THE
NATIONAL LAW REVIEW

US EPA Finalizes Rule Employing "SNUR-Only" Approach for TSCA New Chemical Reviews

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frESH: Perspectives on Environmental, Safety & Health

- Environmental, Energy & Resources
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Monday, April 22, 2019

On April 5, 2019, US EPA finalized significant new use rules (SNURs) for 13 new chemical substances under section 5(a)(2) of the Toxic Substances Control Act (TSCA). Notably, the 13 chemicals are not also subject to orders under TSCA section 5(e) or 5(f) – an approach that differs substantially from US EPA's long-standing past practice. US EPA previously outlined this "SNUR-only" strategy in a "framework" policy document in late 2017 that was challenged in a lawsuit. As discussed below, while the lawsuit was withdrawn without court review, the April 5, 2019 final rule revives the framework's approach, making it likely that US EPA will again face legal challenges related to the issuance of SNURs without enforcement orders.

Under the TSCA New Chemicals Review Process, a prospective manufacturer (or importer) of a chemical substance must submit a premanufacture notice (PMN) to US EPA before the substance can be manufactured, imported or processed in the United States. The PMN must describe the chemical substance and the substance's intended conditions of use. US EPA then reviews the PMN and must determine that the chemical is "not likely to present an unreasonable risk of harm" under its intended conditions of use in order for it to be manufactured, imported or processed in the US. Historically, if US EPA concluded that a certain use of a substance is not likely to present an unreasonable risk of harm but that another use might, the Agency would enter into a TSCA section 5(e) consent order with the PMN submitter

that would restrict the other use and then also issue a SNUR for the substance. The SNUR identifies the use of concern as a "significant new use" for the substance, and once the SNUR is in place, a party must submit a Significant New Use Notice (SNUN) to US EPA before manufacturing, importing or processing the substance for that use. When reviewing the PMNs for the 13 chemicals, US EPA made "not likely" determinations for the intended uses identified in the PMNs. In contrast to the past practice, however, while other uses raised concerns, US EPA did not enter into a consent order (or issue a section 5(f) order) for any of the 13 chemicals. Instead, US EPA concluded that a SNUR alone would be adequate in each case because the use of concern was not likely to commence before the SNUR was finalized.

As noted, the April 5 final rule is not the first time US EPA introduced the idea of a SNUR-only process for determinations on new chemicals. US EPA broached the SNUR-only approach in the "New Chemicals Decision-Making Framework" issued in late 2017. US EPA indicated that SNURs would "generally be effective vehicles to address such concerns and that, as a general matter, EPA will address such concerns through SNURs."

In January 2018, the Natural Resources Defense Council (NRDC) filed a petition for review of the "New Chemicals Decision-Making Framework" in the Second Circuit Court of Appeals. Environmental and industry groups joined the litigation as amici and intervenors. The NRDC argued that the framework improperly limited US EPA's review of new chemicals to the intended conditions of use specified in the PMN and disregarded the Agency's congressional mandate to address risk concerns through enforceable orders. Because the NRDC withdrew the suit after US EPA indicated that it was considering abandoning the framework, there was no judicial consideration of the legality of US EPA's SNUR-only approach.

The April 5, 2019 final rule indicates US EPA intends to go forward with the SNUR-only approach. This could lead to a legal challenge reviving previous arguments about the proper scope of the Agency's review of new chemical substances under TSCA and whether the SNUR-only approach is lawful.