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Regulatory Developments: EPA Issues Third TSCA Test Order for PFAS

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Government Regulation

The U.S. Environmental Protection Agency (EPA) announced on August 15, 2023, that it issued the third Toxic Substances Control Act (TSCA) test order requiring testing on per- and polyfluoroalkyl substances (PFAS) under EPA's National PFAS Testing Strategy. EPA has ordered the Chemours Company FC LLC, E. I. du Pont de Nemours and Company, and 3M Company to conduct and submit testing on 2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoyl fluoride (HFPO-DAF), "a substance used as a reactant in organic chemical manufacturing." EPA states that HFPO-DAF is known to be used to make the chemical hexafluoropropylene oxide dimer acid (HFPO-DA) (Chemical Abstracts Service Registry Number® (CAS RN®) 13252-13-6), also known by the trade name GenX. According to EPA, HFPO-DA is used in the production of nonstick coatings, stain repellent, and other consumer and industrial products and was widely used to replace perfluorooctanoic acid (PFOA). EPA notes that more than one million pounds of HFPO-DAF are manufactured each year, according to TSCA Chemical Data Reporting (CDR) rule reports.

EPA states that after examining existing hazard and exposure data, it concluded that HFPO-DAF may present an unreasonable risk of injury to health or the environment. According to EPA, the potential hazards from exposure to HFPO-DAF could include organ damage, including to the eyes and skin, as well as cancer. EPA also concluded that workers may be exposed to HFPO-DAF. EPA notes that additionally, its recent proposal to regulate six PFAS in drinking water, including HFPO-DA and its salts, isomers, and derivatives, which includes HFPO-DAF, "found there was a meaningful opportunity to reduce health risks to people consuming drinking water contaminated by these PFAS." The test order will help EPA better understand the potential hazards and potential exposures associated with HFPO-DAF. More information on the proposed drinking water standard is available in our March 16, 2023, memorandum.

According to EPA, the information it receives under the test order "will not only improve the Agency's understanding of human health effects of HFPO-DAF, but also the potential effects of dozens of PFAS that are structurally similar to HFPO-DAF and in the same Testing Strategy category of PFAS," improving EPA's overall data on PFAS.

EPA states that the companies subject to the test order may either conduct the tests as described in the order, including testing of physical-chemical properties and health effects following inhalation, or provide EPA with existing information they believe EPA did not identify in its search, but which

satisfies the order requirements. EPA encourages companies to conduct testing jointly to avoid unnecessary duplication of tests and will also consider possible combinations of tests that cover all required endpoints to diminish the amount of time, animal subjects, and costs required.

The order, according to EPA, employs a tiered testing process, as TSCA requires. The results of all the first-tier testing are required to be submitted to EPA within 446 days of the effective date of the order and will inform EPA's decision as to which additional tests are necessary. EPA states that the order and any data submitted in response to the order will be made publicly available on EPA's website and in the applicable docket at www.regulations.gov, subject to confidentiality considerations under TSCA Section 14.

As reported in our January 23, 2023, memorandum, EPA previously issued an order to Chemours Company FC LLC, DuPont De Nemours Inc., E. I. du Pont de Nemours and Company, and 3M Company requiring testing of trifluoro(trifluoromethyl)oxirane (HFPO).

Commentary

This order follows the example from previous orders. EPA has listed all of the testing on its PFAS test plan strategy, seemingly without regard to existing data on whether the tests are appropriate for the substance. While we agree that EPA needs information on each of the listed endpoints, it is difficult to understand why EPA would order melting point testing on a liquid with a fairly low melting point (EPA predicts a melting point of -90 °C). It may be the case that EPA is using the order to ensure that the recipients address each endpoint, even if the recipients do not actually perform testing. A strong case can be made that this is not aligned with EPA's Section 4 authority. EPA appears to be neglecting its duty to consider reasonably available information and to consider how testing of such a low melting point would meaningfully inform EPA's risk assessment.

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