

Global Outlook 2021: Risk assessment and management under TSCA – what should we expect?

REPORT

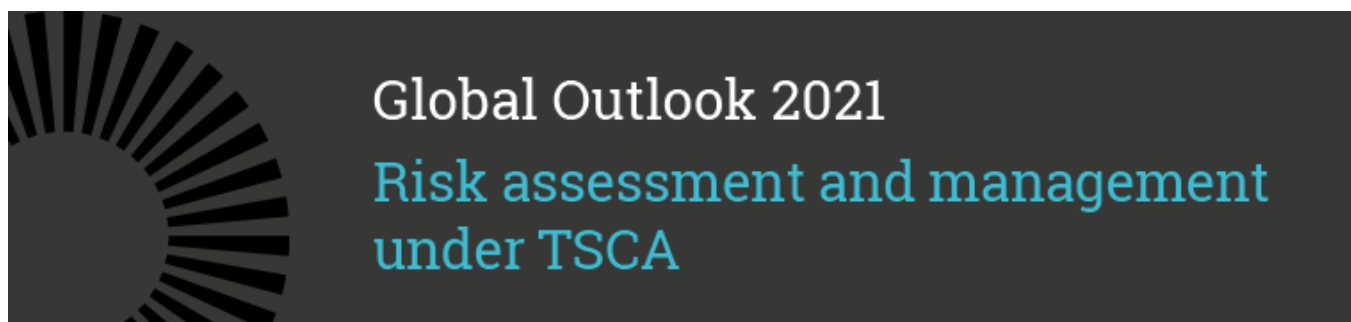
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North America

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TSCA



North America managing editor, Terry Hyland, outlines what to expect from TSCA this year as the Biden administration lays out its priorities

Key points

- Review of TSCA risk evaluation process promised
- Risk management proposals expected this year for majority of first substances subject to evaluation
- Environmental justice could be incorporated within TSCA processes
- US EPA to increase calls for data and testing from companies
- Expanded requirement for asbestos reporting could lie ahead

The US EPA will have a new focus this year as it starts to lay out TSCA risk management proposals for several substances, continues evaluations for more than 20 others, and works to incorporate environmental justice and other priorities of the new Biden administration.

The incoming administration has already called for a [review](#) of all EPA actions over the last four years, a move that could lead to significant changes or even reversals of policies adopted since January 2017.

On his first day in office, President Biden specified a number of TSCA actions for review in particular, including the [2017 rule](#) laying out the TSCA risk evaluation process; five recently completed [rules](#) restricting persistent, bioaccumulative and toxic substances (PBTs); the TSCA evaluation of [methylene chloride](#) and a [2019 ban](#) on its use in consumer paint removers.

There is "certainly a rationale" for taking a closer look at the [first ten](#) risk evaluations, said Steve Owens, a partner with law firm Squire Patton Boggs and former EPA assistant administrator for the Office of Chemical Safety and Pollution Prevention (OCSP) under President Obama. But, he said, it would be a challenge in terms of people and resources.

Beyond this regulatory review, the EPA's new focus – as it reviews both existing and new chemicals – is expected to be [broader](#) than in previous years, potentially looking more at aggregate exposures to substances, susceptible subpopulations and chemical uses that the EPA has previously left under the purview of other federal laws.

Manufacturers or importers that have seen one of their substances undergo a risk evaluation or listed as high-priority for a future review could be especially affected. And companies bringing new substances to market can also expect continued scrutiny on both intended, as well as reasonably foreseeable, uses.

New challenges also lie ahead for the EPA, still working to update its TSCA fees rule and dealing with legal cases that could bring an expansion of asbestos reporting.

Day-to-day actions on TSCA policy, however, may not see significant change for some weeks, as the EPA awaits US Senate confirmation of presumptive new EPA administrator [Michael Regan](#) and deputy administrator [Janet McCabe](#).

Risk management

Most pressing for many companies is what to expect as the EPA prepares to roll out proposed regulations to mitigate unreasonable risks, identified in completed risk evaluations.

Under TSCA, the agency has one year from the date these are finalised to propose a rule to manage any risks found by the review, with final rules due one year after that.

The EPA concluded that at least some conditions of use (CoU) for all ten substances present an unreasonable risk to the environment or human health. That means the agency is slated to release proposed risk management rules for all of them by January next year.

The first proposed risk management rule is due by **24 June** this year, for methylene chloride. However, Mr Biden's call to review the substance's TSCA risk evaluation could push back the risk management process for the solvent as well as for other substances.

Alexandra Dunn, who recently left her post as head of the EPA's chemicals office, **suggested** that the range of actions included in recent rules banning most uses of five PBT substances could offer some hints as to what the risk management process might look like in future. Those rules included a range of restrictions, from an outright ban on certain uses to a more gradual phase-out to allow companies to find suitable alternatives for some applications.

President Biden's directive to review recent regulatory action offers a cautionary note, however. In his order, the new president specifically called for a review of all six of the TSCA section 6(a) rules that have been finalised since the law was amended in 2016 – the 2019 rule banning methylene chloride in consumer paint strippers and the five PBT rules. That might suggest the new administration plans a very different approach towards managing chemical risks.

Mr Owens noted that the EPA also has the option to take immediate action to restrict a substance without a full risk evaluation if it believes there is a pressing need and scientific justification for doing so.

Several NGOs have called for just such action for many of the first ten substances reviewed, including **methylene chloride** and **trichloroethylene** (TCE). The review of the EPA's previous actions on methylene chloride could signal that the new administration intends to pursue faster and more restrictive action for the solvent.

The change of direction at the EPA could also alter the path for agency actions that are currently being reviewed by courts. Attorneys for the agency could ask the court for a stay in litigation or seek to close out the cases altogether.

This could throw into question the status of **litigation** over the EPA's treatment of citizen's petitions to review individual chemicals, risk evaluations of the flame retardant **HBCD** and **methylene chloride** and another **lawsuit** over the latter's use in paint removers.

Next 20 reviews

The EPA is also in the [early stages](#) of risk evaluations for the next [batch of 20](#) high-priority substances, which include seven chlorinated solvents, five phthalates, three halogenated flame retardants and formaldehyde. The agency generally has three years to complete chemical reviews, with an optional six-month extension.

With the new president ordering a review of the 2017 TSCA risk evaluation rule, this process could look very different going forward.

For example, the agency is expected to take an expanded view of uses and exposures which the previous administration did not.

In the future, Mr Owens said, TSCA reviews may include the cumulative effects and aggregate exposures of substances, conditions of use (CoUs) that fall under federal statutes like the Clean Air Act or the Safe Drinking Water Act, and a closer look at the impacts on susceptible subpopulations that may have been disproportionately affected by chemical pollution.

Whether, and how vigorously, the agency revises any of the first ten evaluations that are already finalised, including that of methylene chloride specified for review by President Biden, could be affected by the fact that reviews for the next 20 chemicals are already underway – and the amount of resources required for the task. In addition to the next batch of chemicals, the agency is also working through manufacturer-requested reviews for the phthalates [DINP and DIDP](#) and several substances used in [fragrance ingredients](#).

More orders for data

In addition to more scrutiny of chemical reviews, the EPA has already signaled it will increase use of its authority under section 4 and section 8 of TSCA to order companies to conduct more testing of chemicals or call for data that they might already have.

The chemicals office underwent a [restructuring](#) in the autumn, including the Office of Pollution Prevention and Toxics (OPPT) that implements TSCA.

Ms Dunn said this included the creation of a new data gathering and analysis division, focused on collecting information through sections 4 and 8. This will allow the EPA to see where there might be information gaps "and use our authority to request data", she said.

The EPA used that authority on 15 January, when it [ordered](#) some 90 companies to provide test data on the environmental and occupational effects of nine high-priority substances currently

undergoing risk evaluations.

In its first ten TSCA risk evaluations, the agency did this only **once**.

It is already under pressure to gather more information on asbestos after a federal court **ordered** it to close "loopholes" in asbestos reporting. The EPA's current information on asbestos in products is "only the tip of the iceberg", the court said.

An expanded requirement could ultimately mandate that companies report on any asbestos-containing articles, including cement products, woven or knitted fabrics, floor tiles, window caulking and gaskets for motorcycles.

This also could require reporting where asbestos is present as an impurity, potentially impacting companies that make talc-based cosmetics and other products. Asbestos can develop naturally alongside talc in rock deposits, and has been found as a **contaminant** in a number of such products in recent years.

Environmental justice

One wildcard in future TSCA chemical reviews is the role environmental justice might play, Lynn Bergeson, managing partner at Bergeson and Campbell, said.

Environmental justice is the idea that all people have the right to equal environmental protection under the law, and to live and work in communities that are healthy and safe. Mr Biden has pledged to make that a central part of the EPA's mission.

It's a very important goal, Ms Bergeson said, but it has often been difficult to operationalise it.

The Biden administration already has issued a pair of orders, calling for the EPA and other agencies to advance racial equity and under-served communities and to avoid burdening those that are vulnerable or marginalised.

Once Mr Regan is confirmed as EPA administrator, Ms Bergeson said she would expect a consistent focus "on all things" related to environmental justice, including risk evaluations, data management and the crafting of regulations.

Mr Owens said the EPA could also broaden the scope of susceptible populations under TSCA, including lower income groups, native american, and fenceline communities located near

facilities that make or use toxic substances.

"If you want a fuller picture of the health effects of an exposure, you need to look at cumulative impacts and aggregate exposures, especially for vulnerable populations," Mr Owens said.

New chemicals

The EPA continues to work to improve the process for reviewing and approving new chemicals.

The agency began imposing more restrictions on pre-manufacture notices (PMNs) submitted in the months after TSCA was reformed in 2016, according to Erik Baptist, a partner with Wiley Rein.

Many PMNs saw consent orders imposing various requirements or significant new use rules (Snurs), requiring notification for certain new uses, said Mr Baptist, who previously served as deputy assistant administrator for law and policy in the OCSPP and as former senior deputy general counsel in the EPA's Office of General Counsel.

Part of the reason for the increase in orders and Snurs was that new chemical submissions too often were only focused on intended uses of substances, Mr Baptist said. That led to orders from the EPA to also address reasonably foreseen uses.

The number of orders and Snurs has decreased somewhat more recently. But Mr Baptist said he expects some level of a "reversion back to the EPA's initial approach" under the Biden administration.

At the same time, he said, companies can try to engage with the EPA early on in the process to understand what may be reasonably foreseen for new substances, and then address any concerns in a PMN submission. That could help companies see faster action from the agency and a better result, without the need for a consent order, Mr Baptist said.

Ms Bergeson said her law firm has always prepared as much information as possible in advance of a new chemical submission. "The EPA's approach has always been crystal clear," she said, "if you don't have a thorough submission, then you will pay the consequences." That could mean a slower evaluation process, a potential order with added conditions or even a rejection of a PMN submission.

TSCA fees

The EPA is also due to finalise changes [proposed last year](#) for its TSCA fees programme. The fees help the agency offset the costs of conducting risk evaluation, with different levels for new chemical submissions, existing substance reviews, test orders and more.

The agency proposed maintaining the fees for new chemical submissions and most other categories. It also added several exemptions to limit the number of companies that might have to pay the higher fees for each EPA-initiated high-priority substance review. However, TSCA fees for those could double under the proposed rule – from \$1.35m to \$2.56m for each chemical evaluation.

Comments on the proposal are due by [25 February](#).

Key dates

- June – August 2021: Draft scope for part 2 of asbestos risk evaluation – legacy uses
- June 2021: EPA report to Congress on progress implementing plan for alternatives to vertebrate animal testing
- June 2021: Proposed TSCA risk management rule for methylene chloride
- August 2021: Proposed TSCA risk management rule for 1-bromopropane
- September 2021: Deadline for complete payment of TSCA fees for risk evaluations
- September 2021: Proposed TSCA risk management rule for HBCD
- October 2021: Final TSCA fees rule
- November 2021: Proposed TSCA risk management rule for carbon tetrachloride
- November 2021: Proposed TSCA risk management rule for trichloroethylene (TCE)
- December 2021: Proposed TSCA risk management rule for perchloroethylene (Perc)
- December 2021: Proposed TSCA risk management rule for N-methylpyrrolidone (NMP)
- January 2022: Proposed TSCA risk management rule for asbestos, part 1
- January 2022: Proposed TSCA risk management rule for 1,4-dioxane
- January 2022: Proposed TSCA risk management rule for pigment violet 29 (PV29)