

EPA RELEASES NEW FRAMEWORK ADDRESSING NEW PFAS AND NEW USES OF PFAS IN THE MARKET

Date: 18 July 2023

US Policy and Regulatory Alert

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On Thursday, 29 June 2023, the US Environmental Protection Agency (EPA) announced a new framework (Framework) that will impact manufacturers across the country. The Framework lays out a new process for reviewing and assessing the potential environmental risks posed by new and new uses of per- and poly-fluoroalkyl substances (PFAS). This PFAS Framework establishes more stringent pre-market screening procedures for certain PFAS chemicals that may be harmful to human health or the environment. Under the Framework, the EPA will review and take appropriate action for new PFAS or significant new uses of existing PFAS through pre-manufacture notices (PMNs) and significant new use notices (SNUNs) through the EPA's authority under the Toxic Substances Control Act (TSCA).

BACKGROUND

PFAS are a class of fluorinated chemicals used in various consumer products and are commonly known as “forever chemicals” due to their high resistance to degradation. There are thousands of different PFAS, and only a small fraction of them have been well studied. In October 2021, the EPA announced a broad “PFAS Strategic Roadmap” aimed at researching and regulating the presence of PFAS in the environment. According to the EPA, this new PFAS Framework advances the EPA's Roadmap through the “New Chemicals Program” mandated by TSCA Section 5.

The New Chemicals Program regulates “new chemicals” by requiring anyone who plans to manufacture them to provide the EPA with a PMN at least 90 days prior to manufacture, subject to certain exemptions. Under TSCA, a “new chemical” is any chemical that is not currently on the TSCA inventory, which is a list of chemicals that are already deemed “existing” in US commerce. Therefore, when new chemicals are created, the EPA reviews them under the New Chemicals Program to ensure their entrance into the market will not pose significant health concerns or dangerous environmental releases. Manufacturers are also subject to a 90-day notice requirement if they wish to engage in the use of a chemical that the EPA has deemed a “significant new use” from what had previously been approved by the agency under a prior PMN submission, by way of a SNUN submission.

The new PFAS Framework follows the typical structure of a Section 5 TSCA review for other new chemicals. However, the PFAS Framework provides more transparency on exactly what the EPA is doing in their review of these particular chemicals. Further, it provides PFAS-specific guidance on how some types of PFAS will likely be subject to more comprehensive testing than other chemicals, although other new chemicals are similarly subject

to additional testing requirements if the EPA deems it necessary. Therefore, this Framework has the potential to make it even more difficult to get approval of a new PFAS chemical.

TWO STEPS OF THE PFAS FRAMEWORK

The PFAS Framework consists of two steps to review and regulate a PFAS chemical that is reported through a PMN or SNUN.¹ The first step involves identifying and evaluating the substance and its associated risks. The second step uses that information to determine how the chemical should be properly managed to minimize the risk of exposure.

Step One: Identifying and Evaluating PBT PFAS

In the first step of the PFAS Framework, the substance under review must fall into a defined chemical definition of PFAS. If so, the EPA will then review reasonably available data to evaluate the level of risk associated with exposure of the chemical. In this process, the EPA will consider if the PFAS is a persistent, bioaccumulative, and toxic (PBT) chemical. The EPA defines PBT chemicals as those of particular concern because they accumulate in the environment and humans over extended periods of time, leading to greater exposure and toxic risks. The EPA generally expects most PFAS will be a PBT; however, if a PFAS chemical is not considered a PBT chemical, it will be assessed under the typical review process and not likely to be subject to the additional testing requirements laid out in the PFAS Framework.

Step Two: EPA's Risk Management Decision for PBT PFAS Substances

In the second step of the Framework, the EPA must make a risk management decision for the PBT PFAS. The Framework provides for various actions the EPA must take based on the level of risk associated with the PBT PFAS and its proposed use.

EPA Action For PBT PFAS Not Likely To Present Unreasonable Risk

First, if the PFAS or its significant new use is not likely to present unreasonable risk, the EPA will publish a Section 5(g) statement of findings in the Federal Register and is not required to take any further action. The EPA believes that PBT PFAS are unlikely to receive a determination of “not likely” to present an unreasonable risk.

EPA Action for PBT PFAS that Present Unreasonable Risk

Second, if the EPA determines that a substance or a significant new use presents unreasonable risk, the EPA must issue an order under Section 5(f) or a proposed rule under Section 6(a). A Section 5(f) order would limit or prohibit the manufacture of the chemical as it applies to an individual PMN or SNUN submitter. A Section 6(a) rule would involve restrictions applicable to all manufacturers.

EPA Action for PBT PFAS that May Present Unreasonable Risk

Third, the EPA must issue an order under Section 5(e) of TSCA in situations when there is insufficient information to fully evaluate the risk or there may be unreasonable risk. These consent orders will subject the PMN or SNUN submitter to requirements such as additional testing or safety procedures. The new PFAS Framework lays out three scenarios that illustrate the PBT PFAS risk management approach for submitters subject to Section 5(e) orders: (i) a negligible exposure and environmental release scenario; (ii) a low exposure and environmental release scenario; and (iii) an expected exposure and environmental release scenario.

Negligible Exposure and Environmental Release Scenario

First, in the negligible exposure scenario, the EPA determines that worker exposures will be significantly mitigated, that PBT PFAS will be fully captured and properly disposed of, and that the substance will not be used in consumer products. In this scenario, complete physical-chemical property testing of the PFAS must be completed if the data is not otherwise already available. In this situation, the EPA generally expects to allow the PFAS or the new use of a PFAS to enter commerce after receiving this basic information about the substance. Products in this category will likely include semiconductors and other electronic components that use PFAS in closed systems with occupational protections.

Low Exposure and Environmental Release Scenario

Second, in the low exposure and environmental risk scenario, the EPA determines that worker exposure cannot be sufficiently mitigated and/or environmental releases of the PBT PFAS remain at a level of concern despite the fact that the substance is largely captured. In this scenario, the EPA will likely require both physical-chemical property testing and other testing (e.g., toxicokinetic testing) be completed and submitted to the EPA prior to manufacture before allowing manufacturing to commence.

Expected Exposure and Environmental Release Scenario

Finally, in the expected exposure and environmental release scenario, the EPA determines that release of the PBT PFAS to the environment or exposure of it to consumers is expected based on the substance's intended use. In this scenario, the EPA likely would require a full suite of testing be completed and submitted to the EPA for review prior to manufacture. The extensive suite of required testing may include physical-chemical property testing, other testing such as toxicokinetic, and human health, and environmental toxicity testing. The EPA generally expects that these substances would not be allowed to enter commerce before extensive testing is conducted.

CONCLUSION

Manufacturers who use or plan to use PFAS in production should be familiar with the Framework, as a finding of unreasonable risk by the EPA could subject the PFAS to comprehensive testing requirements. While the Framework describes how the EPA intends to consider the assessment and management of PFAS, it does not impose legally binding requirements on the regulated community as a whole, as each PFAS PMN or SNUN will be evaluated on a case-by-case basis. However, a PNM or SNUN substance subject to assessment under this Framework could ultimately result in a Section 5(e) order that prevents production. Therefore, this Framework could have significant implications for manufacturers using PBT PFAS.

The EPA will host a public webinar about the new PFAS Framework later this summer. K&L Gates' leading Environment, Land and Natural Resources and Policy practice groups are well versed in PFAS regulations and ready to help clients navigate these issues.

We acknowledge the contributions to this publication from our summer associate Patrick Maley

FOOTNOTES

¹ Framework for TSCA New Chemicals Review of PFAS Premanufacture Notices (PMNs) and Significant New

Use Notices (SNUNs), EPA, June 28, 2023, https://www.epa.gov/system/files/documents/2023-06/PFAS%20Framework_Public%20Release_6-28-23_Final_508c.pdf.

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