New TSCA inspires new litigation

Some recent lawsuits have challenged the EPA's interpretation of the latest US chemical laws

Lynn L Bergeson
Managing partner, Bergeson & Campbell

When the Toxic Substances Control Act (TSCA) was legislatively 'modernised' in June 2016, no one in the legal community doubted litigation was in our collective future. We have not been disappointed.

The US Environmental Protection Agency (EPA) and its legal counsel for these purposes, the US Department of Justice (DoJ), are facing multiple lawsuits in several federal appeals courts and the very real possibility of more litigation deriving from TSCA Section 21 citizen petitions in the light of a recent decision. While none of this is especially unexpected, it is nonetheless disquieting. This article is a quick summary of where the cases stand and a discussion of what is at stake.

New TSCA: an overview

TSCA is the federal law that gives the EPA authority to regulate imported, manufactured and processed industrial chemical substances, including those intended for commercial and consumer uses.

Its significant legislative makeover in 2016 in the form of the Lautenberg Chemical Safety Act (LCSA), and the robust implementation measures required of the agency since then, have been the focus of considerable (and laudable) effort.

LCSA extensively amends TSCA, revising and adding definitions, notably by:

- expanding testing authority;
- regulating new and existing chemicals (including, for the latter, sequential prioritisation, risk evaluation and risk management steps);
- expanding information reporting;
- narrowing the scope for confidential business information (CBI) protection; and
- tinkering with preemption.

EPA administrator Scott Pruitt said, at an oversight hearing before the Senate Environment and Public Works Committee on 30 January: "EPA's top priority for ensuring the safety of chemicals in the marketplace is the implementation of [Lautenberg], which modernises [TSCA] by creating new standards and processes for evaluating the safety of chemicals in the marketplace within specific deadlines."

Among the most consequential 'implementation' measures incumbent upon the EPA to effect quickly was to issue three TSCA 'framework' rules. Collectively, these are intended to provide the administrative muscle behind the LCSA's promise to deliver on its commitment to make TSCA a more effective tool in ensuring industrial chemical safety.

Under TSCA, the EPA was to issue final risk prioritisation, risk evaluation and inventory notification rules by June 2017. The former, issued on 20 July 2017, defines the process by which the agency identifies and designates an existing chemical substance as either 'high' or 'low' priority. High priority substances must be evaluated pursuant to a process established by the risk evaluation rule, issued on the same day.

The inventory notification rule of 11 August 2017 implemented the new TSCA's requirement that chemical manufacturers (including importers) identify chemicals as 'active', in order to develop a TSCA inventory that better correlates with the substances actually in US commerce. This should assist the EPA in prioritising chemicals for evaluation.

The agency issued these three framework rules rapidly but not without controversy. They had been proposed under the Obama administration and reflected its interpretation of the many new terms and concepts in the amended TSCA. The Trump administration issued the final rules, however, and, not surprisingly, it did not embrace some of its predecessor's positions.

The Office of Chemical Safety and Pollution Prevention (OCSPP), which oversees TSCA matters, is now under the leadership of Dr Nancy B Beck. She holds a doctorate in environmental health and, for the past five years before joining the EPA, served as director for regulatory science policy at the American Chemistry Council (ACC), the trade association representing the interests of the domestic industrial chemical industry.

The lawsuits

In August 2017, the NGO Safer Chemicals, Healthy Families and 11 other organisations sued the EPA in the US Court of Appeals for the Ninth Circuit in San Francisco, challenging the risk prioritisation and risk evaluation final rules. Other organisations similarly filed suit in the Second Circuit (Environmental Defense Fund (EDF) in New York) and in the Fourth Circuit (Alliance of Nurses for Healthy Environments) in Virginia..

After a series of transfers, the two challenges were consolidated in the Ninth Circuit on 27 November and 11 December 2017, respectively, as *Safer Chemicals, Healthy Families v. EPA and **Alliance of Nurses for Healthy Environments v. EPA, Industry associations and other chemical interests motioned to intervene in these challenges, which the court granted.(*Nos. 17-72260, *et al.*; ** Nos. 17-72260, *et al.)*

The EDF challenged the remaining 'framework' rule, the inventory notification rule, last September in the US Court of Appeals for the DC Circuit (EDF v. EPA, No. 17-1201). It claims that the final rule authorises confidentiality claims that are not consistent with revised TSCA Section 8 and 14. Industry groups and others have been granted leave to intervene in the case.

More recently, on 5 January 2018, the Natural Resources Defense Council (NRDC) filed a petition for review in the US Court of Appeals for the Second Circuit of what it characterised as an EPA final rule. This was issued on 7 November 2017 and is entitled *New chemicals decision-making framework: working approach to making determinations under Section 5 of TSCA*.

This 'framework document', as it has come to be called, is the final rule at issue. It was

posted in the EPA's docket. Comment was requested on it to supplement the EPA's two related TSCA public meetings, which took place in December. It is noteworthy that the agency does not refer to the framework document as a final rule and it was not published in the *Federal Register* as such. Instead, it states that the document outlines a "conceptual approach" to how it may go about making decisions on new chemicals.

The EPA specifically states that the document, referred to as a "draft" in the *Federal Register* notice that announced the two public meetings, "outlines EPA's approach to making decisions on new chemical notices submitted to EPA under TSCA Section 5, as amended by LCSA", and includes its "general decision framework for new chemicals" and a breakdown of how EPA "intends to approach each of the five types of new-chemical determinations required under the statute".

The citizen action petition raises novel and interesting legal questions, and is quite different from the other petitions for review that are pending. It is unclear whether the framework document legal challenge will survive procedural motions that the EPA can be expected to file to dismiss the action.

Citizen petitions

Before we move off these judicial challenges, we need to reflect briefly on another area in hot dispute. TSCA Section 21 authorises 'citizens' to file petitions with the EPA, urging it to issue, amend or repeal a rule or order issued under TSCA Sections 4 (chemical testing), 5 (new chemical notification), 6 (existing chemicals) and 8 (record-keeping and reporting).

This is an EPA administrative procedure that requires the agency to respond within 90 days of submission. Petitioners may seek judicial review by a federal district court of a petition denial or, if the EPA fails, time to respond rapidly to a petition. Under the rules, the reviewing federal district court is granted *de novo* review, which traditionally has meant that it would review the entirety of the administrative record developed by the EPA.

On 23 November 2016, a citizen organisation, Food & Water Watch, along with others, filed a Section 21 petition under new TSCA, seeking a ban on the addition of fluoridation chemicals to drinking water. The EPA swiftly denied the petition.

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The petitioners thereafter appealed the decision by filing a complaint with the US 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 as defined under TSCA. The EPA moved to dismiss the action, which the court denied.

More recently, the agency sought to limit the record on review to its administrative record and to bar the petitioners from seeking discovery. The court denied that motion too, ruling that the scope of the court's review is not limited to this, that a *de novo* 'proceeding,' to quote the statute, "reflected Congress' 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.

The court's decision is well written and compelling, and has sent shock waves through the chemical community. The EPA has not yet appealed the decision and it would appear at present that it does not intend to do so.

Implications

Judicial review of the final framework rules was not unexpected. At this early stage of litigation, it remains to be seen what the key issues are, how the litigants will frame the disputes, and how the court will decide them. No stays of the final rules have been issued. The cases are proceeding and their pending nature has no real impact on the parties or the EPA's implementation or administration of TSCA.

EDF's novel challenge to the new chemicals 'framework document' may or may not survive motions to dismiss. The draft framework document is just that, a draft, conceptual framework outlining the EPA's approach to new chemical review, not a rule amenable to appeal of final agency action. The court may well decide to dismiss the case on procedural grounds.

The real surprise here is the court's ruling in Food & Water Watch. If citizen plaintiffs are able to obtain *de novo* review of EPA decisions in response to these petitions, reviews that are not bounded by the agency's administrative record and greatly supplemented by new record evidence elicited by trial court discovery rules, citizen plaintiffs can be expected to avail themselves of Section 21 petitions as a convenient work-around to unfavourable EPA administrative decisions.

The decision carefully explains all the reasons why district court procedural rules, litigant advocacy tactics, and judicial discretion should allay any EPA (and chemical company stakeholder) fear of being "sandbagged and surprised" with new evidence not presented in the petition. Common sense, however, would suggest otherwise, as that is exactly what the EPA - and industry stakeholders - fear.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch