

# Pause or Play? Preemption under the Biden EPA

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# Greg Clark



- ◆ Greg Clark advises clients on regulatory and environmental issues, focusing on the Toxic Substances Control Act (TSCA), the Clean Air Act (CAA), state volatile organic compound (VOC) regulations, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA).
- ◆ Greg assists clients needing approval of new chemical substances, genetically modified organisms, and pesticides under TSCA, FIFRA, and similar laws abroad. Clients seek his expert guidance through the Premanufacture Notification (PMN), Low Volume Exemption, Microbial Commercial Activity Notice (MCAN), and TSCA Environmental Release Application (TERA) review processes. He also assists clients by negotiating the terms and conditions of TSCA Section 5(e) consent orders and Significant New Use Rules (SNURs). Additionally, Greg advises companies seeking to market biotechnology-derived products and their production platforms (including bacteria, yeast, algae, and plants) to navigate the complex regulatory requirements administered by the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Animal and Plant Health Inspection Service (APHIS).
- ◆ Greg's experience and expertise allow him to advise companies and trade associations on the prioritization, risk evaluation, and risk management of existing chemicals, including chemicals on the 2014 TSCA Work Plan, following the Lautenberg Act amendments to TSCA. Through this work, he develops detailed comments and regularly interacts with EPA staff. He assists companies with periodic reporting under the TSCA Chemical Data Reporting Rule and other agency reporting programs. He also designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy", as well as under other penalty mitigation policies.
- ◆ Greg has extensive experience representing clients in CAA rulemakings and enforcement matters before administrative agencies, including drafting highly technical comments, filing petitions for reconsideration and judicial review, and meeting with agency staff.
- ◆ Greg has a background in molecular biology and emergency preparedness, offering him a unique foundation from which to advise his clients and assist the firm.

# Eric Gotting



- ♦ Eric Gotting represents Keller and Heckman's clients in litigation and related matters, specializing in complex civil and appellate matters, internal investigations, and regulatory compliance. With an extensive background in environmental law, he has expanded his practice over the years to cover many of Keller and Heckman's industry sectors and regulatory areas. Eric is a former Am Law 50 litigation partner and U.S. Department of Justice, Civil Division, Trial Attorney.
- ♦ Eric's practice spans a broad range of legal issues, including administrative and constitutional law, agency enforcement actions, toxic torts, product liability, general business litigation, and regulatory advice. He works with a diverse set of industries, including chemicals, plastics, pesticides, fuels and pipelines, food and packaging, consumer goods, telecommunications, and e-cigarettes.
- ♦ As a litigator, Eric has tried cases to verdict and argued appeals before federal and state courts across the country. His experience includes class actions, mass tort litigation, AAA arbitrations, and agency proceedings. Eric has also litigated challenges to federal and state statutes, regulations, and orders. He has particular expertise involving the Administrative Procedure Act (APA), the Dormant Commerce Clause, the First Amendment, the Due Process Clause, and federal preemption. He has also filed amicus briefs in litigation involving regulatory issues facing a variety of industry sectors.
- ♦ For his toxic tort clients, Eric has defended claims involving all environmental media, including drinking water, soil, groundwater, and air. He has worked with, and defended against, experts in numerous scientific and business-related fields, including toxicology, geochemistry, hydrogeology, structural engineering, neuropsychology, health physics, survey techniques, statistics, real estate appraisal, and environmental remediation. He has extensive experience litigating toxic tort cases involving claims of personal injury and property damage from alleged exposures to volatile and semi-volatile compounds, specialty chemicals, pesticides, gasoline, radioactive waste, and heavy metals.

# Preemption 101



- ◆ Supremacy Clause (Article VI, Clause 2) of U.S. Constitution
  - ◇ Federal law trumps state/local laws
- ◆ Two basic forms
  - ◇ Express Preemption
  - ◇ Implied (conflict) Preemption

# Preemption Under TSCA §18



- ◆ Information Development Preemption (§§ 4, 5, or 6)
- ◆ Safety Finding Preemption (§6)
- ◆ Risk Management Preemption (§6)
- ◆ Notification Preemption (§5)
- ◆ Pause Preemption (§6)

# A Focus on §6 – Pause Preemption



- ◆ Pause Preemption begins when EPA publishes the final Risk Evaluation (RE) Scope document for a *high priority* chemical
  - ◇ New (subsequently enacted) state chemical control laws/rules preempted
    - “no State or political subdivision of a State may establish or continue to enforce...”
- ◆ Preemption applies to the scope of activities covered by the RE
- ◆ Preemption remains in effect until final RE is published (or 3.5 years)
- ◆ Preemption becomes permanent when EPA (1) determines the substance or a use of the substance presents no unreasonable risk, or (2) completes a risk management rule

# Safety Finding Preemption



- ◆ States cannot prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance for which EPA makes a §6(i)(1) determination of no unreasonable risk
- ◆ Consistent with the scope of the risk evaluation under section 2605(b)(4)(D)

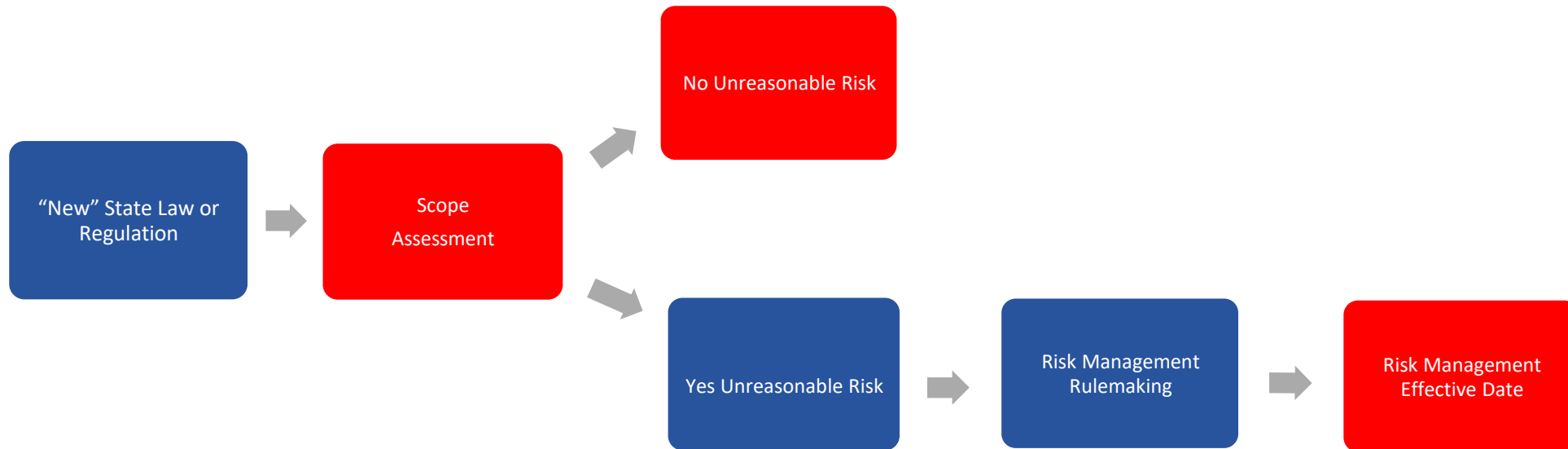
# Risk Management Preemption



- ◆ States cannot prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance for which EPA issues a §6(a) risk management rule
- ◆ Consistent with the scope of the risk evaluation under section 2605(b)(4)(D)



# §6 Preemption Timeline



# Preemption Exceptions and Exclusions



- ◆ Rules issued anytime under statutes enacted prior to September 2003
- ◆ Chemical-specific rules issued prior to April 2016
- ◆ Distinct monitoring and disclosure laws (information laws)
- ◆ Laws to protect air or water, or to manage waste
- ◆ Delegation of federal laws or authority to state or local authority
- ◆ Tort law
- ◆ EPA waivers of preemption may apply

# Preemption Waivers from EPA



- ◆ Discretionary waivers
  - ◇ EPA determines there are compelling conditions, no undue burden on interstate commerce, no violation of Federal law, and state action is based on best available science/weight of the scientific evidence
- ◆ Required waivers (from Pause Preemption)
  - ◇ State law or regulation comes after <18 mo. after prioritization begins but before scope of the RE; or
  - ◇ EPA determines there is no undue burden on interstate commerce, no violation of Federal law, and state action is based on peer-reviewed science

# Key Biden Administration Changes for §6



- ◆ “Whole Chemical” risk determination
  - ◇ EPA will not determine “Unreasonable Risk” or “No Unreasonable Risk” for each condition of use (COU)
- ◆ Deemphasizing §9 (“regulatory nexus”)
  - ◇ Less deference paid to other EPA programs (Clean Air Act, Clean Water Act)
    - Exposures adequately regulated under other laws
  - ◇ EPA will conduct broader risk evaluations, to cover air, water, etc.
- ◆ Missed deadlines
  - ◇ EPA does not intend to complete risk evaluations within the 3-3.5 years provided by §6(b)(4)(G)

# Impact of Biden Administration Policies (1)



## ◆ Pause Preemption

- ◇ Broader scope of risk evaluation = broader Pause Preemption
- ◇ Late risk evaluations = “early” end (but “max”) for Pause Preemption
- ◇ Slower risk evaluations = fewer chemicals designated “high priority”

## ◆ Safety Finding Preemption

- ◇ EPA redoing “first 10” risk evaluations to revoke 6(i)(1) orders
- ◇ “Whole chemical” = no §6(i)(1) findings = no preemption of state law on specific COU

# Impact of Biden Administration Policies (2)



- ◆ Risk Management Preemption (cont'd)
  - ◇ Broader scope of risk evaluation = broader Risk Management Preemption
  - ◇ Late risk evaluations = larger gap between Pause and Risk Management Preemption

# Impact of Biden Administration Policies (3)



- ◆ First 10 Risk Evaluations §6(i)(1) safety findings
  - ◆ Asbestos: 4 conditions of use
  - ◆ *HBCD: 6 conditions of use*
  - ◆ Methylene chloride: 6 conditions of use
  - ◆ n-Methylpyrrolidone: 11 conditions of use
  - ◆ Perchloroethylene: 2 conditions of use
  - ◆ PV29

# Example State Laws (1)

## ◆ New York

- ◆ S.B. 4630: bans **TBBPA** in mattresses, upholstered furniture, consumer electronic displays, TVs, and monitors (starting Jan. 1, 2024)
  - TBBPA subject to Pause Preemption
- ◆ ECL Articles 35 and 37: limits **1,4-dioxane** in household cleansing products and personal-care products to trace concentrations (starting Dec. 31, 2022)
  - Surface cleaner, dish soap, dishwasher detergent, and laundry detergent uses subject to Safety Finding Preemption



# Example State Laws (2)

- ◆ Safer Products for Washington Program
  - ◇ Reviewing **HBCD, TCEP, TBBPA, TPP, DBP, BBP, DEHP** in certain products
    - TCEP, TBBPA, TPP, DBP, BBP, DEHP subject to Pause Preemption
    - HBCD was subject to Safety Finding Preemption
  - ◇ Likely restrictions on use of HFRs in plastic device casings, HFRS and OPFRs in foam, floor mats, flooring, outdoor recreational products
  - ◇ Likely restrictions on use of ortho-phthalates in vinyl flooring

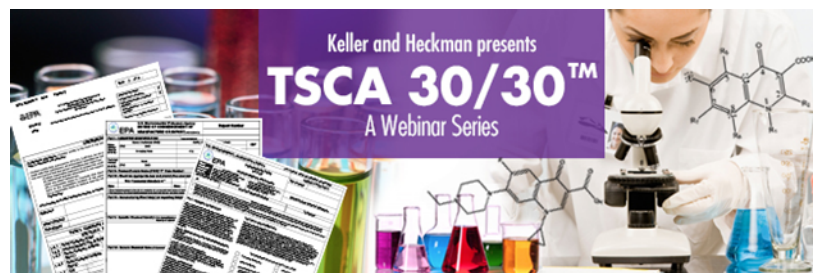
# Can Companies “Enforce” Preemption?



- ◆ Federal Lawsuit (“facial” challenge)
- ◆ State Enforcement Action (“as applied” challenge)
- ◆ State Mini-Administrative Procedure Acts (“APAs”)
- ◆ State Statutes Granting Agency Rulemaking Authority
  - ◆ e.g., California Green Chemistry Program



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Keller and Heckman is pleased to announce that our TSCA Basics Course will be held in-person this year, taking place November 3, 2022, in Washington, DC.

More information at: <https://www.khlaw.com/events/2022-tsca-basics-course>

# Thank You

Any questions?

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