicals. The 10 chemicals are 1,4-dioxane, 1-bromopropane, asbestos, carbon tetrachloride, cyclic aliphatic bromide cluster ("HBCD"), methylene chloride, N-methylpyrrolidone ("NMP"), pigment violet 29, perchloroethylene, and trichloroethylene.

EPA now will reopen the evaluations to remove an assumption that workers are provided and use personal protective equipment ("PPE"). This change may expand risk management regulation to several chemical uses previously found not to present an "unreasonable risk" with the mitigating effect of PPE. EPA also will revise the evaluations to include fenceline community risk assessment scenarios, using presently undeveloped community risk assessment models. Further, EPA will remove consideration of chemical exposure control programs under other statutes potentially resulting in duplicative regulation.

Policy Change on PPE

In the completed evaluations, EPA assumed that PPE is always used in occupational settings, as required by applicable Occupational Safety and Health Administration ("OSHA") rules, and found that some chemical uses did not pose an unreasonable risk. EPA is revisiting this assumption in light of "data on violations of PPE use suggest[ing] that assumptions that PPE is always provided to workers, and worn properly, are not justified." This may change the conclusions about risk on some conditions of use for six of the 10 chemicals: methylene chloride, 1-bromopropane, HBCD, NMP, perchloroethylene, and 1,4-dioxane.

EPA already applied this policy change to the new chemical program. In March 2021, EPA announced that it will identify the absence of worker safeguards as "reasonably foreseen" conditions of use and mandate necessary protection through an enforceable TSCA section 5(e) order. Together, these announcements make clear that EPA may likely broaden its involvement in workplace activities by assuming in chemical evaluations that companies are not compliant with OSHA standards.

Policy Change on Fenceline Community and Other Risk Control Statutes

Where general population chemical exposures are regulated by other EPA-administered statutes, such as the Clean Air Act ("CAA"), Safe Drinking Water Act ("SDWA"), or Clean Water Act ("CWA"), the first 10 evaluations deferred to those statutory programs as already establishing appropriate protections for certain risks to human health and the environment. Finding that this deference "resulted in a failure to consistently and comprehensively address potential exposures to potentially exposed or susceptible subpopulations," EPA will reopen the evaluations of 1,4-dioxane, methylene chloride, trichloroethylene, carbon tetrachloride, perchloroethylene, NMP, and 1-bromopropane to account for potential fenceline community exposures.

This policy change may conflict with TSCA Section 9, which provides that EPA should coordinate TSCA actions with those taken under other EPA-administered environmental laws to reduce duplicative requirements. The shift also could elevate TSCA risk evaluations over risk assessments conducted under the CAA, SDWA, or CWA. Further, the models that EPA will use to conduct fenceline community exposures have not yet been developed. Given the current administration's holistic emphasis on environmental justice, these models could incorporate new assumptions regarding fenceline risk and will benefit from the engagement of the regulated community in their development.

Next Steps

EPA's policy changes will not only affect the reopened 10 chemical evaluations, but also the next 20 ongoing chemical evaluations and their manufacturers. As policies on chemical regulation continue to evolve at a rapid pace, companies may have questions about EPA's risk evaluation process for high priority chemicals, ongoing developments in chemical regulatory activities, and critical issues on worker safety and supply chain. Involving counsel with first-hand knowledge of the changing landscape in EPA's chemical regulation can provide invaluable guidance to a company making decisions during these volatile times.

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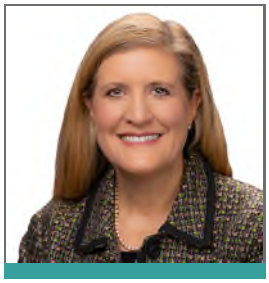

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Fast and Furious PFAS Changes Signal Intensifying Regulatory Ride for Companies

June 15, 2021

Two new U.S. Environmental Protection Agency ("EPA") regulatory actions concerning per- and polyfluoroalkyl substances ("PFAS") will directly impact companies manufacturing or importing PFAS or PFAS-containing articles. Both actions – a broad call for PFAS data/research and withdrawal of recent PFAS guidance – were taken on June 10, 2021. As the PFAS regulatory landscape continues to rapidly change, companies will want to closely consider strategies for information gathering, PFAS reporting, and overall PFAS liability and compliance processes on what promises to be an accelerating PFAS regulatory ride.

PFAS Data Call

As noted, EPA announced it is taking comment on a proposed rule, mandated by the 2020 National Defense Authorization Act ("NDAA"), that will require all PFAS manufacturers since 2011, including importers, to report to EPA information on chemical identity, categories of use, volumes manufactured and processed, byproducts, environmental and health effects, worker exposure, and disposal. EPA is required to finalize the rule in January 2023 under the NDAA, and companies will be required to report to EPA one year after the rule's effective date. EPA's proposal contains information to help companies determine if they have manufactured or imported PFAS during the relevant time period and to help determine applicability. Any company subject to the rule would be required to undertake a comprehensive assessment to identify responsive information, and report all information "known to or reasonably ascertainable by" the company. According to the proposed rule, such efforts may include seeking information from suppliers, downstream users, and other sources outside the company.

Commenting on, and ultimately complying with, a rule requiring data production to EPA on PFAS will be an important endeavor for many companies. Since this is the first-ever data call in under the Toxic Substances Control Act ("TSCA") for PFAS, companies should consider involving counsel in their information-gathering and reporting processes.

Withdrawal of January 2021 PFAS Guidance

EPA also withdrew January 2021 guidance designed to help companies determine if they have a long-chain PFAS "surface coating" on an imported article. Such long-chain PFAS are prohibited from import to the United States under EPA's 2020 PFAS Significant New Use Rule ("SNUR") without 90 days' notice to EPA and EPA's authorization. The January 2021 guidance defined surface coating as either: (1) a coating on any surface of an article that is in direct contact with humans or the environment during the article's normal use or reuse; or (2) a coating on any internal component if that component is in contact with humans or the environment during the article's normal use or reuse.

On withdrawing the January 2021 guidance, EPA announced that it considers any long chain PFAS "containing coating on any surface of any article, whether the coating is applied to the interior facing surface or the exterior surface of an article or has

been cured or undergone a chemical reaction, to be covered by the SNUR" and that "EPA considers all coating layers and their chemical components, even when they are not the outermost layer of an article, to be included as part of a 'surface coating.'" The guidance's "direct contact" standard was of particular concern to environmental organizations, and, appearing to concur with the groups EPA noted on withdrawal that the guidance "inappropriately narrowed the scope and weakened the prohibitions included in the SNUR."

With the Agency's position that a "surface coating" should be interpreted broadly, companies may wish to consult counsel as they take steps to ensure that their supply chains and products do not contain long-chain PFAS.

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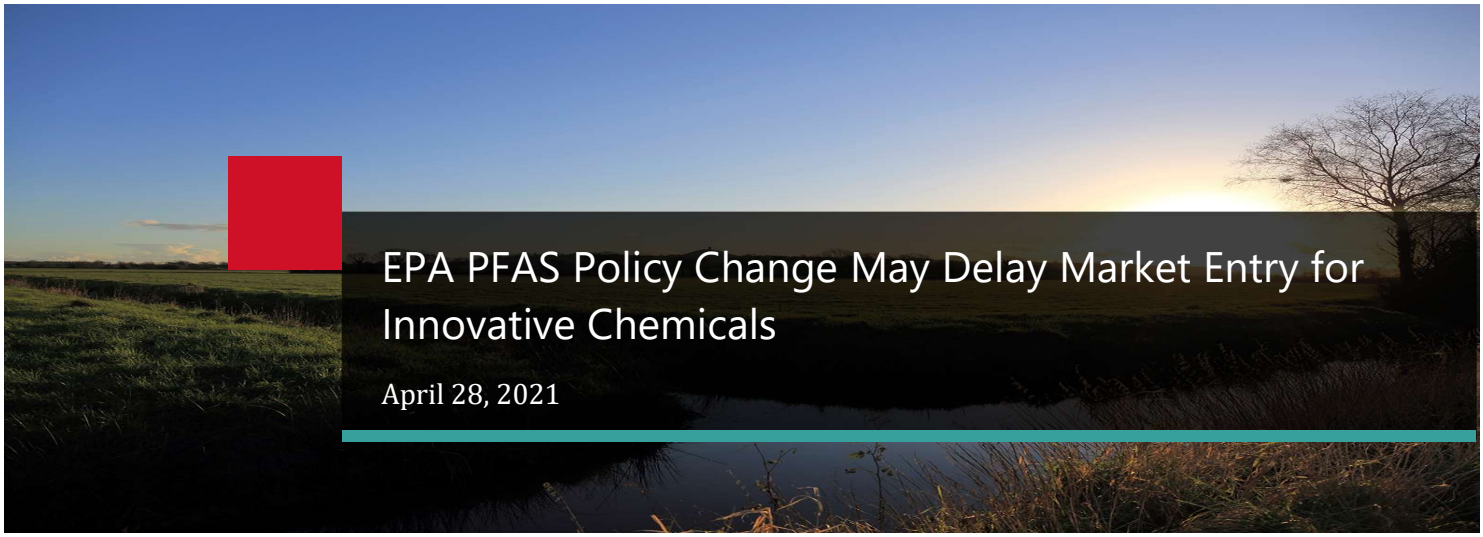

EPA PFAS Policy Change May Delay Market Entry for Innovative Chemicals

April 28, 2021

On April 27, 2021, the U.S. Environmental Protection Agency ("EPA") announced an important policy shift in its pre-market review of new per- and polyfluoroalkyl substances ("PFAS") under the Toxic Substances Control Act ("TSCA"). EPA's change, which is immediately effective, removes all types of PFAS from eligibility for the expedited 30-day low volume exemption ("LVE") market entry process. The new policy means that PFAS must now go through the pre-manufacture notice ("PMN") review process that should take 90 to 180 days, but often takes much longer. It also means that innovative replacement PFAS, which can be less environmentally persistent and more effective than existing chemistries, could face a longer horizon for market entry.

The LVE process has been used for PFAS and other chemical approvals since the 1990s, and to enter market through the LVE program, EPA must find that the chemical "will not present an unreasonable risk of injury to health or the environment." In removing PFAS from eligibility for the LVE program, nothing suggests that EPA conducted a scientific assessment to find that its prior approval of over 400 PFAS LVEs were scientifically unsupported or failed to meet the statutory "not present an unreasonable risk" test. Additionally, this statutory language was not changed in 2016 when Congress comprehensively overhauled TSCA through the Lautenberg Amendments.

Spotlight on the LVE Program

Under TSCA, a new chemical may not enter commerce until EPA has completed the PMN review process and issued any orders or significant new use rules to address any risks identified by EPA. Due to the lengthy PMN process, EPA created the 30-day LVE process for companies that commit to a limited production volume for the chemical at issue. Environmentalists have long viewed the LVE as a "loophole" to approving PFAS and other chemicals without robust review. However, there is nothing to suggest that EPA has not conducted proper, sufficient safety reviews prior to market entry for PFAS – or any other chemicals in the LVE program – up to the point of the immediately-effective policy change.

EPA supports the change by stating that "[g]iven the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment, an LVE submission for a PFAS is unlikely to be eligible for this kind of exemption under the regulations. While EPA will consider each LVE application individually, the agency generally expects that pending and new LVE submissions for PFAS would be denied."

EPA's announcement is notable also because it applies broadly to all PFAS, without distinguishing between particular PFAS

classes and subclasses that can have quite different characteristics of persistence, toxicity or bioaccumulative effect. While the Agency has not formally announced any intent to regulate PFAS collectively as a single class under TSCA, the LVE policy change may signal EPA's current inclination toward such an approach.

What's Next?

Companies should expect more lengthy review processes of new chemicals, including PFAS, before being allowed to enter the market. EPA also is exploring ways in which to "work cooperatively" with companies to voluntarily withdraw previously granted LVEs.

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EPA Policy Changes Expected to Slow New Chemical Approvals

March 31, 2021

Chemical companies should take note of two immediately effective policy changes in the U.S. Environmental Protection Agency's ("EPA's") new chemicals program under the Toxic Substances Control Act ("TSCA"). These new changes, announced March 29, mean that EPA's new chemical application reviews will take longer and that companies will be subject to stringent enforceable orders addressing hypothetical uses and mandating additional worker protections to bring almost all new chemicals to market.

The announced changes reverse policies established during the prior Administration that were put in place to ensure safety, meet TSCA's goals, and advance efficiency in new chemical reviews by EPA. The policy changes, which make it highly unlikely EPA will meet the statutory timeline of reviewing new chemicals in 90 days, were welcomed by non-governmental organizations.

Foreseeable Chemical Uses Policy Change

When a company submits a TSCA Section 5 new chemical application to EPA for review, the Agency is required to look at all "reasonably foreseeable" uses of the chemical under the Lautenberg Act Amendments to TSCA, which turn five years old in June 2021. EPA is required to make a finding that a new chemical or a significant new use is not likely to present an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations, before authorizing a new chemical. See 15 U.S.C. § 2604(a)(3)(A). This determination is based on known, intended, and reasonably foreseen conditions of use ("COU"). See 15 U.S.C. § 2602(4).

A company may apply only for two COUs, but EPA may find other COUs to be "reasonably foreseeable." Prior to the instant policy change, to advance efficiency, EPA would address any risks by those other foreseeable COUs through a "follow on" Significant New Use Rule ("SNUR"), allowing the new chemical to enter the market safely but ensuring that no possible risky COUs could commence. This approach kept the new chemical approval pipeline moving, brought innovation to the marketplace, and highly increased the likelihood of EPA meeting TSCA's 90-day deadline for completing new chemical reviews.

Under the new policy, when EPA's review concludes that one or more uses may present an unreasonable risk or when EPA lacks the information needed to make a safety finding, the Agency will issue a TSCA Section 5(e) order to the new chemical applicant. The TSCA Section 5(e) order will order the company not to manufacture, process, or use a chemical in a way that

could pose risk, even if the company has shown no intention of pursuing such scenarios. This new policy will add administrative burden and an increased level of EPA control into the chemical manufacturing process, and will require companies to agree to not undertake hypothetical and never planned activities.

OSHA-EPA Policy Change

Also under EPA's newly announced policies, the Agency will no longer assume that workers are adequately protected under the Occupational Safety and Health Administration's ("OSHA's") worker protection standards and updated Safety Data Sheets ("SDS"). EPA's new policy will presume that the absence of worker safeguards is a "reasonably foreseen" COU, and then issue an order to the new chemical applicant to mandate worker protections through a TSCA section 5(e) order. Notably, EPA had taken this approach early in the Lautenberg Amendment implementation, but abandoned ordering basic personal protective equipment ("PPE"), such as gloves, masks, or respirators, as unnecessarily duplicating OSHA requirements. Instead, EPA pursued an agreement with OSHA to improve interagency coordination on new chemical reviews and worker protection. The worker protection policy changes also respond to environmental groups' and labor unions' criticism of the prior Administration's assumptions that OSHA, PPE, and SDS offer adequate worker protection. By adopting these changes EPA is signaling it plans to assert authority over worker safety in the chemical sector irrespective of OSHA's involvement.

Orders and Delays to Increase

As a result of these two new policies, companies should expect to see an uptick in new chemical TSCA Section 5(e) orders. A section 5(e) order usually contains conditions such as use of PPE, hazard communication language, and restrictions on releases. New chemical cases are supposed to be processed by EPA within 90 days of receiving a notice of the manufacture of a new chemical or significant new use. See 15 U.S.C. § 2604(a); id. at (i)(3). Cases taking over 90 days for review are considered part of the new chemical backlog. In January 2021, there were approximately 185 backlogged cases. While EPA "remains committed to meeting statutory deadlines for review and determinations on new chemicals submissions," the reality is that even more cases will now fall into the new chemical backlog – slowing the innovation pipeline.

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EPA Chemical Phase Out Date Emphasizes Importance of Participating in TSCA Implementation

March 9, 2021

Recent developments from EPA reinforce how important it is for companies to keep a close eye on implementation of the Toxic Substances Control Act (TSCA) as the statute's overhaul, by the Frank R. Lautenberg Chemical Safety for the 21st Century Act amendments, moves into its fifth year. The message to take home is that TSCA chemical rulemakings can affect more than the chemical manufacturers – they can also affect chemical users and imported and distributed articles.

The importance of this point was emphasized earlier this week, when, after hearing from electronics companies and other importers that the March 8, 2021 effective date of a prohibition on the processing and distribution of PIP (3:1) for use in articles was unfeasible, EPA announced it would exercise enforcement discretion for six months. EPA's temporary 180-day "No Action Assurance" states the Agency will not pursue enforcement around PIP (3:1) in articles, or articles to which PIP (3:1) has been added, to allow companies to assess their supply chain. EPA also announced it may extend the compliance date if needed after gathering more information.

The PIP (3:1) rule is one of five TSCA Persistent, Bioaccumulative, and Toxics (PBT) rules that were finalized by the TSCA deadline of December 22, 2020 and went into effect February 5, 2021. The PBT rules address five chemicals – DecaBDE, PIP (3:1), 2,4,6-TTBP, HCBD, and PCTP – and contain various phase outs, substitution requirements, packaging changes, and other risk management approaches to reduce exposure to these chemicals for the general population, consumers and commercial users, and susceptible subpopulations.

Revealing the Agency may make some tweaks or changes to all five PBT rules, EPA also announced a 60-day public comment period to collect additional input on the final PBT rules. EPA is seeking comments on potential further exposure reductions, implementation issues, and additional or alternative measures or approaches. In particular, EPA notes that it is "seeking comment on specifics of recently raised issues regarding the compliance date for the prohibition on the processing and distribution of PIP (3:1) for use in articles, and PIP (3:1)-containing articles."

Illustrating the broad reach of TSCA regulations, electronics and electrical companies raised significant concerns about the PIP (3:1) Final Rule's compliance date and potential disruptions to supply chains throughout the U.S. economy because of the prevalence of PIP (3:1) in their products. These companies needed additional time to identify, replace, and certify the absence of PIP (3:1) in their goods to avoid further disrupting consumer access to their products. This new comment period provides an opportunity for chemical users, like electronics and electrical companies, who may not have participated in the prior PBT rulemakings to ensure they no longer use these chemicals and can meet the rules' various phase out and substitution

requirements.

Companies should closely monitor EPA regulatory activities under TSCA going forward. The PBT final rules will certainly affect chemical manufacturers but, as described above, will also have impacts on companies down the supply chain that use these chemicals. Chemical manufacturers and users should be encouraged by the additional opportunity for public comment. In the PIP (3:1) Final Rule, EPA included a number of phase outs and other accommodations for companies that submitted comments during the first public comment period. The automotive and aerospace industries, for example, are allowed to continue the processing and distribution of PIP (3:1) for use in new and replacement parts. Likewise, the rule carves out an exception for PIP (3:1) use in aviation hydraulic fluids.

Industry participation in public comment periods and engagement in the rulemaking process is essential to developing rules that both respond to business realities and still achieve statutory goals. Including counsel in developing and tracking these complex and fast-moving TSCA developments can help a company manage its supply chain, plan, make its issues known, and be ready for the future.

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EPA Report Identifies New Source of PFAS Contamination; Spotlights Role of Citizen Science

March 8, 2021

Last week, the United States Environmental Protection Agency ("EPA") released a lab report on per- and polyfluoroalkyl substances (collectively "PFAS") that reinforces the importance of companies fully understanding how their liquid products may interact with containers used for storage and transportation. The lab report describes a recent situation where fluorinated high molecular weight polyethylene ("HDPE") containers and drums used to store and transport a pesticide product are purportedly leaching PFAS compounds into the products. The situation described in the report also shines a light on the increasingly important role of "citizen science" in informing EPA's investigation and possible enforcement of contamination concerns.

An environmental group, Public Employees for Environmental Responsibility ("PEER"), recently began purchasing and testing pesticide products for PFAS, and notified EPA when the group identified PFAS compounds in the product. EPA's independent testing of the affected pesticide product confirmed the presence of PFAS compounds and confirmed that no PFAS are registered product ingredients. Based on EPA's testing of the pesticide, unused unfluorinated and fluorinated containers, and the fluorinated containers used to store the product, EPA concluded the fluorinated containers were likely the source of the PFAS contamination.

EPA's testing detected eight different PFAS compounds that purportedly leached from the fluorinated containers, some of the longer chain more persistent forms, and at levels ranging from 20-50 parts per billion, much higher than EPA's current drinking water Health Advisory Level of 70 parts per trillion.

Based on these initial results, EPA is now gathering more information about this possible contamination issue. EPA is also testing different brands of fluorinated containers and drums to determine the extent of the PFAS leaching problem. EPA has used its Toxics Substance Control Act ("TSCA") authority to obtain more information from the fluorination company about the fluorination process. According to EPA, the pesticide manufacturer has begun to contact its customers about the PFAS contamination issue and is adjusting its product packaging.

Although EPA has only identified PFAS leaching in agricultural pesticides stored in one company's fluorinated containers and drums, the problem may impact more than just agricultural pesticide products. These containers are widely used by companies to store and transport liquid product. Notably, between twenty and thirty percent of all agricultural pesticides are stored and transported in fluorinated containers – fluorination is known to increase the stability and resilience of the container, allowing longer shelf and storage life.

This development is illustrative of the growing role of citizen science at EPA. For example, PEER continues to purchase and test pesticide products for PFAS contamination and has identified five additional manufacturers that they believe may be selling PFAS-contaminated pesticides. It is expected that EPA will continue to welcome support from citizen science groups to help identify potential environmental concerns for EPA investigation and possible enforcement.

Companies that use fluorinated containers and drums for their products should consider evaluating cross-contamination concerns between container and liquid product. When conducting internal reviews of this kind, it is important to consult with experienced counsel regarding best practices for collecting and using data based on the company's specific circumstances.

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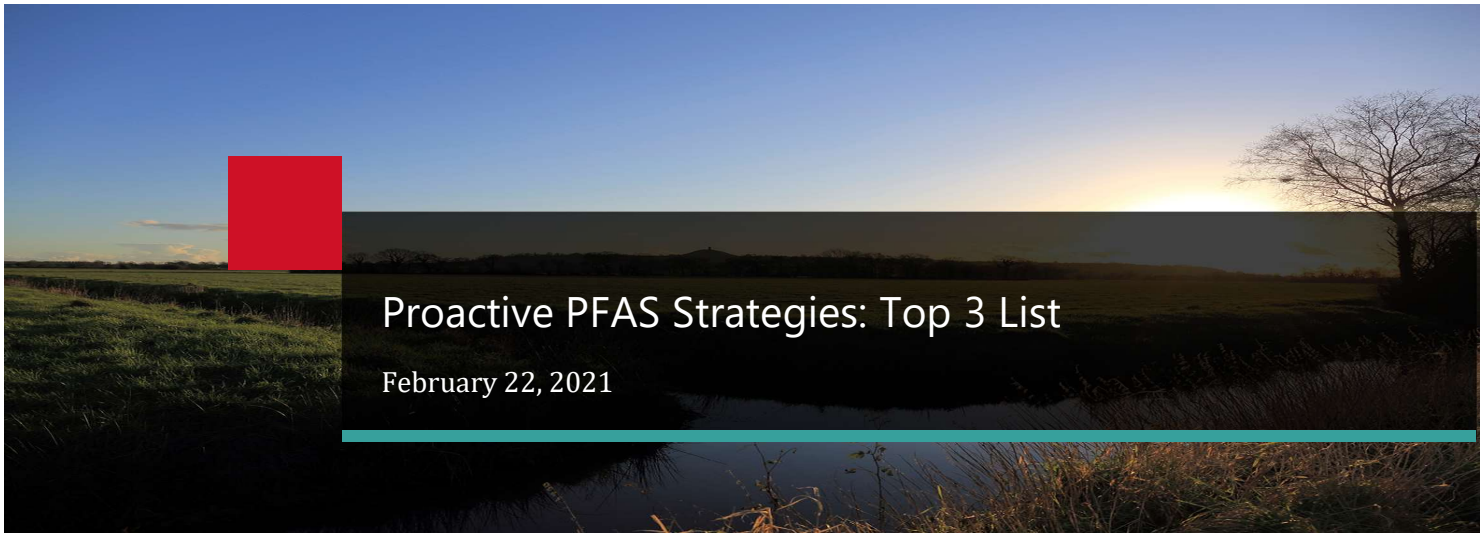

Proactive PFAS Strategies: Top 3 List

February 22, 2021

With thousands of per- and polyfluoroalkyl substances (collectively "PFAS") manufactured since the 1940s, hundreds in commerce today, new sources of PFAS contamination being identified, and PFAS found in the environment as far away as the Arctic, it is important for companies to take stock of their connection to these chemicals. No matter how an entity comes into the PFAS conversation - having used PFAS in a product, or manufactured PFAS as a chemical commodity, or used PFAS containing firefighting foams, or otherwise - implementing the following three proactive strategies will be well worth the investment of time and resources.

1. Stay Current with Legal, Regulatory, and Policy Developments Across Relevant Governmental Levels.

Given the constant changes in PFAS requirements, it is essential to remain up to date on legal, regulatory, and policy developments at the federal, state, and local levels relevant to historic or current operations. Some companies may also need to track global developments regarding PFAS based on operations. An important upcoming federal requirement for companies not eligible for the de minimis exemption is the July 1 reporting deadline for the first time for 175 PFAS compounds under the Toxics Release Inventory ("EPCRA"), with a reporting threshold of 100 pounds for the 2020 reporting year.

The federal PFAS regulatory landscape is shifting and evolving quickly as the new administration evaluates several regulatory and science actions before the U.S. Environmental Protection Agency ("EPA"). On February 22, the administration announced it would move ahead with two key drinking water PFAS actions. EPA will issue the final regulatory determination that will set in motion the process of proposing national drinking water standards, Maximum Contaminant Levels, for perfluorooctanesulfonic acid ("PFOS") and Perfluorooctanoic acid ("PFOA"), and EPA will collect new PFAS data under the fifth Unregulated Contaminant Monitoring Rule. EPA is also determining whether to:

- list PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA") or as hazardous wastes under the Resource Conservation and Recovery Act ("RCRA");
- regulate PFAS as a class of compounds or to continue a chemical by chemical basis;
- further advance an interim strategy to address PFAS in federally issued Clean Water Act discharge permits;
- publish an advance notice regarding soliciting data and information regarding manufacturers of PFAS and the presence and treatment of PFAS in discharges from the Organic Chemicals, Plastic, and Synthetic Fibers point source category.

- maintain the May 2016 lifetime health advisories ("LHAs") for PFOS and PFOA in drinking water as non-enforceable and non-regulatory values at a combined limit of 70 parts per trillion (ppt), as various states adopt lower limits;
- address interim recommendations for addressing PFOA and PFOS contaminated groundwater under federal cleanup programs using a screening level of 40 ppt to determine if PFOA/PFOS is present at a site and may require further attention, with the 70 ppt LHA used as the preliminary remediation goal where no state/tribal or other applicable or relevant and appropriate requirements ("ARARs") are available or sufficiently protective;
- develop PFAS destruction guidance; and
- finalize toxicity assessments for perfluorobutanesulfonic acid ("PFBS") and Gen-X, while continuing other research activities.

When it comes to state regulatory actions, the landscape is varied and volatile, and requires vigilant tracking of new developments. Some states already have enforceable limits for certain PFAS in water, soil, or air, while others have non-regulatory screening levels or advisories. The Environmental Council of the States regularly publishes an inventory of state activities, as does the Interstate Technology and Regulatory Council, and the National Council of State Legislatures tracks PFAS legislation introduced in statehouses. Keeping tabs on these resources is very helpful, but it is also important to ensure that your teams are also closely following the actions in the states most relevant to your operations.

2. Evaluate the Corporate PFAS Risk Profile.

Comprehensive PFAS due diligence is essential to obtaining a full understanding of PFAS risks facing your company. Appropriate diligence activities may include, among others: investigating PFAS content in current and past company products, formulations, and purchased goods (including oil-, stain- and water-repellent materials, lubricants, coatings, etc.); identifying past handling and use of fluorinated fire-fighting foams (both in training and any emergency incidents); reviewing off-site disposal of PFAS-containing wastes; and evaluating possible liability protections under contracts with suppliers of PFAS-containing materials. Related to due diligence is developing and implementing a program of PFAS governance with appropriate structure, content, and shared management understanding. Corporate information sharing; monitoring and reporting; managing PFAS stockpiles and PFAS disposal; protocols for any litigation holds resulting from PFAS concerns or claims; and approaches to Securities and Exchange Commission ("SEC") disclosures are just a few of the issues worth exploring. Also key is ensuring updated policies and practices related to external engagement.

3. Be Aware of PFAS Enforcement Trends.

PFAS enforcement is increasing at the federal and state level. EPA took 16 enforcement actions in recent years related to PFAS, ranging from administrative orders under CERCLA to complete removal actions abating health or environmental threats, to information requests under the Toxic Substances Control Act, CERCLA, and RCRA, to increased inspections. EPA also used its Safe Drinking Water Act Section 1431 authority to address identified imminent and substantial endangerment situations where PFAS contaminated drinking water sources. Some state enforcement actions have begun to target PFAS-contaminated sites, while others have focused on issuing information requests and placing monitoring requirements in permits. Private legal actions based on common law theories of nuisance or trespass are also being explored as ways to mitigate PFAS contamination or to seek compensation. To be sure, class action suits and toxic tort cases are on the rise.

Now is the time for companies to gain a better understanding of their own entanglements in the rapidly growing realm of PFAS regulation and litigation. Managing a company's PFAS situation requires intentionality, thoughtfulness, and careful

diligence. Once a full understanding is gained, and knowledge of shifting external landscapes is maintained, accounting for PFAS issues becomes a known, rather than an unknown, which is the better position. A proactive PFAS regulatory, compliance, and litigation strategy now will likely pay dividends later.

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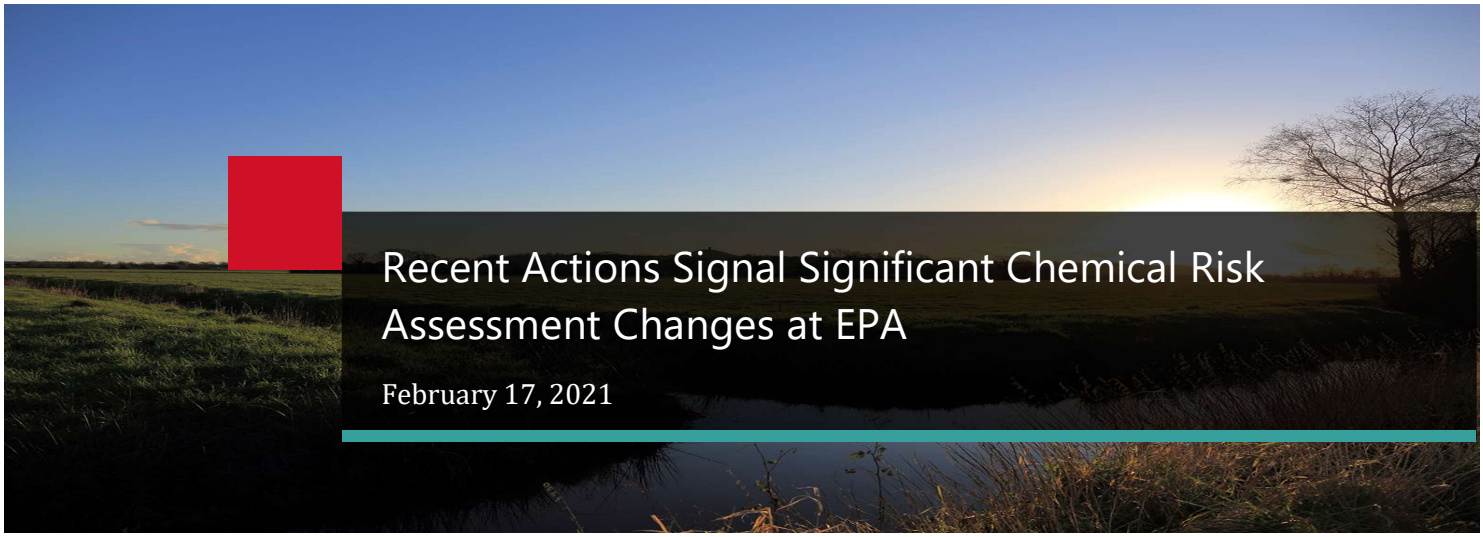

Recent Actions Signal Significant Chemical Risk Assessment Changes at EPA

February 17, 2021

Companies should note two new EPA decisions on chemical risk assessment which together signal that new leadership at the U.S. Environmental Protection Agency (EPA) will take some different approaches to chemical risk assessments and analysis of underlying scientific studies.

On February 16, EPA announced that, under the new administration's memorandum on scientific integrity and evidence based policy making, EPA "will refine its approach to selecting and reviewing the scientific studies that are used to inform Toxic Substances Control Act (TSCA) chemical risk evaluations (systematic review)." On February 9, EPA removed from its website the final toxicity assessment for perfluorobutanesulfonic acid (PFBS), a PFAS compound, stating the final version eroded "the trust that the American public has in EPA, the quality of our science, and our ability to protect their health and the environment."

In these early efforts, EPA is leaning on new "Executive Orders and other directives provided by the Biden-Harris Administration to ensure that all agency actions meet statutory obligations, [are] guided by the best available science, ensure the integrity of Federal decision-making, and protect human health and the environment." At least initially, the chemical manufacturing and chemical user communities should remain vigilant in monitoring EPA's new directions and actions to ensure that the pursuit of the best available science follows the applicable laws and regulations and does not result in excessive layers of scientific conservatism.

EPA's February 16 commitment to update its 2018 systematic review approach to chemical literature assessment, made within hours of the National Academies of Sciences (NAS) release of a related peer-review, was of little surprise – EPA was already well into the updating process. Worth noting, however, is EPA's response to the NAS recommendations, particularly that EPA will incorporate "approaches from the Integrated Risk Information System (IRIS) Program." The IRIS program is long acknowledged as highly conservative in its development of chemical toxicity assessments.

The final PFBS assessment removed February 9 from EPA's website included a range of toxicity values instead of a single number to account for uncertainties in the PFBS literature and science. When withdrawing the assessment, EPA expressed concern with toxicity ranges because they can result in companies picking and choosing among numbers. A reasonable

expectation is that any PFBS assessment re-posted by EPA will include a single toxicity value. The inherent compounded uncertainty could affect air and water quality permit limits or cleanup requirements.

Chemical manufacturers and chemical users should keep a watchful eye on further adjustments and changes to EPA's chemical assessment policy. These changes, while subtle, when combined will impact chemical manufacturers and chemical users. EPA is working on 10 risk management rulemakings under TSCA and is early in risk assessment for 20 more chemicals, including invoicing the responsible parties. As such, there is no shortage of opportunities to engage in EPA's chemical assessment activities, and no time to lose.

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How are the first 100 days of the Biden administration shaping chemicals regulation?

Chemicals regulation is front and centre for the Biden-Harris administration thanks to its relevance to the president's top priorities of transparency, science and environmental justice, say Alexandra Dapolito Dunn, Allison Watkins Mallick, Jeff Oliver and Jeff Wood of Baker Botts LLP

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When day 100 of the Biden-Harris administration arrives on 30 April, chemical manufacturers and users will want to be updated on several important regulatory and policy actions affecting the sector, to enable business planning, engagement and operation in a dynamic and changing industry.

TSCA

High on the priority list is continued implementation of TSCA as the industry looks for smoke signals regarding potential changes in policy and approaches. Work continues on the first ten chemical risk management rulemakings with extensive engagement and outreach taking place. For all ten, the US EPA has established small business advocacy review (SBAR) panels, which is required for rules that may have a significant economic impact on a substantial number of small entities. The panels provide input on how the agency might develop proposed rules so that any unreasonable risks identified in the final risk evaluation for each chemical are addressed. Additionally, the EPA is conducting formal consultations with state and local governments, tribes and environmental justice communities. There will also be an open public comment period on any draft risk management regulation.

The EPA has stated that while it continues with the risk management outreach and engagement process, it is "reviewing [each] final risk evaluation to ensure it uses the best available science and protects human health and the environment". The agency could embark on making some changes to the final ten risk evaluations, but the more likely way forward is that it will address any identified limitations in them through the risk management rulemaking process.

The administration moved forward promptly with the TSCA persistent, bioaccumulative and toxic (PBT) rules which were finalised by the 22 December 2020 deadline and went into effect on 5 February. The PBT rules address five chemicals – decaBDE, PIP (3:1), 2,4,6-TTBP, HCBD and PCTP – and contain various phase-outs, substitution requirements, packaging changes, and other risk management approaches to reduce exposure to these chemicals for the general population, consumers and commercial users, and susceptible subpopulations. One important lesson from their implementation came to light when several electronics and other article importers realised for the first time that the final PIP (3:1) rule would prohibit processing and distribution of the substance for use in articles from 8 March this year.

On learning of the implementation concerns, the EPA issued a temporary 180-day no action assurance, stating it will not pursue enforcement around PIP (3:1) in articles, or articles it has been added to, to allow companies to assess their supply chain. It also said it may extend

the compliance date if needed after gathering more information. And the agency also announced a 60-day public comment period to collect additional input on the final PBT rules, suggesting that it may revise them. This provides an opportunity for chemical users that may not have previously participated in the PBT rulemakings to ensure they do not use these chemicals and can meet the various phase-out and substitution requirements.

As for the next 20 chemicals, the scoping documents remain available, although the administration may assess the scopes and determine if changes are needed. Companies responsible for the risk evaluation fees have been invoiced and are making payments. Recent EPA presentations indicate that the agency hopes to spread out the work on the 20 chemicals, allowing stakeholders to engage more thoughtfully and with less time pressure. As the agency embarks on the three-year risk evaluation process, it has announced that it will "refine its approach to selecting and reviewing the scientific studies that are used to inform TSCA chemical risk evaluations" and that it is not using, and will not again use, the 2018 systematic review approach that was reviewed by the National Academies of Sciences in a report issued in mid-February. The agency has not fleshed out how the systematic review process will change, although some concern has rippled through the chemical community with its statement that it will "incorporate approaches from the Integrated Risk Information System (IRIS) programme". IRIS is known for conservative risk evaluation, and for long timeframes to complete the work. Chemical companies and users will have an opportunity to engage in the reframing of systematic review, because the EPA has said it will publish and take comment on a revised protocol later this year.

PFAS

The administration will prioritise activities to reduce exposures to emerging contaminants of concern such as per- and polyfluoroalkyl substances (PFASs). An important upcoming federal requirement for companies not eligible for the de minimis exemption is the 1 July reporting deadline for 172 PFAS compounds under the Toxics Release Inventory, with a reporting threshold of 100lbs for the 2020 reporting year. The EPA moved ahead in February with the final regulatory determination that will set in motion the process of proposing national drinking water standards, 'maximum contaminant levels', for perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA). The agency removed the toxicity assessment for perfluorobutane sulfonic acid (PFBS) from its website – completed in mid-January by the Trump administration – after expressing concern with the conclusions.

Transparency

The new administration quickly and successfully went to federal court to have the controversial EPA science transparency rule taken off the books and sent back to the agency. The heart of the rule was the principle that less weight should be assigned to scientific studies where underlying data – particularly medical and confidential human study information – could not be made available for stakeholder review. Environmental groups asserted this would prevent the EPA from using many key toxicology studies that contain personal data yet offer important information for agency regulatory decision making. Given the opposition from environmental groups and even some industry groups to the final science transparency rule, it is highly unlikely that the EPA will take this up in any form soon.

The administration also quickly halted further implementation of the Clean Air Act (CAA) cost benefit rule, which became effective on 23 December 2020 and is on its list of rules for further review. The rule required the EPA to prepare a benefit-cost analysis for significant rulemakings under the CAA, including separating out benefits directly linked to the rulemaking from secondary benefits.

Finally, the industry should be prepared for a potential second boomerang effect from the EPA's Risk Management Program (RMP) requirements, which apply to sources that use, manufacture or store certain hazardous chemicals. These sources are required to develop a risk management plan and implement measures to prevent accidental releases. Soon after President Trump's inauguration, his administration began working on modifications to President Obama's 2017 RMP amendments. Published on 19 December 2019 these rescinded the major accident prevention programme provisions added by the 2017 RMP amendments and most other minor changes to the prevention programme. They also eliminated the public information availability provisions required by the 2017 RMP amendments. President Biden has identified the rule as among those that will be reviewed.

Emissions regulations

Chemical facility operators should watch several potential changes to emissions requirements under the CAA, as several of the prior administration's notable rulemakings in this area are likely to be reversed or significantly modified. For example, the EPA is reviewing its decisions in December 2020 to maintain the current levels of the National Ambient Air Quality Standards (NAAQS), retaining the current NAAQS for both PM2.5 and ozone instead of

making them more stringent. The review of these rules is particularly newsworthy in light of recent studies linking air quality to Covid-19 risk and the administration's focus on environmental justice issues.

The administration is also reviewing the EPA's 9 October 2020 guidance memorandum that reflected the Trump administration's efforts to reverse course on its predecessor's treatment of excess emissions during periods of startup, shutdown and malfunction (SSM). As a result, the prospect that facilities may be able to rely on exemptions or affirmative defences for exceeding emissions limitations during SSM periods has dimmed.

Finally, the EPA's "once in, always in" rule, which was final on 19 November last year, may be ripe for review. This amended the general provisions of the National Emission Standards for Hazardous Air Pollutants (NESHAP) to allow major sources to 'reclassify' themselves as area sources (by limiting their potential to emit hazardous air pollutants to below the major source thresholds) so they can immediately become subject to generally less stringent requirements. The rule may be a target for the Biden administration, because NGOs have raised particular concerns about the potential for it to increase emissions in overburdened communities (including from chemical plants).

Environmental justice

Environmental justice and climate are other areas where the administration has moved rapidly. While currently being addressed together, the subjects have many independent parts. For example, the President's Executive Order 13990 (Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis at Home and Abroad) puts a focus on "environmental and economic justice", establishes a White House environmental justice council, and would form a specialist office at the Department of Justice to develop a comprehensive environmental justice enforcement strategy. The Order also directs that 40% of government sustainability investments be spent in disadvantaged communities. Under it, the White House Council on Environmental Quality (CEQ) will create a geospatial climate and economic justice screening tool and annually publish interactive maps highlighting disadvantaged communities. The EPA is directed to strengthen enforcement of environmental violations that have a disproportionate impact on under-served populations, and to create a community notification programme to monitor and provide real-time data to the public on current environmental pollution, including emissions, criteria pollutants and toxins, in frontline and fenceline communities. Certainly, chemical manufacturers and users should be aware of their releases and interactions with their communities. Proactive outreach and engagement approaches should be accompanied by robust internal policies, ensuring that environmental justice is embedded in an organisation's activities and mission from top to bottom. Auditing and measuring progress on internal environmental justice integration and protocols to assure accountability is also important.

Environmental enforcement

As for environmental enforcement, chemical manufacturers and users should be watching for new developments and actions at the governmental and non-governmental levels. New leaders at the EPA and DOJ are charting a new direction on this, promising an increase in resources for facility inspections and enforcement activities. While the prior administration moved away from industry-specific enforcement initiatives, most observers expect the new administration to place renewed attention on the energy and industrial sectors, including the chemicals sector. Early indications of new directions would include more frequent government information requests for facility compliance data and records. Federal enforcement cases may also become more costly to resolve, as the new administration has already rescinded several Trump-era enforcement policies and signalled a return of third-party payments and supplemental environmental projects as part of major settlements. Alongside civil enforcement, the industry should also be mindful of the new administration's stated intention of enhancing criminal enforcement of environmental laws as well.

At the non-governmental level, the chemical sector should anticipate an increase in citizen suits under the Clean Air Act, Clean Water Act, and other statutes. After contesting the Trump administration's regulatory rollbacks for the last few years, citizen groups are now expected to refocus their resources on enforcement activities. Industry should be alert to an increase in Freedom of Information Act (Foia) requests submitted to federal and state agencies seeking compliance records, as well as increased use of 'citizen science' to support their enforcement initiatives.

The views expressed in this article are those of the expert authors and are not necessarily shared by Chemical Watch.

Environment & Energy

INSIGHT: Key PFAS Provisions in Defense Bill to Impact Military, Industry Handling

By J. Barton Seitz, Martha S. Thomsen, and Jennifer Golinsky

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Baker Botts attorneys look at key provisions pertaining to per- and polyfluoroalkyl substances (PFAS) in the National Defense Authorization Act legislation. They say the final NDAA is more limited in scope than prior versions of the bill, but the law will still have important consequences.

On Dec. 17, the Senate joined the House in agreeing to the conference report to S. 1790, the Fiscal Year 2020 National Defense Authorization Act (NDAA), which includes substantive provisions addressing per- and polyfluoroalkyl substances (PFAS) at military facilities as well as across the United States more broadly.

While some of the PFAS provisions from the original House and Senate defense bills were retained in the final NDAA, several notable provisions were *not* included. Nevertheless, the NDAA has important implications that extend beyond the military to industries that handle or have handled PFAS-containing materials.

Major PFAS Provisions Not Included

Unlike earlier versions, the final enacted bill does not:

- Designate any PFAS as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA);
- Require the Environmental Protection Agency to list PFAS on the Clean Water Act (CWA) toxic pollutant list, nor does it require the agency to publish enforceable standards for PFAS; or
- Direct the EPA to set a national drinking water standard for any PFAS under the Safe Drinking Water Act (SDWA).

Key PFAS Provisions

- At military installations, the final bill prohibits the use of firefighting foam containing PFAS (*i.e.*, fluorinated aqueous film-forming foam, or AFFF) after Oct. 1, 2024, and immediately prohibits the use of fluorinated AFFF in training exercises. Sections 322 to 324 prohibit the uncontrolled releases of fluorinated AFFF at military installations—except for purposes of an emergency response or aboard military ships—and call for issuance of a military specification for fluorine-free AFFF by Jan. 31, 2023.
- Section 7321 of the NDAA requires immediate addition of perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and certain other PFAS or classes of PFAS—including "GenX")—to the Toxics Release Inventory (TRI). Facilities that manufacture, process, or use listed PFAS in quantities of more than 100 pounds per year would be required annually to report their releases (including disposals) of such PFAS. The addition of these PFAS to the TRI becomes effective on Jan. 1, 2020; covered facilities must therefore report their calendar year 2020 PFAS releases by July 1, 2021.
- Section 7311 of the NDAA requires SDWA monitoring by most public water systems for PFAS and classes of PFAS for which the EPA has validated a method of measuring levels in drinking water. As noted above, the final bill does not require the EPA to set national drinking water standards for any PFAS under the SDWA; however, should the EPA do so, the PFAS or class of PFAS subject to a national drinking water standard would be exempt from this monitoring requirement.
- Sections 7331 to 7335 require the director of the U.S. Geological Survey to (1) establish a performance standard for detecting PFAS; and (2) use the standard to carry out a nationwide PFAS sampling program of various waterbodies and soil.

Related PFAS Initiatives

The House is likely to revisit some or all of the provisions not included in the final NDAA early in 2020. However, Senate action on these proposals is uncertain.

Regardless of congressional efforts, the EPA continues to pursue various regulatory options related to PFAS. In February 2019, the EPA released an "Action Plan" to address potential risks and contamination from PFAS. Among other initiatives, the EPA indicated that it would designate PFOA and PFOS as hazardous substances under CERCLA.

Meanwhile, this month the EPA took initial steps toward establishing a maximum contaminant level for PFOA and PFOS. Additionally, the EPA is working on a supplemental proposed rule addressing Toxic Substances Control Act Significant New Use Rules for certain long-chain PFAS; and is also considering adding certain PFAS to the TRI and seeking comment about which PFAS warrant listing.

Primary Impacts of the NDAA's PFAS Provisions

Although the final NDAA is more limited in scope than prior versions of the bill, especially with respect to non-military requirements, the law will have important consequences.

First, while many of the PFAS provisions are military-specific, the ban on military use of fluorinated AFFF is likely to have downstream impacts in private industry. Historically, fluorinated AFFF has been important for addressing flammable liquid hazards not only at military facilities, but also at chemical plants, refineries, airports, and in various other industries.

While the efficacy of fluorine-free foam in industrial firefighting remains debated, by forcing the military to shift away from fluorinated AFFF, the legislation now has the opportunity to set the new firefighting foam standard. Airports and other private-sector facilities typically are required or encouraged to use firefighting foams that meet military specifications.

Industry, which has already been considering alternative types of firefighting foam, will therefore be mindful of the new military standard for replacement foams. Key features of replacement foams will include fire suppression capability as well as foamability, foam lifetime, and film sealability.

Second, the addition of certain PFAS to the TRI will likely result in the identification of facilities across the United States where certain types of PFAS are being used, processed, and/or disposed of, and may cause facilities to reduce their use of PFAS. The TRI requirements begin in 2021 and will mandate reporting of the subject chemical identity, and the quantities handled, disposed of, and/or released to the environment by the facility.

TRI data are regularly scrutinized by the public and non-governmental organizations to identify facilities handling particular substances, which has sometimes led to facilities becoming targets of community opposition. Moreover, facilities subject to TRI reporting must supply the EPA with information about their pollution prevention and waste minimization efforts.

As a result, TRI reporting can encourage facilities to reduce the amount of TRI chemicals they manage, opt for safer or less toxic chemicals, and/or implement improved chemical management practices.

Third, the final NDAA mandates information-gathering regarding the persistence—and sources—of PFAS in the environment, which could raise potential liability concerns for companies that have handled PFAS. PFAS manufacturers have been the focus of a wave of class actions and suits brought by state governments, but the prevalence of PFAS in a wide variety of commonly used products means that other companies also might face lawsuits.

Some states, including California, have already begun to require PFAS sampling in water systems. But by requiring public water systems to monitor for PFAS across the nation and also requiring a sampling program for waterbodies, the NDAA expands the amount of PFAS data that will be available and that could potentially serve as the basis for future claims.

This column does not necessarily reflect the opinion of The Bureau of National Affairs, Inc. or its owners.

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