Environmental Quality Management

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TSCA Citizen Petitions and Risk Evaluations: Are These Critical TSCA Tools Aligned?

By Lynn L. Bergeson

The citizen suit provisions of the Toxic Substances Control Act (TSCA) are turning out to be a potentially powerful tool for advocates dissatisfied with risk evaluations conducted under TSCA Section 6. What is unclear is whether anyone intended this result. This column discusses the new and somewhat surprising role TSCA Section 21 citizen petitions may play in defining chemical risks under TSCA. The issue involves an interesting TSCA Section 21 petition filed in 2016 that has been the subject of litigation ever since. How the lawsuit plays out will have significant implications for TSCA stakeholders.

TSCA Section 21 and Section 6

Two sections of TSCA are relevant for present purposes: TSCA Section 21, the provision authorizing citizen petitions, and TSCA Section 6, the provision authorizing EPA to conduct chemical risk evaluations. TSCA Section 21 empowers "any person" to file a petition to initiate a proceeding for the "issuance, amendment, or repeal of a rule under" TSCA Section 4 (data generation), 6 (risk evaluation), or 8 (recordkeeping and reporting). In other words, anyone may ask EPA to create a new rule or amend or withdraw an existing rule pertinent to these provisions of TSCA.

The process under Section 21 is straightforward. Section 21 requires EPA to respond to a petition within 90 days of its filing. To grant a Section 21 petition for a TSCA Section 6(a) rulemaking, a petitioner must provide facts sufficient to establish that the requested rulemaking is necessary. The facts must be sufficiently clear and robust for EPA to be able to conclude, within the 90-day time frame, that the chemical presents an unreasonable risk of

injury to health or the environment and that issuance of a TSCA Section 6(a) rule is the appropriate response to the petition. To make the threshold finding, EPA must consider hazard and exposure data and other information that enables the Agency to assess risk and conclude whether the risk is unreasonable. In the absence of these data and information, EPA would need additional factual information to make a determination, which would trigger either a denial and possible resubmission by the petitioner, or judicial review.

If the citizen petitioner requests a TSCA Section 6(a) rulemaking and EPA grants that petition, TSCA Section 21 requires that EPA promptly commence an appropriate proceeding under TSCA Section 6. Similarly, if a petitioner seeks the initiation of a new information-gathering rule under TSCA Section 8 and EPA grants that relief, Section 21 requires that EPA commence a proceeding under TSCA Section 8. Over the years, many such petitions have been filed seeking a broad range of outcomes.

Congress amended TSCA Section 21 in 2016 and revised the judicial review provisions. Under old TSCA, petitioners were required to demonstrate to a reviewing court that a preponderance of the evidence supported the view that there was a "reasonable basis to conclude that the issuance of [ ] a rule or order is necessary to protect health or the environment against an unreasonable risk." This standard placed the burden of proof, by preponderance of the evidence, in demonstrating the need for a rule to protect against an unreasonable risk. Under new TSCA, the petitioner must now demonstrate, by a preponderance of the evidence, that the "chemical substance or mixture to be subject to a [Section 6(a) or 8] rule or order presents an unreasonable risk of injury to health or the environment …" This subtle change shifted the focus from whether there was a reasonable basis to conclude that the issuance of a rule or order was necessary to protect health and the environment to whether a chemical substance or mixture itself presents an unreasonable risk of injury to health or the environment, precisely the same exercise EPA is tasked with exploring in conducting risk evaluations under TSCA Section 6.

As noted, if EPA denies a petition or fails to act timely within the 90-day period, the petitioner may commence a civil action in a federal district court to compel EPA to initiate the action requested under the petition.

Importantly for purposes of this discussion, petitioners seeking to initiate a proceeding *to issue a rule*, in contrast to petitioners seeking to amend an existing rule, under TSCA Section 6 or 8 must be provided an opportunity to have the petition considered by the court in a *de novo* proceeding. Traditionally, this has meant that the reviewing court is authorized to review the entirety of the administrative record developed by EPA *and* to develop that record, meaning new facts and information can be introduced into evidence. This *de novo* standard and its relevance to TSCA risk evaluations have been the subject of debate, as discussed below.

The TSCA Section 6 chemical risk evaluation processes Congress mandated under new TSCA are a key element of the new law. EPA must prioritize active, existing chemical substances into "high" and "low" priority categories and to assess the potential risks of high-priority substances. EPA is to publish the intended scope of the risk evaluation according to aggressive timelines and to complete the risk evaluation no later than three-and-one-half years after its initiation. Chemical uses found to pose unreasonable risks must be mitigated until the risk is abated. Since EPA has identified more than 40,000 active existing chemical substances, the process will continue for decades.

To get things started, EPA was required under the Frank R. Lautenberg Chemical Safety for the 21st Century Act to initiate risk evaluations on ten chemicals drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments (TSCA Work Plan) 180 days after Lautenberg's enactment, or by early 2017, which EPA timely did. EPA is also required by the end of December 2019 to ensure that risk evaluations are underway for a least 20 high-priority chemical substances and to ensure that at least 20 chemicals have been designated as low-priority substances. EPA published on March 21, 2019, a list of 40 chemicals, including 20 high-priority and 20 low-priority chemicals, for risk evaluation prioritization purposes. EPA intends to issue timely final designations (EPA, 2019a)

Unsurprisingly, not everyone is pleased with EPA's implementation efforts. Since new TSCA was passed, more than 20 lawsuits have been filed against EPA challenging many regulatory actions, including the chemical risk evaluation process. Several environmental, health, and labor organizations challenged in two different federal appellate courts EPA's final prioritization

and risk evaluation rules. The cases were consolidated in the U.S. Court of Appeals for the Ninth Circuit with Safer Chemicals, Healthy Families as the lead petitioner. *Safer Chemicals, Healthy Families v. EPA*, No. 17-72260. (U.S. Court of Appeals for the Ninth Circuit, 2019)

The Fluoride Petition

It is against this statutory background that we review what has turned out to be a significant TSCA Section 21 petition filed in November 2016. The petitioners are the Fluoride Action Network, Food & Water Watch, Organic Consumers Association, American Academy of Environmental Medicine, International Academy of Oral Medicine and Toxicology, and Moms Against Fluoridation. The petition requests EPA to promulgate a rule pursuant to TSCA Section 6 and to seek regulatory action under Section 6 to "prohibit the purposeful addition of fluoridation chemicals to U.S. water supplies" and announced that it was making available its response to the petition. On February 27, 2017, EPA reported that it was denying the Section 21 petition and that it was making available its response to the petition (EPA, 2017).

The citizen petitioners appealed the decision to the U.S. District Court for the Northern District of California, asking the court to declare that they had properly shown that the addition of fluoridation chemicals to drinking water poses unreasonable risks under TSCA. EPA sought to dismiss the action, which the court denied. EPA also sought to limit the record on review to the EPA administrative record and to bar the petitioners from seeking discovery. The court denied that motion, ruling that the scope of the court's review is not limited to the administrative record, that a *de novo* "proceeding," to quote the statute, reflected Congress's desire to allow the reviewing court to consider additional evidence beyond the administrative record, and ruled that petitioners were entitled to seek discovery beyond the administrative record. On November 15, 2019, the court held a motion hearing to determine whether the case will proceed to oral argument (Cutler & Rizzuto, 2019). If the case does proceed, a bench trial is scheduled for February 3, 2020.

Other Section 21 Petitions

Other suits challenging EPA's denial of TSCA Section 21 petitions are relevant for present purposes, especially two suits in the U.S. District Court for the Northern District of California dismissing TSCA Section 21 petitions concerning asbestos. In the first case, the Asbestos Disease Awareness Organization (ADAO) and five other non-governmental organizations (NGO) petitioned EPA on September 27, 2018, requesting that EPA initiate rulemaking under TSCA Section 8(a) to amend the Chemical Data Reporting (CDR) rule to increase reporting of asbestos to CDR. EPA denied the petition on December 21, 2018, on the grounds that the petitioners did not demonstrate that it is necessary to amend the CDR rule. (EPA, 2019b). On February 18, 2019, ADAO filed suit regarding EPA's denial of its petition. *ADAO v. EPA*, 19-cv-871. On September 5, 2019, the court held a hearing on EPA's motion to dismiss for lack of jurisdiction. Parties filed briefs on September 27, 2019, addressing whether the underlying Section 21 petition constituted a request to initiate a proceeding for the issuance of a new rule (and thus subject to Section 21(b)(4)(B)) or an amendment of an existing rule (and thus subject only to Section 21(b)(4)(A)).

In the second, related case in the U.S. District Court for the Northern District of California, following EPA's dismissal of a January 31, 2019, petition, a coalition of 11 state attorneys general filed a lawsuit on June 28, 2019, against EPA for its failure to initiate an asbestos reporting rule under TSCA Section 8(a). *California v. EPA*, No. 19-cv-3807. The coalition argues that EPA wrongfully denied the states' January 31, 2019, petition asking EPA to issue a rule for the reporting of the manufacture, import, and processing of asbestos. The coalition includes the Attorneys General of California, Connecticut, Hawaii, Maine, Maryland, Massachusetts, Minnesota, New Jersey, Oregon, Washington, and the District of Columbia. According to the coalition, the rulemaking they requested is necessary under TSCA, and the denial of their petition was arbitrary and capricious and violates EPA's obligations under TSCA. Importantly in this case, the attorneys general seek issuance of a new rule under TSCA Section 8, presumably to avail themselves of the *de novo* standard of review on judicial appeal, as contrasted with the earlier citizen's petition that requested an amendment to an existing Section 8 rule. On September 9, 2019, the court granted the

parties' stipulation to stay EPA's responsive pleading deadline pending resolution of the motion to dismiss in *ADAO*.

In another Section 21 petition, on August 7, 2019, the Public Employees for Environmental Responsibility (PEER) filed a petition for rulemaking, asking that oil refineries be prohibited from using hydrofluoric acid in their manufacturing processes and that oil refineries be required to phase out the use of hydrofluoric acid within two years (Whitehouse & PEER, 2019). According to PEER, TSCA and the Clean Air Act (CAA) regulate hydrofluoric acid and provide the statutory authority for EPA to issue a regulation prohibiting the use of hydrofluoric acid in oil refineries. PEER states that under TSCA, EPA "possesses the power to promulgate rules banning chemicals that pose an unreasonable risk to human health." On November 4, 2019, EPA denied PEER's petition, based on the petition's lack of sufficient facts establishing that it is necessary for EPA to issue a rule under TSCA Section 6(a). According to EPA, the petition lacks the analysis that would be expected in a TSCA risk evaluation preceding a Section 6(a) rulemaking. Whether PEER will challenge EPA's dismissal of its Section 21 petition in court is unclear. As noted, there has been an uptick in the filing of Section 21 petitions, a trend unlikely to change in 2020.

Discussion

Petitioners seeking judicial review by a federal District Court of a petition denial or failure timely to respond to a petition to initiate a proceeding to issue a rule under TSCA Sections 6 or 8 appear to be entitled to *de novo* review. If citizen plaintiffs are able to obtain *de novo* review of EPA decisions in response to administrative petitions, reviews that are unbounded by the Agency's administrative record and able to be supplemented by new evidence elicited by trial court discovery rules, citizen plaintiffs may be inclined to do just that as a convenient work-around to unfavorable TSCA risk evaluations.

The opportunity for *de novo* review of TSCA Section 21 citizen petitions offers a generous pathway for determined litigants to invite a District Court to conduct a risk evaluation, as opposed to EPA, where Congress appears to have intended them to be prepared. It is curious that asbestos, one of the first ten chemicals to be evaluated under new TSCA, is already the subject of

multiple Section 21 petitions and headed for more litigation. And while this anomalous situation exists, it is unclear whether many will avail themselves of the litigation option. Litigation is costly, courts can be difficult fact finders on scientific issues, and results are always uncertain. That said, certain substances, under certain conditions, and litigated in certain venues may well offer a more promising outcome than a risk evaluation conducted by EPA under TSCA Section 6. It also begs the question whether Congress intended this result, or whether we are we now enduring the unwanted consequences of hurried law making. Stay tuned to this issue, especially if the Administration changes in 2020.

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