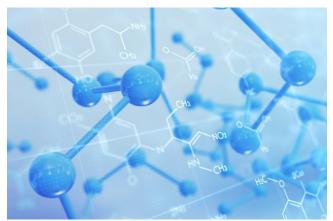


EPA's Path Forward on TSCA Becomes Clearer



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After a period of uncertainty, how the U.S. Environmental Protection Agency (EPA) plans to revise its implementation of the Toxic Substances Control Act (TSCA) during the second Trump administration is coming into focus:

- Risk management rules EPA intends to revise at least some of the risk management rules that the Biden EPA promulgated, including the exposure limits in some cases.
- Risk evaluations EPA plans to reconsider at least one risk evaluation, and reconsideration of others is likely.
- New chemicals EPA is allocating resources to review of premanufacture notices (PMNs) under the amended rules.
- Reporting requirements EPA is likely to reduce some reporting burdens.

In the coming weeks and months, these announcements will lead to multiple opportunities to comment on EPA's proposed changes and offer suggestions for additional changes. Potentially affected stakeholders should plan to submit comments.

Background

Within EPA, the Office of Chemical Safety and Pollution Prevention (OCSPP) administers TSCA and the pesticide program. Under the Biden administration, OCSPP continued to work up until the January 20 Inauguration to promulgate or propose TSCA rules (see our alerts here, here, here, and here) under the direction of Assistant Administrator for OCSPP, Michal Freedhoff.

In the first few months of the second Trump administration, the administration neither confirmed, nor named a nominee for that job. Nor has the administration appointed an interim Assistant Administrator. Instead, the administration appointed a Principal Deputy Assistant Administrator, Nancy Beck, and a Deputy Assistant Administrator, Lynn Dekleva.



Due to this situation, we believe that EPA has held off on making some of the substantial changes to the TSCA program that some had anticipated. Now, however, the changes that EPA plans to make are becoming clearer.

Section 6 – Existing Chemicals

Risk Management Rules

Shortly after President Trump's inauguration, EPA asked all courts reviewing risk management rules finalized during the Biden EPA for more time to brief EPA management on the positions EPA should take. Recently, EPA has begun informing those courts of its intentions. EPA has already announced its intention to consider revisions to three Biden EPA risk management rules. Other final risk management rules may also undergo further rulemaking.

Methylene chloride, 40 C.F.R. Part 751, Subpart B EPA informed the Fifth Circuit that it intends to initiate a new rulemaking to reconsider the "single risk determination issue" (also known as the "whole chemical" issue) and "the no-assumption of personal protective equipment issue" (the PPE issue). On the other hand, at oral argument, EPA defended other aspects of the rule, including the assertion that the best available science supports the unreasonable risk determination.

Trichloroethylene, 40 C.F.R. Part 751, Subpart D – EPA informed the Third Circuit that it intends to reconsider the trichloroethylene rule through rulemaking, including the rule's Existing Chemical Exposure Limit (ECEL) of 0.2 ppm for uses with TSCA section 6(g) exemptions. EPA may also reconsider other aspects of the trichloroethylene rule in a rulemaking expected to take 18-24 months. To facilitate that rulemaking, EPA has already published a notice announcing a postponement of the effective date (until June 20, 2025) of the conditions for each of the TSCA section 6(g) exemptions.

Perchloroethylene, 40 C.F.R. Part 751, Subpart G – EPA informed the Fifth Circuit that it also intends to reconsider the perchloroethylene rule through rulemaking, including the rule's ECEL of 0.14 ppm, and whether the rule went beyond the extent necessary to eliminate unreasonable risk. We anticipate the rulemaking to take 12 to18 months.

Other risk management rules – EPA has not yet announced plans to amend the other challenged risk management rules whose court challenges remain under abeyance – those for chrysotile asbestos, carbon tetrachloride, and decabromodiphenyl ether (which may be a special case, as the decabromodiphenyl ether rule was adopted under TSCA section 6(h) rather than section 6(c)). Nevertheless, a rulemaking for at least the carbon tetrachloride rule is foreseeable.

In June 2024, the Biden EPA issued a proposed rule for N-methylpyrrolidone under Section 6(a) of TSCA. In August 2024, it released a proposed risk management rule for 1bromopropane, setting a deadline for the final rule in August 2025. In January 2025, just a week before the Inauguration, the Biden EPA also proposed a risk management rule for



C.I. Pigment Violet 29. The Trump EPA is expected to revise each proposed rule before finalizing them.

The Biden EPA published a proposed risk management rule for 1-bromopropane in August 2024, meaning that the final rule is due in August 2025. The Biden EPA also published a proposed risk management rule on C.I. pigment violet 29 in January 2025, a week before the inauguration. The Trump EPA will likely make changes in both rules before adopting them as final.

Risk Evaluations

Risk evaluation framework rule, 40 C.F.R. Part 702, Subpart B

EPA has informed the Fifth Circuit in litigation challenging the risk evaluation framework rule that it intends to reconsider all aspects of the rule. EPA has filed declarations by Nancy Beck stating that EPA plans to propose a revised rule by June 2025; provide 60 days for public comment on the proposal; and finalize a revised rule by April 2026. Among the changes that the proposed rule may address are:

- The requirement to make a single determination of unreasonable risk (the "whole chemical" issue).
- The requirement to assume that workers are not using personal protective equipment in conducting the risk evaluation (the PPE issue).
- The addition of "overburdened communities" to the definition of "potentially exposed or susceptible subpopulations".
- The requirement that a risk evaluation must address all conditions of use.
- The requirements and process by which chemical manufacturers may request that EPA conduct a risk evaluation on a chemical substance.
- The circumstances under which EPA will undertake substantive revisions to TSCA risk evaluations. EPA intends to reconsider these requirements and seek public comment on the appropriateness of reconsidering TSCA risk evaluations under certain circumstances.
- EPA's commitment to make publicly available any risk-based occupational exposure values calculated as part of the risk evaluation.

1,4-Dioxane risk evaluation

In other Fifth Circuit litigation, EPA informed the court that it intends to reconsider the final 1,4dioxane risk evaluation. This reconsideration will determine whether the Biden EPA completed the cancer risk analysis in the hazard assessment using the best available science, including whether it reviewed all relevant and available cancer mode of action information in a manner consistent with EPA's *Guidelines for Carcinogen Risk Assessment*. Other changes, such as the "whole chemical" issue and the PPE issue, may also be considered. We expect the review process to take between 12 and 24 months.



This first announcement of reconsideration of a finished risk evaluation may signal reconsideration of other completed risk evaluations (such as that for formaldehyde) and draft risk evaluations (such as that for 1,3-butadiene).

Section 5 – New Chemicals

EPA is taking steps to speed up the processing time for PMNs. Administrator Zeldin announced that "OCSPP will gain more than 130 scientific, technical, bioinformatic, and information technology experts to work directly on the backlogs of over 504 new chemicals in review that are beyond the statutorily required timeframes and over 12,000 pesticide reviews that are well beyond their expected timelines." Those employees will need training, but eventually, we expect the added personnel to expedite EPA's reviews.

It is noteworthy that the Trump EPA did not stay the amendments to the new chemical regulations adopted by the Biden EPA a month before the inauguration. EPA expects that those amendments will improve the efficiency of its review processes. Those amendments, including the additional data elements for PMNs, are in effect, as are the provisions restarting the 90-day clock if a submitter provides important new information during the review period. EPA has been working to revise the Central Data Exchange (CDX) software to incorporate the new data elements in the electronic PMN form.

In the meantime, EPA released guidance on how to meet the amended new chemical regulations.

Reporting Rules

PFAS reporting rule, 40 C.F.R. Part 705

As discussed in our previous alert, the Trump EPA announced a 9-month delay in the submission period, which was originally set to open on November 12, 2024 and close (for most companies) on May 8, 2025. In 2024, the Biden EPA first delayed this submission period by 8 months, and with the Trump EPA's second delay, the submission period is now to open on April 13, 2026 and close (for most companies) on October 13, 2026. The Trump EPA's announcement also indicated that EPA intends to publish "a separate notice of proposed rulemaking in the near future." The proposed rule will address the submission period timing and, presumably, other issues, including possibly the adoption of exemptions for importers of articles containing PFAS.

Section 8(d) reporting rule for 16 chemicals, 40 C.F.R. Part 716

Shortly before the inauguration, the Biden EPA published a final rule under TSCA section 8(d) requiring manufacturers to submit health and safety studies on 16 chemicals that were mostly either about to be designated as high-priority substances (triggering the risk evaluation process) or as candidates for that designation (triggering the formal designation process). Reports were originally due March 13, 2025. The Trump EPA extended that deadline to June 11, 2025, for vinyl chloride, and to September 9, 2025, for the other 15 chemicals. In litigation challenging



the rule, EPA asked for and received an indefinite abeyance of the court proceedings to allow the parties to engage in settlement negotiations to resolve some or all of the matters at issue. On June 5, 2025, EPA published a pre-publication version of the final rule to extend the reporting deadline to May 22, 2026, for all 16 chemicals covered under this rule.

Comments

Starting this month, companies and trade associations can expect a flurry of rulemaking proposals and other opportunities to comment on changes that the Trump EPA is considering making to Biden EPA actions under TSCA. If implemented, those changes could significantly affect company obligations. Beveridge & Diamond is available to assist in preparing comments on these actions and helping companies navigate the evolving TSCA regulatory landscape.

Beveridge & Diamond's Chemicals Regulation practice group and Chemicals industry group provide strategic, business-focused advice to the global chemicals industry. We work with large and small chemical and products companies whose products and activities are subject to EPA's broad chemical regulatory authority under TSCA and state chemical restrictions.



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