Risk evaluations under TSCA: The state of play

Lynn L. Bergeson of Bergeson & Campbell summarises how the EPA is going about implementing Congress's risk evaluation mandate

AMONG THE CHANGES when the Toxic Substances Control Act (TSCA) was amended by the Frank R. Lautenberg Chemical Safety Act for the 21st Century, also known as Lautenberg or 'new TSCA', none is more consequential than the requirement that the US Environmental Protection Agency (EPA) conduct risk evaluations for 'high priority' chemical substances. We are now three years into new TSCA and this is being done, amid spirited debate and, inevitably, litigation.

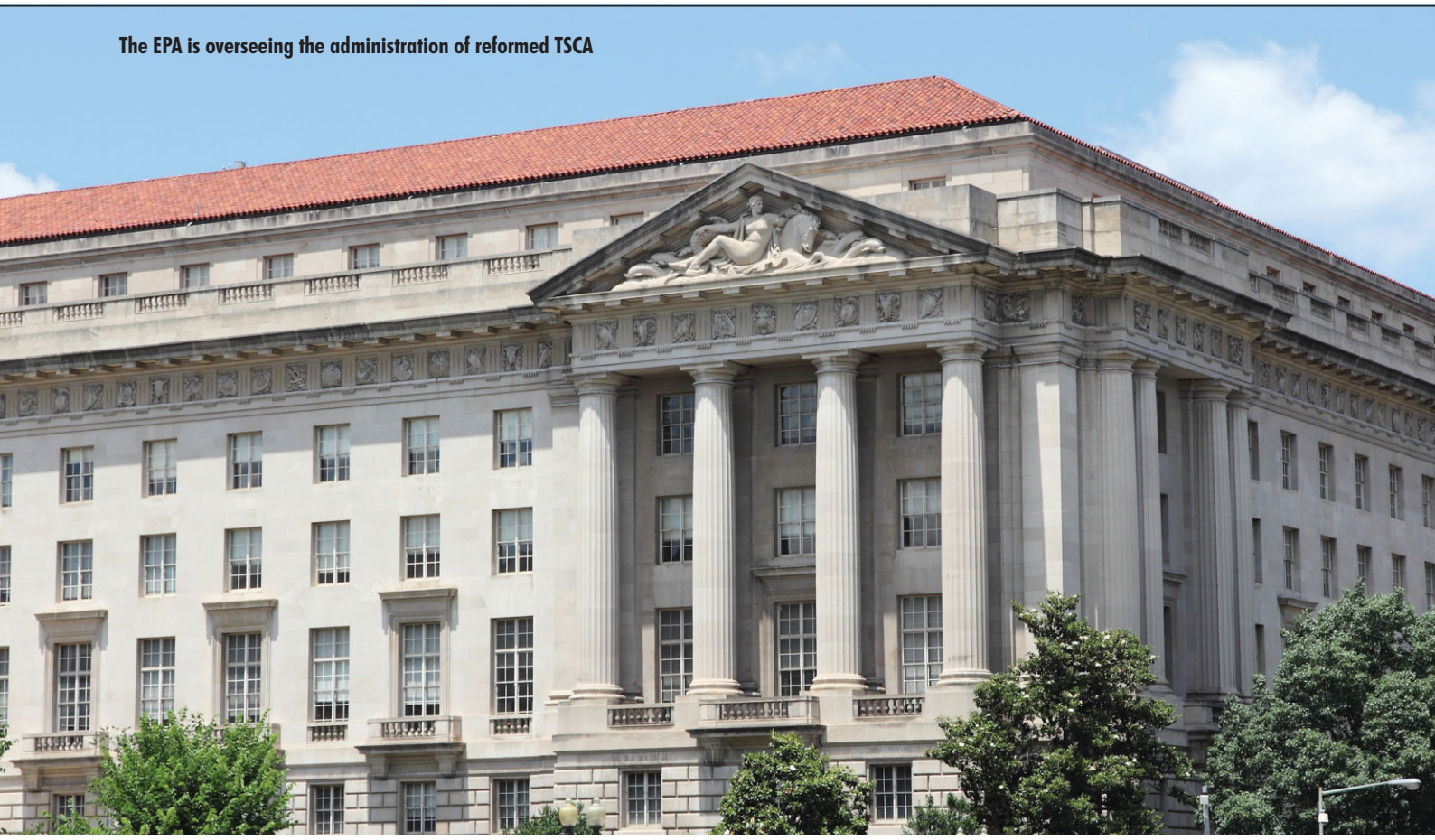
Risk evaluation process

Under TSCA, the EPA was not required to assess the potential risks posed by existing chemical substances to any discernible schedule. This glaring omission was the subject of chronic, withering criticism and a key rallying cry for reform.

New TSCA included specific requirements for the agency to develop and implement chemical prioritisation and risk evaluation processes by June 2017, a deadline it met.

The processes Congress mandated are fairly straightforward. The EPA is to:

- Prioritise active, existing chemical substances into 'high' and 'low' priority categories
- Assess the potential risks of high priority substances
- Publish the intended scope of the risk evaluation to aggressive timelines
- Complete the risk evaluation no later than 42 months after its initiation



The EPA is overseeing the administration of reformed TSCA

Chemical uses found to pose unreasonable risks must be mitigated until the risk is abated. Since the EPA has identified more than 40,000 active existing chemical substances, the process will continue for decades.

To get things started, the EPA was required to initiate risk evaluations on ten chemicals drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments. The agency released its first draft risk evaluation of the ten substances in November 2018 concerning the chemical Colour Index (CI) Pigment Violet 29. The Science Advisory Committee on Chemicals (SACC) has since conducted a peer review on this.

Three other risk evaluations for substances included in the first ten have been released for comment and peer-reviewed by the SACC, including 1-bromopropane, 1,4-dioxane and cyclic aliphatic bromide cluster. The EPA intends to release four of the remaining draft risk evaluations for public comment by the end of 2019 and the other two in January 2020, while the SACC intends to peer-review two in 2019 and the remaining four in 2020.

The EPA is also required to ensure that risk evaluations are under way for a least 20 high priority substances and to designate at least 20 chemicals as low priority substances by the end of 2019. On 20 March, the agency published a list of 40 chemicals, 20 of each, for prioritisation purposes. It intends to issue timely final designations.

The inevitable: Litigation

Unsurprisingly, not everyone is pleased with the EPA's efforts. Since Lautenberg was passed, more than 20 lawsuits have been filed against, challenging regulatory actions, including the chemical risk evaluation process. Several NGOs challenged the rules in two different federal appellate courts. The cases were consolidated in the US Court of Appeals for the Ninth Circuit, with Safer Chemicals, Healthy Families as the lead petitioner.

At the litigation's heart is the EPA's interpretation of chemical use conditions that must be considered in a risk evaluation. The petitioners argue that its decision to exclude certain conditions of use, and any resulting exposures deriving from the risk evaluations, violates TSCA. They argue that the law's mandate to determine whether a chemical substance presents an unreasonable risk requires an evaluation of its total risk and the phrase 'under the conditions of use' "unambiguously means all of the chemical's conditions of use".

The petitioners also argue that the EPA unlawfully rewrote the definition of conditions of use to omit a chemical's current and future use and disposal if its manufacture, processing, and distribution for that specific use are not ongoing – so-called 'legacy uses'. Congress's inclusion of 'use' and 'disposal' as 'conditions of use' rule out this construction, they assert.

On 16 May, the court heard oral arguments. It questioned whether petitioners had standing to be before the court and suggested that they could wait to see whether the EPA will ignore certain uses of chemicals in its risk evaluations. Next, the court ordered the petitioners to file a supplemental brief addressing why they should be

allowed to bring a lawsuit against the EPA, potentially foreshadowing a determination that the case is not yet ripe for review.

Administrative challenges

Before we move off judicial challenges, we should 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, among other TSCA provisions, Section 6. This is an 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 may appeal if the EPA fails to respond in time. Under the rules, the reviewing federal district court is granted *de novo* review, which has traditionally meant that the reviewing court would be authorised to review the entirety of the administrative record developed by the EPA and develop that record.

In late 2016, Food & Water Watch and others filed a Section 21 petition under new TSCA seeking to prohibit the addition of fluoridation chemicals to drinking water. The EPA denied the petition. The citizen petitioners appealed the decision to the US District Court for the Northern District of California, asking the court to declare that they had properly shown that this poses unreasonable risks under TSCA.

The EPA sought to dismiss the action, which the court denied. The agency then 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 its 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.

The implications of this decision are considerable. If citizen plaintiffs are able to obtain *de novo* review of EPA decisions in response to administrative petitions, reviews unbounded by the agency's administrative record and supplemented by new evidence elicited by trial court discovery rules, they may be inclined to do this as a convenient work-around to unfavourable TSCA risk evaluations.

Litigation is expected to continue. And the chances are not motivated stakeholders will pursue administrative remedies under Section 21. ●

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