



Judicial Challenge to the 2024 TSCA Risk Evaluation Procedural Rule: Issues and Implications

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- ◆ Allison Payne is an environmental law associate at Keller and Heckman focusing on regulatory and compliance matters under FIFRA, TSCA, and EPCRA. Prior to joining Keller and Heckman, Allison served as an attorney-advisor within the Pesticides and Toxic Substances Law Office for the U.S. Environmental Protection Agency's Office of General Counsel, where she advised EPA program offices on a wide variety of matters under chemical and pesticide laws.



Agenda



1. Brief background & history of the Framework Rule
2. Issues and arguments raised by the parties
3. Recap of the oral argument
4. Implications for policy

Background: Risk Evaluation Framework Rule



- ◆ **Important because it determines how risk evaluation will be performed**
 - ◇ All uses and exposure circumstances or can EPA exclude some?
 - Limit to significant uses?
 - Exclude / defer risk from impurities?
 - Conditions regulated under other statutes?
 - Conditions regulated by other Agencies?
 - ◇ Use-by-use determinations or single determination?
 - ◇ Take PPE into account when determining risk?

Background: Risk Evaluation Framework Rule (2)



- ◆ **2016** – Lautenberg Amendments direct EPA to promulgate risk evaluation framework rule
- ◆ **2017** – Proposed rule (Obama Administration)
- ◆ **2017** – Final rule (Trump Administration)
 - ◇ Changed aspects of the Obama Administration proposed rule
- ◆ **2019** – *Safer Chemicals, Healthy Families v. EPA* (9th Cir)
 - ◇ ‘Whole chemical approach’ required – *not ripe (EPA intent uncertain)*
 - ◇ ‘Must consider all conditions of use’ – *not contravened by rule language*
 - ◇ Statute does not exclude foreseeable future chemical use and disposals from risk evaluation
 - ◇ EPA required to rework the Asbestos risk evaluation for legacy uses
- ◆ **2021** – Trump EPA completes last of first 10 risk evaluations

Background: Risk Evaluation Framework Rule (3)



- ◆ **2021-25** – Biden EPA reworks first 10 risk evaluations to address these principles
 - ◇ “Whole chemical approach”
 - ◇ PPE baseline scenario and
 - ◇ Fenceline risks
- ◆ **2024**: Framework Rule amended – previous policy choices incorporated into rule
 - ◇ Immediately challenged in court (petition for review)
 - ◇ *Meanwhile - 5 final risk management rules completed – and challenged*
- ◆ **2025**: Trump Administration: will reconsider the Framework Rule in its entirety
 - ◇ “Whole chemical approach,”
 - ◇ PPE baseline scenario
- ◆ **Now**: Judicial challenge to Amended Framework Rule in front of the DC Circuit
 - ◇ Argued March 21st

Final Risk Management Rules



EPA has issued five final risk management rules and all have been challenged

Substance	Final Rule Date	U.S. Court of Appeals Hosting Judicial Challenge
Trichlorethylene	12/17/24	3 rd Circuit
Carbon Tetrachloride	12/18/24	8 th Circuit
Perchloroethylene	12/18/24	5 th Circuit
Methylene Chloride	05/08/24	5 th Circuit* (Oral argument early June 2025)
Chrysotile Asbestos	03/28/24	5 th Circuit* (~ fully briefed)

Current Judicial Challenge – Industry Arguments



- ◆ Industry stakeholder groups (***Industry Petitioners***) challenged the following aspects of the 2024 Framework Rule:
 - ◆ Inclusion of “all conditions of use” in risk evaluations
 - Argued EPA should have the discretion to exclude conditions of use from scope
 - E.g., impurities and byproducts
 - ◆ Single Risk Determination (“Whole Chemical Approach”)
 - Argued TSCA requires EPA to issue separate risk determinations for each COU, rather than one for the entire chemical
 - Would allow lower risk uses to be unregulated
 - ◆ No Assumptions of PPE Use
 - Argued TSCA requires EPA is required to consider PPE use, including OSHA standards & industry practices when determining exposure (and risk)

Current Judicial Challenge – Industry Arguments (2)

- ◆ Company intervening on behalf of Industry (***Industry Intervenor***) challenged the following aspects of the 2024 Framework Rule:
 - ◇ Rule adding “overburdened communities” as an example of potentially exposed or susceptible subpopulations
 - Argued “overburdened communities” do not meet the TSCA criteria for potentially exposed or susceptible subpopulation

Current Judicial Challenge – Labor Arguments



- ◆ Unions and workers' right groups (***Labor Petitioners***) challenged the following aspect of the 2024 rule:
 - ◇ Consideration of PPE use in risk evaluation is discretionary (where warranted)
 - Argued TSCA prohibits EPA from considering PPE use, full stop
 - Not properly part of the “condition of use” – a “non-risk factor”

Current Judicial Challenge – EPA Arguments



- ◆ In briefing, EPA defended the provisions of the 2024 Framework Rule (supported by NGO intervenors), arguing:
 - ◇ TSCA requires EPA to include all conditions of use in risk evaluations
 - ◇ TSCA requires EPA to issue one risk determination for the entire chemical
 - ◇ TSCA allows EPA to expand on the list of example “potentially exposed or susceptible populations”

Current Judicial Challenge – EPA Arguments (2)



- ◆ In briefing, EPA defended the provisions of the 2024 rule under challenge, arguing:
 - ◇ TSCA requires EPA to consider PPE use, but prohibits EPA from *assuming* PPE use when determining risk
 - ◇ Labor and Industries' PPE challenges *are not ripe for decision*
 - Court does not know how EPA will implement the rule
 - Must wait until EPA applies PPE provision (improperly) in a particular case and then file a petition for review

EPA's Motion for Remand

- ◆ There was a change in Administration between the final briefing and the Oral argument
 - ◇ EPA moved to defer the scheduled oral argument to allow the new Administration determine its position on the issues in the litigation
- ◆ EPA filed a motion for remand without vacatur on 3/10/25
 - ◇ 'EPA intends to reconsider the 2024 rule in all respects'
 - ◇ Remand would allow EPA to amend the rule again (via rulemaking)
 - ◇ Likely to undo the Biden Administration changes
 - ◇ Industry supported. Labor opposed.
 - ◇ Court decided to hear arguments on remand and the merits together
- ◆ Tough position for Agency – arguments in its briefs may no longer represent its positions

Oral Argument Recap:



- ◆ Discussion of EPA's motion for remand
- ◆ Questions on Labor Petitioners' standing
- ◆ Discussion of substantive issues

Potential Implications: TSCA Program (1)



- ◆ If the court denies EPA's motion for remand and decides case...
 - ◇ Opinion would likely decide “*whole chemical approach*” and “*all conditions of use*” issues
 - ◇ Statutory interpretations by court – *Loper Bright* “best interpretation”
 - ◇ EPA is bound to follow; cannot change by rulemaking ∴ **potential rework**
- ◆ But court decision not likely before fall 2025; meanwhile ...
 - ◇ Oral argument in Methylene Chloride and Asbestos cases (new briefing?)
 - Setting up potentially different interpretations on same issues in the Fifth Circuit
 - ◇ Briefing in three other risk management rule challenges (TCE, CTC, PCE)
 - ◇ EPA completing final 5 final risk evaluations and 10 draft evaluations
 - ◇ EPA proposing and finalizing a revised Framework Rule
- ◆ In the interim EPA may need to conduct these analyses in the alternative or risk missed future deadlines with rework + lawsuits

Potential Implications: TSCA Program (2)



- ◆ If the court remands the case to EPA's (or holds in abeyance) ...
 - ◇ Current rule would remain in effect until changed
 - ◇ Planned amended rule issued Spring 2026 – likely reversing Biden era change
 - ◇ Revised rule may be supported by favorable decisions in the Fifth Circuit (?)
 - ◇ *Revisions will trigger another round of lawsuits and briefing on many of the same issues in 2026*
- ◆ Same uncertain effect on ongoing TSCA risk evaluation actions
 - ◇ Would extend the uncertainty into 2027
 - ◇ Uncertain how Agency will hedge against uncertain outcomes
 - ◇ Rework and delay seems inevitable

Upcoming Events



Please join us at 1:00 PM Eastern U.S.
Wednesday, April 16, 2025
<https://www.khlaw.com/OSHA3030>



Please join us at 10:00 AM Eastern U.S.
Wednesday, 11 June 2025
<https://www.khlaw.com/REACH-3030>



Please join us at 1:00 PM Eastern U.S.
Wednesday, June 11, 2025
<https://www.khlaw.com/TSCA-3030>

Thank You

Any questions?



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