Prepping For PFAS Approval Under EPA's New Framework

By **David Edelstein and Charles Dennen** (August 1, 2023)

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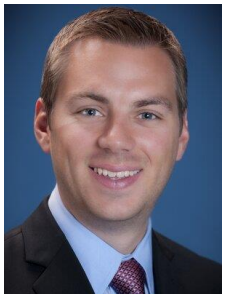

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On June 29, the U.S. Environmental Protection Agency announced its framework for addressing new per- and polyfluoroalkyl substances, or PFAS — and new uses of PFAS.

The framework is one of the EPA's latest steps in advancing its PFAS Strategic Roadmap and is intended to ensure that, before new PFAS and new uses of PFAS are allowed to enter into the stream of commerce, the EPA will undertake an extensive evaluation to help ensure they do not pose a risk of harm to human health or the environment.

Under Section 5 of the Toxic Substances Control Act, or TSCA, the EPA is required to review new chemicals, including new PFAS and new uses of PFAS, assess the potential risks to human health and the environment, and make potential risk determinations.

When potential risks are identified, the EPA is required to act to mitigate those risks before the chemical can enter commerce.

Under the TSCA, a new chemical is designated as any chemical that is not currently on the TSCA inventory, which is a list of chemicals that are deemed to already exist in commerce. The TSCA also subjects manufacturers to a 90-day notice requirement if they want to use a chemical that the EPA has deemed a significant new use from what it previously approved.

This long-threatened change consists of a multistep process, which is expected to bring greater transparency to the way the EPA reviews and regulates PFAS chemicals that are reported through a premanufacture notice or a significant new use notice.

However, the new framework also imposes important complications for members of the regulated community, who should prepare for the likelihood of increased scrutiny when transitioning away from the use of materials that contain trace amounts of PFAS that are already regulated.

Companies, meanwhile, should proactively develop the necessary data prior to submitting the premanufacture notices and/or significant new use notices, in order to avoid the new framework's de facto ban on new PFAS or new uses of PFAS entering into the stream of commerce. Below, we review the EPA's framework and outline key takeaways for entities looking to comply with this new regulatory regime.

The PFAS framework consists of a multistep process by which the EPA reviews and regulates a PFAS chemical that is reported through a premanufacture notice or a significant new use notice submitted to the EPA.

PFAS Framework's Multistep Process

In the first step, the chemical under review must fall into a defined chemical definition of PFAS. If the EPA concludes that a chemical submitted as a premanufacture notice or

significant new use notice is a PFAS, the EPA will begin reviewing all available data on the PFAS to evaluate the level of risk associated with exposure to the particular compound.

During this process, the EPA will consider whether the PFAS is a persistent, bioaccumulative and toxic, or PBT, chemical.

If a PFAS is not considered a PBT chemical, it will be assessed pursuant to the typical TSCA review process and is unlikely to be subject to additional testing requirements.

However, for those PFAS that the EPA deems to be a PBT chemical — according to the EPA, it "generally expects that most PFAS will be PBT" — it will divide the chemical into one of three categories and differentiate the level of scrutiny required based on the likelihood of exposure:

- PFAS with negligible exposure and environmental release potential;
- PFAS with low — but greater than negligible — exposure and environmental release potential; and
- PFAS that are expected to lead to exposure and environmental release.

PFAS With Negligible Exposure and Environmental Release Potential

Under the framework, the EPA expects that some PBT PFAS will not result in worker, general population or consumer exposure, and are not expected to result in releases to the environment.

In this scenario, if the EPA can ensure that such PBT PFAS can be disposed of properly and no consumer exposure is expected, the EPA expects to allow the new PFAS or new use of PFAS to enter commerce after receiving some basic information about the PFAS.

If that information gives cause for concern, the EPA will require additional testing and risk mitigation before moving forward. Examples of products that are likely to fall into this category include PFAS used in a closed system with occupational protections.

PFAS With Low — but Greater Than Negligible — Exposure and Environmental Release Potential

For PFAS with low — but greater than negligible — exposure and environmental release potential, the EPA expects to require test data in addition to information on the chemical's physical properties before allowing manufacturing to begin.

If complete physical and chemical property data is not already reasonably available to the EPA, it is likely to require that both physical-chemical property testing and other testing, such as toxicokinetic testing, be completed and submitted to the EPA before manufacturing can commence.

Moreover, if the initial test results give cause for concern, the EPA will require additional testing and risk mitigation before moving forward.

PFAS Expected to Lead to Exposure and Environmental Release

For PBT PFAS that are expected to lead to exposure and environmental releases — and that do not have a critical use or military need that necessitates limited and restricted

manufacture while testing is ongoing — the EPA expects that the PFAS would not be allowed to enter into commerce prior to extensive testing on physical and chemical properties, toxicity, and fate.

Use of PFAS in spray-applied stain guards is an example of a PFAS-containing product that inherently involves release to the environment. On the other hand, the critical use exception may apply to PFAS-containing products used in hospitals or healthcare settings, for example.

Based on the EPA's review of test data submitted, manufacturing may be allowed to commence with limitations in order to sufficiently mitigate exposure and releases, or manufacturing may be prohibited altogether.

Implications for Regulated Community

The TSCA's New Chemicals Program is nothing new to the regulated community. And while the EPA has threatened increased scrutiny around new PFAS for quite some time, that time seems to have come with the issuance of the PFAS framework.

Indeed, the EPA's framework for new PFAS or new uses of PFAS arguably provides greater transparency than is typically available when the EPA is undertaking a review of new chemicals under the TSCA's New Chemicals Program.

While the increased level of transparency is being touted as a positive, the framework may actually make it more difficult for the regulated community who submit premanufacture notices and/or significant new use notices.

Members of the regulated community that intend to submit premanufacture notices and/or significant new use notices for PFAS should also be aware of the EPA's stated expectation that "most PFAS will be PBT."

As a result, the chemical will be divided into one of the three aforementioned categories and may be subject to stringent scrutiny, depending on the anticipated likelihood of exposure and release to the environment.

Moreover, the framework established a de facto ban on new PFAS or new uses of PFAS entering into the stream of commerce until testing is complete if necessary data is not reasonably available.

Accordingly, it is imperative that members of the regulated community who intend to submit premanufacture notices and/or significant new use notices for PFAS develop the necessary data prior to submitting the premanufacture notices and/or significant new use notices.

Otherwise, there is a risk that products containing new PFAS or new uses of PFAS will not be permitted to enter the stream of commerce until the necessary data is developed.

For these reasons, it may be increasingly difficult for manufacturers to transition away from the use of materials that contain trace amounts of PFAS that are already regulated — such as perfluorooctanoic acid — because such a transition may trigger greater scrutiny than the manufacturer is currently subject to, while also requiring development of additional data and posing potential challenges to enter products into the stream of commerce.
In sum, members of the regulated community should familiarize themselves with the

various categories contained in the framework and develop as much information and data as possible before submitting a premanufacture notice and/or significant new use notice.

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