Expert Focus: What lies ahead for the next four years of TSCA?

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The Frank R Lautenberg Chemical Safety for the 21st Century Act is four years old. While to some 22 June 2016 seems like yesterday, the past four years have been transformational. The US EPA has worked hard, been timely and done well in thoughtfully implementing the changes.

Anniversaries tend to inspire reflection on the past, and this year was no exception. The Environmental Law Institute, Bergeson & Campbell and the George Washington University Milken Institute School of Public Health convened for an all-day seminar on TSCA reform, four years after the enactment of Lautenberg. Diverse stakeholders offered their perspectives on TSCA implementation and shared candid reviews on where we are as a TSCA community.

Rather than look back, this article looks forward to the *next* four years and speculates on some of the many challenging topics the EPA and other TSCA stakeholders are likely to address.

The election

In addition to being the four-year anniversary of TSCA reform, 2020 is an election year – an inconvenient fact that makes it difficult to reliably speculate on what the future might look like. If the administration changes, it is safe to assume the EPA's implementation of Lautenberg, and the administration of the Act itself, could be quite different.

The Trump administration revisited some of the early EPA policy positions under the Obama administration before the inauguration in January 2017. This is illustrated in the section 5 new chemicals area where, early on, the EPA interpreted the phrases "reasonably foreseen" and "conditions of use" in a way that dramatically increased the number of notices subject to section 5(a)(3)(b) determinations. This led to many more consent orders and/or significant new use rules (Snurs) relative to the historical record under old TSCA.

While some increase was expected under the new law, the approach under the Trump administration strikes us as more balanced and appropriately measured, as reasonable people can disagree on which interpretation of "reasonably foreseeable" is scientifically and legally justifiable. There are other examples of controversial decisions under both the Obama and Trump administrations, and some are now the subject of judicial review, which, depending on how the cases are decided, could profoundly affect TSCA implementation in the future.

While it is impossible to know what exactly would change, it seems intuitively clear that a Biden administration could interpret TSCA, and the many legal, science and policy issues it invites, quite differently.

Lautenberg provisions to be implemented

The EPA has completed much of the foundational work required by Lautenberg. The framework rules are in place, the agency has reset the TSCA chemical inventory and the section 5 new chemicals review process is progressing well. Confidentiality claims are being reviewed, the Science Advisory Committee on Chemicals (Sacc) has been formed and is operational, and the "first ten" risk evaluations are completed or underway. The first iteration of the prioritisation

process was completed with the selection of 20 high- and 20 low-priority chemicals, and the risk evaluation process initiated for the high-priority chemicals. Section 6(a) regulatory action was proposed for five persistent, bioaccumulative and toxic (PBT) chemicals, the EPA issued its strategic plan for reducing vertebrate animal testing, and the crucial TSCA fees rule is now in effect. A few statutory mandates remain and will be implemented as noted below.

The final TSCA section 6(a) regulations on the five PBT chemicals are required to be issued by December 2020 under section 6(h)(2). The agency is required to have proposed (within one year) and promulgated (within four years from now) regulatory actions on methylene chloride to the extent necessary that the chemical substance no longer presents an unreasonable risk. The EPA's order that certain of methylene chloride's conditions of use do not present an unreasonable risk is likely to be challenged judicially.

Once the agency completes its risk evaluations on the other nine chemicals, it will need to take section 6(a) action on any unreasonable risks according to the above schedule – and to issue no unreasonable risk determination orders when relevant.

By 22 June 2021, the agency is required to evaluate exports for disposal of certain mercury compounds and report to Congress under section 12(c)(7)(b). By June 2021, the EPA must assess the adequacy of the policies, procedures and guidance it has issued, including its work with respect to health effect test methods under section 26(l)(2). It must also report to Congress on implementation of its plan for alternatives to vertebrate animal testing.

The next four years will be eventful, with or without a change in administration, but definitely more so with a change. Below we discuss the issues associated with a range of expected developments.

TSCA risk evaluations

The EPA's risk evaluation process remains the most fluid aspect of Lautenberg's implementation. A close second is the agency's process for identifying high-priority chemicals destined for TSCA section 6 risk evaluations. The EPA did a good job in promulgating the section 6(b) prioritisation and risk evaluation rules, and in releasing scoping documents for the first ten chemicals selected for evaluation by 22 June 2017.

While the agency has worked hard to develop and implement the risk evaluation process for the first ten chemicals, much remains to be done. Going forward, a range of issues will be refined, revised and reconsidered, including, in no particular order:

- the EPA's authority to exclude conditions of use in risk evaluations;
- developing a coherent policy regarding chemical exposures;
- TSCA section 4 orders; and
- section 21 petitions.

EPA authority to exclude conditions of use in risk evaluations

The EPA's final risk evaluation rule reflects the agency's view that it has legal authority under TSCA to exclude conditions of use from risk evaluations. Several non-governmental

organisations challenged the EPA's view in the Safer Chemicals, Healthy Families v EPA, 943 F.3d 397 (9th Cir 2019) case, as well as other aspects of the framework rules, and the cases were ultimately consolidated in the US Court of Appeals for the Ninth Circuit.

In the Safer Chemicals case, the court ruled the regulations implementing the risk evaluations rule do not provide a basis for the EPA to assert discretion "to exclude conditions of use from evaluation". While the petitioners did not prevail on their reading of the rule in the context of the lawsuit, the ruling would appear to align more with the petitioners' interpretation of what is required under section 6, namely to disallow the EPA from excluding conditions of use from the risk evaluation.

In the same decision, the court determined the agency could not exclude legacy uses of chemicals and associated disposals from a risk evaluation. How the EPA will revise its process to reflect the ruling is unclear. Some speculate that it will need to revisit all ten risk evaluations, but this is by no means clear.

Developing a coherent policy regarding chemical exposures

It is increasingly clear that the EPA and other stakeholders face significant challenges in providing and interpreting exposure information for chemicals undergoing risk evaluation. This deficit has been the subject of Sacc criticism of various risk evaluations, including, among others, pigment violet 29 (PV29) and 1,4-dioxane. The committee has been critical of the EPA for omitting exposure pathways and relying on overly optimistic exposure estimates.

A related concern is the EPA's omission of certain exposure pathways based on its legal interpretation that other federal statutes and their implementing regulations provide the authority for adequately mitigating those exposures. The Sacc and various NGOs are critical of this view.

A final exposure-related issue is whether the EPA is required to evaluate risks from uses collectively, as opposed to each use individually. Petitioners in the Safer Chemicals case raised this issue, but the court found the agency's risk evaluation rule itself ambiguous and declined to rule on the merits in the case. The court noted, however, that if petitioners were to assert harm deriving from the EPA's failure to review risks holistically at some future date, then petitioners could seek judicial review of any 'no unreasonable risk' determination.

How these issues are framed and resolved will have a significant impact on the risk evaluation process. Stakeholders should consider how best to assist the EPA in developing coherent and thoughtful approaches that best advance the law's goals.

TSCA section 4 orders

The EPA has been slow to exercise its new section 4 testing authority. While the agency issued a test order for PV29 earlier this year, one order is hardly enough. The EPA has much on its plate and its lacklustre showing here is understandable. This may change, especially if the administration changes. We hope it does, regardless of the election result, as, in our view, it is to all stakeholders' benefit if the EPA's hazard and risk judgments are appropriately and adequately informed by empirical data.

On a related note, according to the EPA's Unified Regulatory Agenda issued in June, the agency intends to propose a rule that would allow it to "obtain information about potential hazards and exposure pathways related to certain chemicals on the TSCA work plan." The agency had previously expressed its intention to invoke its section 8 authority to "fill data gaps" for its chemical reviews. The agenda item outlines a more specific plan going forward, as well as a much-needed change in direction. The EPA should exercise its broad authority under sections 4 and 8, as this would go a long way towards addressing information deficits and provide valuable information for prioritisations and risk evaluations.

Section 21 petitions

NGOs and industry have now submitted section 21 petitions and we expect this trend to continue. Litigation in this area is expected to produce important results.

Many other issues will be in play. TSCA's new preemption provisions are expected to ripen and their effect will be both influential and controversial, alternative testing strategies will emerge, and more litigation across the board is expected.

Conclusion

The next four years will almost certainly reflect significant regulatory developments in the EPA's implementation of Lautenberg. Much will depend on the November election results. Regardless, the agency's supporters and detractors will maintain pressure on it through notice and comment, section 21 petitions, congressional influence and litigation. We believe, come what may, the EPA will be up to the challenge.