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EPA's PFAS Policy Change May Delay Market Entry for Innovative Chemicals

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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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