



TSCA:

A change of course

Lynn L. Bergeson of **Bergeson Campbell** explains why the Biden administration's new chemicals policies portend major delays to new chemical commercialisation

Just as the industrial chemical community was getting into a predictable, somewhat comfortable groove regarding commercialising new chemicals under the Toxic Substances Control Act (TSCA), the US Environmental Protection Agency (EPA) decided to blow up the process. With it went any hope for business certainty in this highly volatile regulatory area.

While new administrations are entitled to shape policies to align with their agendas, the Biden administration's decision to rescind the new chemicals policies bodes badly for when chemical innovation at the very time new, sustainable chemical innovations are most needed.

Background

The new chemical review was not the subject of fierce criticism leading up to the 2016 amendments to TSCA. Most stakeholders agreed that the old TSCA was deficient in key respects.

These included the EPA's seemingly limited ability to regulate existing chemicals under Section 6; its blunted

authority to compel the production of chemical data under Section 4; and the fact that it bore the burden of demonstrating that a chemical posed unreasonable risks, as opposed to a manufacturer proving that it did not.

Under Section 5, the EPA assesses a new chemical based on the information presented in the pre-manufacture notification (PMN). Most experts were not anticipating wholesale revisions to Section 5 when TSCA was amended in 2016, as the new chemicals programme was relatively popular.

The 2016 amendments retain much of Section 5 but make important

changes. In particular, the EPA is now required to make one of three determinations and to take required actions. In determining whether a new chemical poses an unreasonable risk, the agency cannot consider costs or other non-risk factors and is explicitly required to consider risks to potentially exposed or susceptible populations and conditions of use.

The three alternative determinations under 'new TSCA' are as follows. First, the new chemical presents an unreasonable risk of injury to health or the environment. If so, the EPA must regulate it under Section 5(f) and issue a significant new use rule (SNUR) or explain why not.

Second, the EPA can determine that it lacks sufficient information to make a determination, or that the chemical will be produced in sufficient quantities to pose significant human exposure potential. In either case, it is required to issue an order under Section 5(e) and implement a SNUR, or explain why it did not.

Thirdly, the EPA can determine that a new chemical is 'not likely' to





Non-use of proper PPE when required is very rare

pose an unreasonable risk, in which case the submitter can commence manufacturing immediately, notwithstanding any remaining portion of the applicable review period. This is the determination innovators seek. Under the new polices, it is also the one least likely to be made.

New policies

The agency in March said that the EPA is "conducting an evaluation of its policies, guidance, templates, and regulations under the ... TSCA new chemicals programme" to ensure they "adhere to statutory requirements".

The agency identified several instances where its "approach for making determinations and managing risks associated with new chemicals can more closely" align with TSCA's requirements "to ensure protections for human health and the environment, including the use of SNURs and assumptions related to worker exposures".

The announcement added that the EPA will, effective immediately, stop

issuing determinations of 'not likely to present an unreasonable risk' based on the existence of proposed SNURs. Rather than excluding reasonably foreseen conditions of use, the EPA said, "Congress anticipated that EPA would review all conditions of use when making determinations on new chemicals and, where appropriate, issue orders to address potential risks".

Going forward, when the EPA concludes that one or more uses may present an unreasonable risk or believes that it lacks the information needed to make a safety finding, it will issue an order to address those potential risks.

The EPA stated that, as has been the "long-standing practice", it intends to continue issuing SNURs following TSCA Section 5(e) and 5(f) orders for new chemicals to ensure the requirements imposed on the submitter via an order apply to any person who manufactures or processes the chemical in the future. This ensures that other manufacturers of the substance are held to the same conditions.

The second policy reversal relates to what many regard as the reasonable assumption that the use of PPE in the work place is a "reasonably foreseen" condition of use.

Where the EPA identifies a potential unreasonable risk to workers that could be addressed with appropriate PPE and hazard communication, it will no longer assume that workers are protected adequately under the Occupational Safety and Health Administration's (OSHA) worker protection standards and updated safety data sheets (SDS). Instead, it will identify the absence of worker safeguards as "reasonably foreseen" conditions of use and will mandate necessary protections through a TSCA Section 5(e) order, as appropriate.

Discussion

These policy reversals are a big deal. The first policy change - that EPA will no longer employ the so-called 'non-order SNUR' construction to regulate new chemicals without an order - was not entirely surprising. Since it was implemented under the Trump



EPA offices in Washington, DC

administration, this construction has raised eyebrows, leading some to question whether this interpretation meets the requirements under TSCA Section 5.

Many in industry were of the view that, in issuing a SNUR to prohibit conditions of use that the EPA identifies as potentially leading to an unreasonable risk, the agency was deploying its discretion under TSCA to achieve the protective end (the TSCA regulation) without the inefficiency and delays associated with the development of a consent order.

In other words, the non-order SNUR was an effective and efficient expedient. The EPA would only use this option when it concluded that the intended conditions of use were not likely to present an unreasonable risk.

For reasons that will never be clear, a SNUR is viewed as being somehow less protective than an order, even though an order applies only to the PMN submitter and a SNUR applies to all entities in the supply chain. The EPA is required to promulgate a SNUR that conforms to an order, absent a reason otherwise.

The belief that undertaking a condition of use that is defined in a SNUR as a significant new use "requires only notification to EPA" grossly misrepresents the scientific and regulatory rigour of the significant new use notice (SNUN) process.

A SNUN is functionally identical to a PMN, with a comparable level of effort required on the submitter's and the EPA's part and nearly identical determination outcomes (a consent order, modification of the existing SNUR or revocation of the existing SNUR, if warranted).

Detractors might also assert that orders include testing, but that presumes that testing is required for the EPA to make an informed decision. If it can - as it routinely does - make a decision based on conservative assumptions with chemical analogues, models, and information provided by the submitter, the EPA can similarly make an informed decision about what measures are necessary to achieve its protective goal without new test data. Many fear that this policy change will require significant additional effort for both the EPA and the submitter, while bringing marginal, if any, protective benefit.

Use of PPE

The EPA's decision that it no longer views use of PPE as reasonably foreseeable is an unwelcome and unprincipled development. At the request of the EPA's Office of Pollution Prevention & Toxics (OPPT), chemical stakeholders presented a robust data set that demonstrated that the non-use of proper PPE is rare in an industrial or commercial setting.

Specifically, stakeholders identified a database of 40 years of OSHA violations that contained few glove, goggle or general dermal protection violations. This supports the view that standard PPE use is reasonably foreseeable, highly likely and, based on the data, demonstrably so.

The EPA's unexplained and unilateral policy reversal is difficult to align with the facts. If the agency is required to issue orders for every PMN that may present a risk if workers do not take routine protective measures, which in our view they can be reasonably foreseen to do, then it will be required to regulate nearly every PMN in which it identifies a hazard other than 'low' for health and ecotoxicity.

This was the agency's practice when the TSCA amendments were passed in 2016. In those days, delays in new chemicals reviews were extraordinary and, to many innovators, intolerable. In short, it would mean that the EPA will be implementing TSCA as a hazard-based law, instead of the clearly risk-based law that it is.

Chemical stakeholders may wish to urge the EPA to revisit its decision. Chemical innovation is needed now and this policy reversal will slow the commercialisation of more sustainable chemicals for years to come. ●



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