



TSCA Litigation Update

December 6, 2023

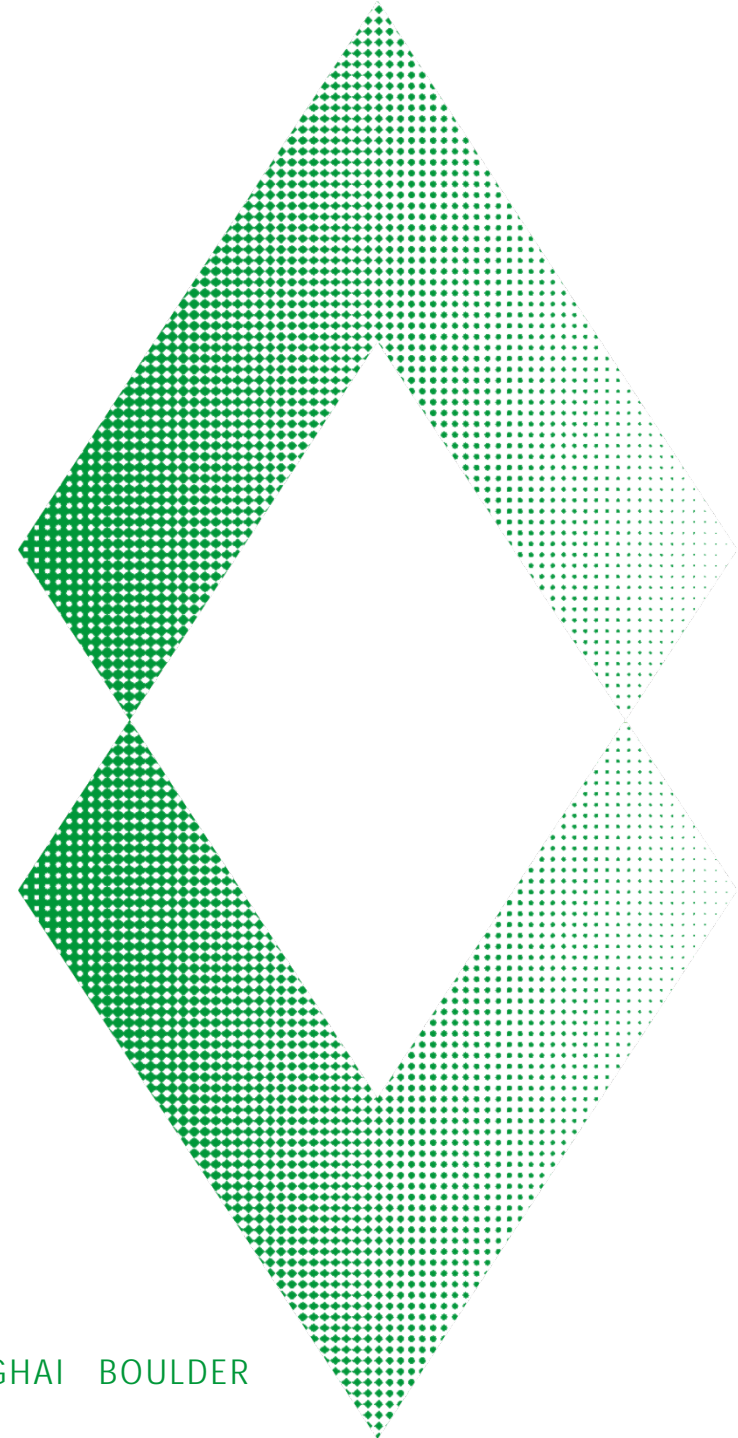
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Judicial Review 101

- ◆ How do courts review challenges to agency action?
- ◆ Basic Rules
 - ◆ Review of agency order is limited to administrative record
 - Parties cannot introduce new or additional data or comments
 - ◆ Court does not substitute own judgment for agency's
 - As long as agency decision was rational or reasonable, court will likely defer
 - ◆ Court limits review to agency's decision-making process
 - I.e., did agency engage in reasoned decision-making?
 - Consider all relevant evidence and factors
 - Explain decision and underlying rationale
 - Explain why it discounted contrary evidence
 - Explain why it used certain models and not others
 - Did agency deviate from past practice and, if so, justify departure
 - ◆ Spectrum – “Hard Look” Doctrine vs. “Super Deference”

Judicial Review Under TSCA

- ◆ Section 19 (15 USC 2618) Judicial Review Provision
 - ◆ “shall hold unlawful and set aside such order if the court finds ... [the] order is not supported by **substantial evidence** in the record taken as a whole”
 - ◆ Requires something akin to “hard look” review
 - ◆ Court must “carefully scrutinize” agency findings; conduct a “rigorous” review
- ◆ Court must ensure EPA...
 - ◆ Set forth facts and evidence underlying decision
 - ◆ Explained rationale for decision
 - ◆ Identified policy choices and explained how they fill data uncertainty gaps
 - ◆ Identified all assumptions made
 - ◆ Explained why rejected contrary evidence
- ◆ I.e., TSCA guards against a “super deference” approach

Cherokee Concerned Citizens v. EPA

Challenge to 5(e) Order

Background

- ◆ Suit filed in DC Circuit by Mississippi citizens group in April 2023
 - ◇ Challenges 5(e) order issued in August 2022
- ◆ Allows manufacturing, processing, distribution, use, and disposal of new chemical substances derived from pyrolysis (plastics recycling)
 - ◇ But limited to fuel uses (additives, blending, feedstock)
- ◆ EPA issued 5(e) order due to lack of data on risks
 - ◇ EPA found chemicals “may” present unreasonable risk
- ◆ Litigation in beginning stages (no merits briefing yet)
 - ◇ Case filings and public statements hint at disputed issues
 - ◇ Implicates many issues being debated under TSCA

Reliance On Other Statutes And Regulations



- ◆ Can EPA address unreasonable risks through other regulatory schemes?
 - ◇ Citizens group might argue EPA identified risks but did not impose regulations
 - ◇ Will complain 5(e) order only imposes dermal protections for workers
- ◆ 5(e) order relies on other EPA and OSHA regulations limiting exposures
 - ◇ Provides long list of potentially applicable regulations for fuels i.e., worker safety, emissions, handling, storage, transport, and use
- ◆ E.g., worker inhalation
 - ◇ 5(e) relies on OSHA PELs (outdated? new data?)
- ◆ E.g., stack emissions
 - ◇ 5(e) relies on air emission regulations
 - ◇ EPA found 1 in 4 lifetime cancer risk for one chemical (uncertainty? conservative?)
 - ◇ Deviates from 1 in 1 million standard typically used

How Much Industry Testing To Require

- ◆ Should EPA impose testing requirements under Sections 4 and 5(e)
 - ◇ Testing is expensive and time-consuming
- ◆ Section 5(e) order does not require any further testing on chemicals
 - ◇ Petitioner claims high degree of uncertainty regarding risks (e.g., non-cancer risks like dermal, eye, and respiratory)
 - ◇ Petitioner also claims uncertainty as to toxic constituents resulting from the pyrolysis process

Susceptible Subpopulation Considerations



- ◆ To what extent does EPA need to consider risks to potentially exposed and susceptible subpopulations
 - ◇ Section 5(e) requires EPA to consider susceptible subpopulations
- ◆ Petitioner will argue EPA did not consider fenceline communities
 - ◇ Only considered infants and workers

Additional Issues

- ◆ Petitioner may challenge some EPA “assumptions” in risk assessment
 - ◇ E.g., assuming concentrations of certain constituents remain constant as a result of the pyrolysis manufacturing process
- ◆ Petitioner may question certain “model inputs” when estimating releases from industrial and commercial activities
 - ◇ E.g., vapor pressure inputs did not reflect real world conditions

What Will Judicial Review Look Like?

- ◆ Did EPA justify filling-in data gaps with policy choices
 - ◇ I.e., relying on existing regulatory schemes instead of additional testing
- ◆ Did EPA adequately explain how existing regulatory schemes address identified unreasonable risks and susceptible populations
 - ◇ E.g., why are OSHA PELs sufficient
- ◆ Did EPA adequately explain deviation in cancer risk standard
 - ◇ I.e., why a 1 and 4 lifetime cancer risk is irrelevant
- ◆ Did EPA explain how it discounted contrary data and evidence
 - ◇ E.g., EPA had calculated lower inhalation risk values for workers
- ◆ Did EPA discuss why it used certain assumptions or model inputs

Industry Risks Going Forward

- ◆ What signals will DC Circuit Court send to EPA, NGOs, and industry?
- ◆ Increased backlog of risk assessments for new chemicals
 - ◇ More risks to consider (e.g., cumulative risks for fenceline communities)
 - ◇ More difficult to rely on other statutes and regulations to manage risks
- ◆ More expensive new chemicals process
 - ◇ E.g., increased testing burdens
- ◆ Increased litigation burdens
 - ◇ High profile chemicals (e.g., PFAS) in NGO crosshairs
 - ◇ Risk of judicial stay (i.e., stop manufacturing and lose investments)
 - ◇ Need to intervene and litigate to protect interests

Community In-Power and Dev. Ass'n v. EPA Missed Section 6 Risk Evaluation Deadlines

Background

- ◆ TSCA Section 6 (15 USC 2605(b)(4)(G))
 - ◇ 3.5 years to complete risk evaluation after initiation
- ◆ Risk assessments for 20 chemicals initiated Dec. 2019
 - ◇ June 2023 deadline
- ◆ Manufacturer requested assessments for 2 chemicals initiated Jan. 2020
 - ◇ July 2023 deadline
- ◆ NGOs sued in DC federal district court because EPA missed deadlines
 - ◇ Asking court to set new deadlines
- ◆ ACC is expected to re-file a motion to intervene
 - ◇ Worried about how court will order the deadlines for each assessment

Balancing Approach

- ◆ Citizens Suit Provision – TSCA Section 20 (15 USC 2619(a))
 - ◇ Any person may sue EPA to compel performance of a non-discretionary act
- ◆ Administrative Procedure Act (APA) – 5 USC 706(1)
 - ◇ Court shall compel agency action unlawfully withheld
- ◆ Most federal appeals courts would set new deadlines
 - ◇ Or at least have EPA propose reasonable deadlines or require prompt action
- ◆ But DC federal courts apply TRAC balancing factors in these cases
 - ◇ Does statute contain specific deadline
 - ◇ Does statute involve human health concerns or just economic interests
 - ◇ Will expediting agency action impact higher or competing agency priorities
 - ◇ What interests will be prejudiced by further delay
 - ◇ Is delay due to agency bad faith

Sue-and-Settle

- ◆ NGOs may try to settle case and enter into consent decree
- ◆ Risks to industry
 - ◆ Aggressive deadlines
 - Will industry have time to generate relevant data or public comments
 - ◆ Difficult to correct agency mistakes on judicial review
 - Remember, agencies get lots of deference (even under substantial evidence standard)
 - ◆ Negotiations between EPA and NGOs are not public
 - EPA under pressure to settle (reduce litigation costs, avoid bad press)
 - ◆ Consent decree may re-order priorities to disadvantage of manufacturer requested risk assessments

Upcoming Section 6 Risk Management Orders And Challenges

Preparing for Section 6 Challenges

- ◆ **Build the administrative record**
 - ◇ Cannot challenge risk evaluation until risk management rule is issued
 - ◇ Don't wait for Section 6 risk management stage to participate
 - ◇ Participate at each stage of Section 6 process
- ◆ Focus on three key EPA obligations (15 USC 2625) at prioritization, risk evaluation, and risk management stages
 - ◇ Consider all reasonably available information
 - ◇ Consistent with best available science (e.g., peer reviewed, acceptable methods)
 - ◇ Based on weight of scientific evidence (e.g., strengths, weaknesses, limitations)
- ◆ Identify additional issues impacting decisions
 - ◇ Are inappropriate policy agendas driving decision-making
 - ◇ Are there important legal arguments to address (e.g., other regulatory schemes)



Thank You

Any questions?

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