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The Future Of Chemical Risk Evaluations Under TSCA

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Practice Areas

Environment & Product Regulation
Toxic Substances Control Act (TSCA)

Sometimes the best of intentions can go awry. This article addresses just such a situation: how a largely unnoticed provision of the Toxic Substances Control Act, or TSCA, is undercutting the chemical prioritization and evaluation process that the 2016 Lautenberg Chemical Safety Act's TSCA amendments clearly intended to assign to the U.S. Environmental Protection Agency, and may even threaten to circumvent the agency's substantive judgments. For these reasons, a newly filed case by a group of state attorneys general relating to asbestos regulation merits far more attention from the regulated community than it has received to date.

The 2016 Lautenberg Act amended Section 6 of the TSCA to empower the EPA to evaluate and regulate existing chemicals that present unreasonable risks to human health and the environment. But Congress's failure to make proper and permissible changes to Section 21 — the TSCA's citizens' petitions provision — threatens to undermine the entire framework. By invoking Section 21, litigants are attempting to shift responsibility for prioritizing chemicals for review, conducting risk evaluations, and issuing restrictions on chemicals from the EPA to the federal judiciary.

A recent lawsuit filed by a group of state attorneys general is trying to take advantage of this situation, building on another pending lawsuit to have federal district courts independently conduct risk evaluations of chemicals. If these efforts are successful, and critics of

the EPA's risk evaluations continue to lack faith in the agency process, litigants may increasingly ask the federal judiciary to undercut the EPA's authority.[1] Those who want to preserve the EPA's role in evaluating the potential risks of chemicals would benefit from intervening in the litigation.

Background: The Section 21 Dichotomy

The amendments to TSCA Section 6 redesigned the statutory framework for the EPA's risk evaluations of chemical substances already in the marketplace and established a thoughtful mechanism for prioritizing that work. Pursuant to the newly amended Section 6(b), the EPA has been evaluating an initial group of 10 chemicals. The agency must increase the number of substances undergoing risk evaluations to at least 20 by January 2020.

If any of the EPA's risk evaluations finds that a chemical substance presents an unreasonable risk, the agency is mandated to use its authority under Section 6(a) to issue regulations to overcome that risk. TSCA Section 19 (c)(1)(B) authorizes judicial review of any such exercise of agency authority. Federal courts of appeal must evaluate the agency's record and may set aside Section 6(a) rules — and the accompanying risk-evaluation determinations — if they are not supported by substantial evidence in the rulemaking record taken as a whole.

TSCA Section 8 authorizes the EPA to require chemical manufacturers and processors to maintain records and report data to the agency "only to the extent ... necessary for the effective enforcement of [the TSCA]." Judicial review of an EPA Section 8(a) chemical data reporting rule is subject to the Administrative Procedure Act's arbitrary, capricious abuse of discretion, and otherwise not in accordance with law standards.

Among other things, TSCA Section 21 allows any person to petition the EPA to initiate a proceeding for the issuance, amendment or repeal of a rule under Section 6 or Section 8. If the EPA denies the petition or fails to act within 90 days, the petitioner may file a civil action in federal district court to compel agency action. Notably, in a lawsuit over a petition to issue a new rule under Section 6 or Section 8, a district court is directed to conduct a de novo proceeding to consider the merits of the petition.

The Lautenberg Act also substantively and significantly amended Section 21(b)'s judicial review provisions. When challenging the EPA's refusal to issue a new rule under Section 6 or Section 8, the old version of TSCA Section 21(b)(4)(ii) had required a petitioner to demonstrate to the court by a preponderance of the evidence that "there is a reasonable basis to conclude that the issuance of such a rule or order is necessary to protect health or the environment against an unreasonable risk."

Under amended Section 21(b)(4)(ii), however, the petitioner must now convince the court by a preponderance of the evidence that "the chemical substance or mixture to be subject to such rule or order presents an unreasonable risk of injury to health or the environment." With this revision, Congress arguably shifted a reviewing court's focus from whether there was a reasonable basis for a rule to whether a chemical substance presents an unreasonable risk.

Moreover, the court's obligation upon finding that a petitioner meets its burden is uncertain: The court must order the EPA to "initiate the requested action." Just what that means is subject to debate — it could mean the EPA must initiate a rulemaking proceeding, or perhaps that the EPA must issue the rules and regulations a petitioner has proposed. And recent analogous decisions may provide support for those who urge a court to order the EPA to adopt the specific restrictions or requirements that the petitioners sought in their administrative petition.[2]

The potential end run around the EPA created by this scheme may well violate the U.S. Constitution's nondelegation doctrine by impermissibly placing a legislative or executive function with the federal judiciary. Arguably, the Constitution's separation of powers provisions do not authorize federal courts to conduct their own risk evaluations or dictate chemical policy decisions. The EPA and any intervenors in Section 21 lawsuits should be mindful of the U.S. Supreme Court's renewed interest in cases challenging Congress's delegation of power to the other branches of the federal government.

Section 21 Petitions on Asbestos Reporting

The foregoing background puts the new asbestos suit into context. But a bit more explanation is still necessary.

On Jan. 31, the attorneys general of California, Massachusetts, and a handful of other states filed a petition for rulemaking with the EPA. The petition asked the EPA to initiate a new rulemaking under TSCA Section 8(a) to potentially obtain additional information on the manufacture — including import — and processing of asbestos.

Notably, the attorneys general filed their petition the month after the EPA had denied a similar petition to initiate a proceeding for a TSCA Section 8(a) information-gathering rule on asbestos from the Asbestos Disease Awareness Organization and five other organizations. Both petitions argued that the EPA needs to obtain additional information under Section 8(a) on the quantity of imported asbestos and asbestos-containing articles moving through commerce in the United States. The petitions claimed that the EPA will be unable to satisfy the risk evaluation requirements under Section 6(b) without this data. The EPA denied the attorneys general petition on April 30.

Why would the attorneys general file a petition that imitated one just denied? Because the earlier petition asked the EPA to amend its current Section 8(a) regulations, while the attorneys general petition asked the EPA to issue a new rule under TSCA Section 8(a). This nuance allows the attorneys general to argue that they are entitled to de novo court review — i.e., an opportunity to demonstrate to the court by a preponderance of the evidence that asbestos presents an unreasonable risk.

That appears to be precisely what the attorneys general are seeking. On June 28, they filed a complaint in the U.S. District Court for the Northern District of California asking for a de novo proceeding to direct the EPA to issue a new Section 8 information-gathering rule on asbestos because the preponderance of the evidence demonstrates that asbestos presents an unreasonable risk. Although the attorneys general have asked the court only to mandate the initiation of a rulemaking under Section 8 in the current complaint, they nonetheless

ultimately may ask for more — i.e., the dictation of the content of that rule. Even if they do not, however, that expansion of judicial authority may be the target of the case discussed below.

The Fluoride Precedent

Another Section 21 test case is pending in the Northern District of California, and is not going well for the U.S. Department of Justice and the EPA.[3] On Nov. 23, 2016, the Fluoride Action Network, Food & Water Watch, and other petitioners filed a Section 21 petition asking the EPA to ban the addition of fluoridation chemicals to drinking water. The petitioners alleged that "fluoride is neurotoxic at doses within the range now seen in fluoridated communities."

Because fluoride's beneficial use comes from topical contact, the petitioners asserted that "there is no reasonable justification to expose hundreds of millions of Americans to the neurotoxic risks of systematic fluoride via water."[4]

On Feb. 17, 2017, the EPA denied this petition on both procedural and substantive grounds. The petitioners filed their complaint in the district court two months later. After denying the EPA's motion to dismiss on Dec. 21, 2017, the court has permitted the parties to engage in discovery in preparation for trial. The court has scheduled its de novo proceeding on fluoridation chemicals for February 2020.

Forecasting the Future of TSCA Risk Evaluations

If the attorneys general were to succeed in convincing the district court that asbestos presents an unreasonable risk of injury to health and the environment, this finding will inevitably lead them to file another Section 21 petition. This time the petition would use the district court's finding of unreasonable risk to compel the EPA to issue a Section 6(a) risk management rule for asbestos — regardless of what the EPA's pending Section 6(b) asbestos risk evaluation concludes.

Such an outcome would likely encourage future Section 21 petitions for new rules under Section 8(a) for chemical substances pending TSCA risk evaluations. If the EPA were to deny those petitions, then the petitioner plaintiffs could seek to create a dual-track risk evaluation process that allows the federal judiciary to perform the task that the 2016 TSCA reforms intended to give the EPA.

Depending on their outcomes, the fluoride and asbestos cases could motivate more Section 21 petitions for Section 6(a) management rules on chemical substances, as activists seek to avoid waiting years, or even decades, for the EPA to prioritize and evaluate those chemicals. For example, those advocating for restrictions on per- and polyfluoroalkyl substances, or PFAS, may soon decide to file a Section 21 petition for a Section 6 (a) restriction on these chemicals. Flame retardants, phthalates and chemicals on the EPA's 2014 work plan not currently scheduled for risk evaluation are other potential candidates for this approach.

The future of chemical risk evaluations under the TSCA thus appears to be in flux, but there is time to influence the outcome. Interested stakeholders can still seek to intervene in the attorneys general asbestos litigation, and perhaps the fluoride case, or can seek to file amicus briefs to defend the chemistries in question and set

forth strong legal defenses. Ultimately, intervenors or amici may be able to help convince the courts to dismiss the litigation or, at a minimum, constrain judicial review enough to disincentivize future Section 21 lawsuits.

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[1] https://www.law360.com/articles/1173954/epa-chemical-risk-evaluations-draw-criticism-from-enviros.

[2] See, e.g., LULAC v. Wheeler , No. 17-71636, slip op. at 32 (9th Cir. Aug. 9, 2018) (granting petition for review and directing the EPA "to revoke all tolerances and cancel all registrations" for a pesticide); In re A Community Voice , 878 F.3d 779, 785 (9th Cir. 2017) (concluding that "[h]aving chosen to grant the petition for rulemaking ... [the EPA] does not comply with that duty merely by 'begin[ning] an appropriate proceeding'").

[3] Food & Water Watch Inc. v. EPA, No. 17-cv-02162-EMC (N.D. Cal.).

[4] Section 21 Petition Regarding the Neurotoxic Risks Posed by Fluoride Chemicals in Drinking Water, https://www.epa.gov/sites/production/files/2017-02/documents/tsca_fluoride_petition.pdf.