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2023
EARTH DAY
WEBINAR SERIES

**EPA's Chemicals Regulatory Agenda:
Testing, Reporting, Rulemaking, and Litigation**

John McGahren and Debra Carfora | April 19, 2023

Presenters



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Upcoming Earth Day Webinars

- **Environmental Justice and the E in ESG**

April 20, 2023 | 1:00 – 2:00 PM ET

- Presenters: Duke McCall, Rick Rothman, Gina Waterfield (Berkeley Research Group)

Recordings and slides available:

- **Evolving Environmental Laws: Endangered Species Act and WOTUS Under the Clean Water Act**

April 17, 2023

- Presenters: Doug Hastings, David Brown

- **Regulation and Litigation on the (PFAS)t Track in 2023**

April 18, 2023

- Presenters: Stephanie Feingold, Jeremy Esterkin, Kate Deal, Drew Jordan

Agenda

1. Scope
2. Relevant Framework
3. What's Ahead in 2023
4. Ongoing Litigation
5. Compliance Audits and Assessments



TSCA Scope

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What Does TSCA Cover

- TSCA's unique focus is on chemicals in commerce
- Six chemical substances receive special attention under TSCA: PCBs, asbestos, radon, lead, mercury, and formaldehyde.
- Eight types of materials are generally exempt from TSCA's regulatory authorities: pesticides, tobacco, specified nuclear material, firearms and ammunition, food, food additives, drugs, and cosmetics

Scope is Expansive

Extending to the full lifecycles of chemicals, chemical mixtures and chemical-containing products and, in principle, providing EPA with authority to regulate virtually all activities involving chemicals and chemical information

- Applies to the full lifecycle of chemicals:
 - Manufacturing
 - Processing
 - Distribution
 - Use
 - Waste management
- Provides potential authority over:
 - Chemicals/mixtures/products
 - Chemical testing and monitoring
 - Review and regulation of new and existing chemicals
 - Regulation of imports and exports
 - Information collection
 - Information sharing and trade secret protection

New Chemicals

Before a new chemical* can enter the market, EPA must determine whether the chemical:

- Presents an unreasonable risk
- May present an unreasonable risk
- Whether the available information is sufficient to permit a reasoned evaluation of risk

*A chemical is defined as “new” if it is not on the TSCA inventory. EPA estimates that 500-1,000 new chemicals enter commerce each year.

Existing Chemicals

- EPA must evaluate risks for all existing chemicals* in commerce.
 - Expectation is ultimately for EPA to examine all chemicals in production and use.
- EPA must have 20 high-priority and 20 low-priority chemicals undergoing evaluation at any time.
 - high-priority: the chemical may present unreasonable risk and must go through a “risk evaluation.”
 - low-priority: the chemical does not *currently* warrant risk evaluation.

* Currently includes approximately 85,000 chemicals



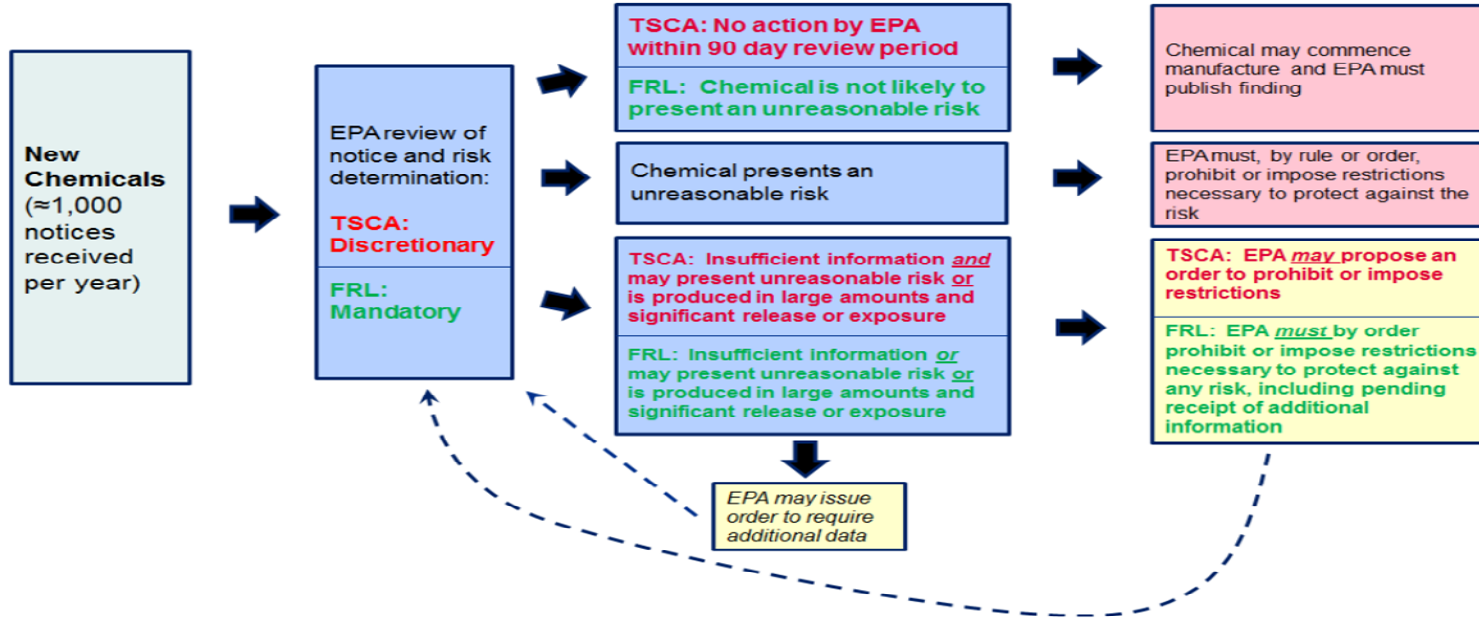
Relevant Statutory Framework

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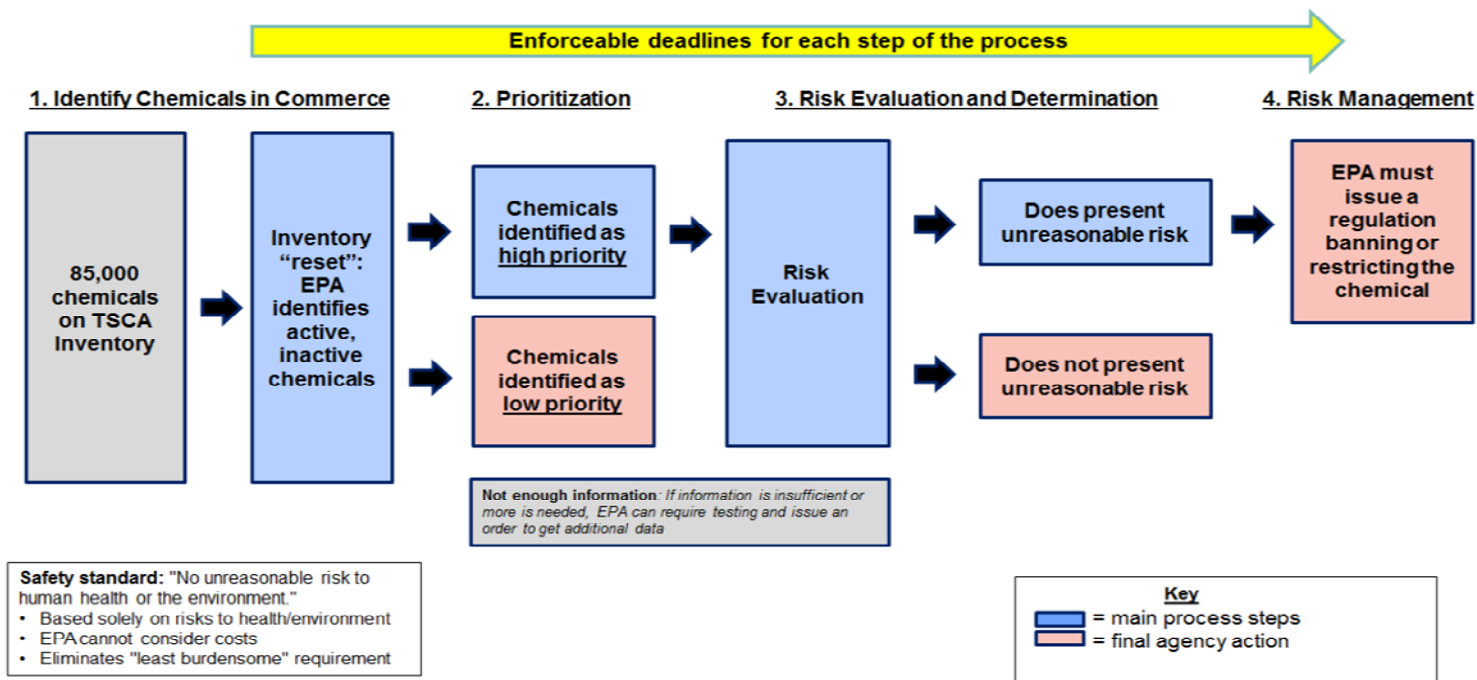
Sec. 4. Testing of Chemical Substances and Mixtures

- EPA can now issue orders to require testing (Sections 4(a)(1) and (2)), instead of engaging in the rulemaking process or negotiated consent agreements.
- Test Orders can be used to generate information needed to inform or conduct any of the major activities called for under the law to meet the regulatory testing needs of any other federal agency.
- Several conditions apply:
 - EPA must provide a statement of need.
 - EPA must generally utilize a “tiered” approach to testing.
 - EPA must provide a justification for its use of an order rather than a test rule or consent agreement.

Sec. 5. [New Chemicals] Manufacturing and Processing Notices



Sec. 6. [Existing Chemicals] Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures



Sec. 8. Reporting and Retention of Information

- To aid EPA in its duties under TSCA, the agency was granted considerable authority to collect information from industries.
- EPA may require maintenance of records and reporting of chemical identities, names, and molecular structures; categories of use; amounts manufactured and processed for each category of use; descriptions of byproducts resulting from manufacture, processing, use, and disposal; environmental and health effects; number of individuals exposed; number of employees exposed and the duration of exposure; and manner or method of chemical disposal.
- Manufacturers, processors, and distributors of chemicals are required to maintain records of significant adverse reactions to health or the environment alleged to have been caused by a substance or mixture.
- Industry also must submit lists and copies of health and safety studies. Studies showing adverse effects previously unknown must be submitted to EPA as soon as they are completed or discovered.

Sec. 8(a)

- Preliminary Assessment Information Reporting (PAIR) Rule - producers and importers of a chemical substance or mixture listed under §8(a) are required to submit to EPA certain specified production, importation, and exposure information.
- The Chemical Data Reporting Rule - requires that manufacturers (including importers) of chemical substances periodically report on the production volume and other exposure-related information (including manufacturing, processing, and use) of their chemicals.

Sec. 8(d)-(e)

- Sec. 8(d): Manufacturers (including importers), processors, and distributors of a chemical substance or mixture identified in EPA regulations are required to submit to EPA lists and copies of unpublished health and safety studies of those chemicals or mixtures
- Sec. 8(e): Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to human health or the environment must immediately inform the administrator of such information unless the person has actual knowledge that the administrator has already been adequately informed of such information.

Sec. 14. Confidential Information

- Certain specified types of information are presumed to be protected if claimed CBI, and substantiation of those claims is not required, nor are they subject to time limits.
 - Examples include the identity of a chemical prior to commercialization, a company's customer or supplier lists, and the specific process used to make a chemical.
- Other types of information are not eligible for CBI protection, including general information on chemicals' uses and functions.
- For all other types of information, including the identity of a chemical after commercial introduction, they can only be protected if substantiated at the time a CBI claim is asserted.
 - Claims expire after 10 years unless reasserted and resubstantiated.



What's Ahead in 2023

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What's Ahead in 2023

- Test Orders
- Reporting Rules
- Risk Evaluation
- Risk Management Rulemaking

Test Orders

- EPA believes it is reasonable to assume that approximately 75 test orders per year will be initiated between fiscal year 2023 and fiscal year 2025.
 - Approximately 45 of these test orders are expected to be associated with the agency's actions on PFAS.
 - EPA's estimate for the number of test orders in the 2018 fee rule assumed 10 test orders per year.
- This increase in test orders is anticipated to close data gaps identified in the prioritization process or the scoping stage of the risk evaluation process for high-priority substances.
- EPA anticipates issuing additional collection activities through to address EPA's priorities, such as generating information to inform the agency's understanding of PFAS.

Test Order Best Practices

- EPA will communicate with manufacturers and processors before issuing a test order to encourage voluntary data submissions.
- Companies subject to the test order may either conduct the tests as described or provide EPA with existing information that they believe EPA has not yet identified.
- EPA “encourages companies to jointly conduct testing to avoid unnecessary duplication of tests and will also consider possible combinations of tests that cover all required endpoints to diminish the amount of time, animal subjects and costs required.”

Reporting Rules

- EPA's highly anticipated regulations governing PFAS reporting, originally slated for final publication in January 2023, have been delayed.
- EPA expects to promulgate a final reporting and recordkeeping rule for asbestos in May 2023. The proposed rule appeared in May 2022.
- The next Chemical Data Reporting (CDR) rule report is due between June 1 and September 30, 2024. That makes 2023 the principal reporting year for that report. Manufacturers should ensure that they keep the records that will enable them to report in 2024.

Preparing for Risk Evaluation

- June 2021: EPA announces policy changes surrounding the first 10 chemicals to undergo risk evaluation completed by the previous administration
 - Expanding consideration of exposure pathways and fence-line community exposure screening level approach
 - Use of personal protective equipment
 - Whole Chemical Approach
- Other anticipated changes
 - Revisions to its framework regulation on risk evaluations anticipated in May 2023
 - Propose a rule to establish a framework of data reporting requirements that establishes a series of reporting obligations for certain chemicals based on their position in the existing chemicals evaluation process (prioritization, risk evaluation, risk management)

Risk Evaluation Rulemaking

- The regulatory agenda predicts that EPA will issue proposed risk management rules for:
 - Anticipated August 2024
 - Methylene chloride, Perchloroethylene, Carbon tetrachloride, 1-Bromopropane, N-methylpyrrolidone
 - Anticipated September 2024
 - Trichloroethylene
- The EPA's risk management options include labeling, recordkeeping or notice requirements, actions to reduce human exposure or environmental release, and a ban of the chemical or of certain uses.

Rules Can Affect Entire Supply Chains

- Keep Records
 - Take reasonable precautions by retaining, for three years, bills of lading, invoices, or comparable documents that include a written statement from the supplier of compliance with regulations.
- TSCA Inventory
 - The inventory also contains “flags” for certain chemical substances that may be subject to manufacturing restrictions.
- TSCA Audits

Strategies for Engagement with EPA

- Public comment
- One-on-one sessions
- TSCA Section 21 Petitions



Overview of Ongoing TSCA Litigation

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Enforcement Action

EPA v. Inhance Technologies

Allegations against a plastics maker's fluorination process violates the TSCA significant new use rule (SNUR) for many PFAS despite the company's claim that its methods were in place years before the rule, arguing that SNURs can limit not only "new" uses but also any "ongoing" ones that were never reported to the agency.

Sec. 19. Petitions for Judicial Review

- *Vinyl Institute [VI] v. EPA* a novel suit over one of the eight test orders the agency issued last year to aid ongoing chemical evaluations. VI is asking the US Court of Appeals for the District of Columbia Circuit to enforce what it says are “numerous conditions” Congress set out for EPA to justify use of the expanded test-order authority lawmakers gave the agency in the 2016 TSCA reform.
- A chemical manufacturer is asking a federal appellate court to review EPA’s TSCA test order—issued under section 4—requiring the company to develop a range of “tiered” toxicity studies regarding the PFAS known as GenX, the second such suit challenging an order issued under EPA’s category-based testing and research strategy, which officials are now working to refine.

Sec. 20. “Mandatory Duty” (or “Deadline”) Suits

- Authorizes civil suits by any person against any person in violation of the act.
- Authorizes suits against EPA to compel performance of nondiscretionary actions under TSCA.
 - Risk Evaluation Deadlines

Sec. 21 Petitions

- Under TSCA section 21, any person may petition EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule or order under:
 - Section 4 - rules or orders requiring chemical testing;
 - Section 6 - rules imposing regulatory controls on chemicals;
 - Section 8 - rules requiring information; or
 - Section 5(e) or (f) - orders affecting new chemical substances.
- Pending Polyvinyl Alcohol (PVA) Petition - requesting “an order under section 4 of TSCA requiring the manufacturers and processors of polyvinyl alcohol (PVA) and “ultimately regulate PVA used in dishwasher and laundry pods and sheets as a toxic substance, pending the results from testing.”
 - EPA must grant or deny by April 26, 2023.



Complying With TSCA: Facility Audits

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TSCA Compliance Audits and Assessments

- Planning for compliance with TSCA reforms
 - Starting or modifying corporate chemical programs in light of TSCA reforms
- Supply chain relationships and engagement
 - Opportunity to update chemical data from and with suppliers
- Identify potential recordkeeping gaps
- Post-reform enforcement may increase
 - Enforcement focus on CDR, inventory, SNUR, and substantial risk reporting
 - Significant penalty exposures
- EPA self-disclosure policy
 - Reduction of 100% penalties if all nine of the policy's conditions are met

Biography



John McGahren

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John is the Princeton litigation practice leader and deputy chair of the firm's global environmental practice. John counsels clients on litigation, enforcement, and transactional matters. He prosecutes and defends citizen suits, Superfund and RCRA disputes, Clean Water and Air Act litigation, state law actions, and natural resource damage claims. He represents clients in commercial litigation, products liability, toxic tort, and government contract claims. John frequently provides counsel on US federal and state regulatory matters and investigations.

Biography



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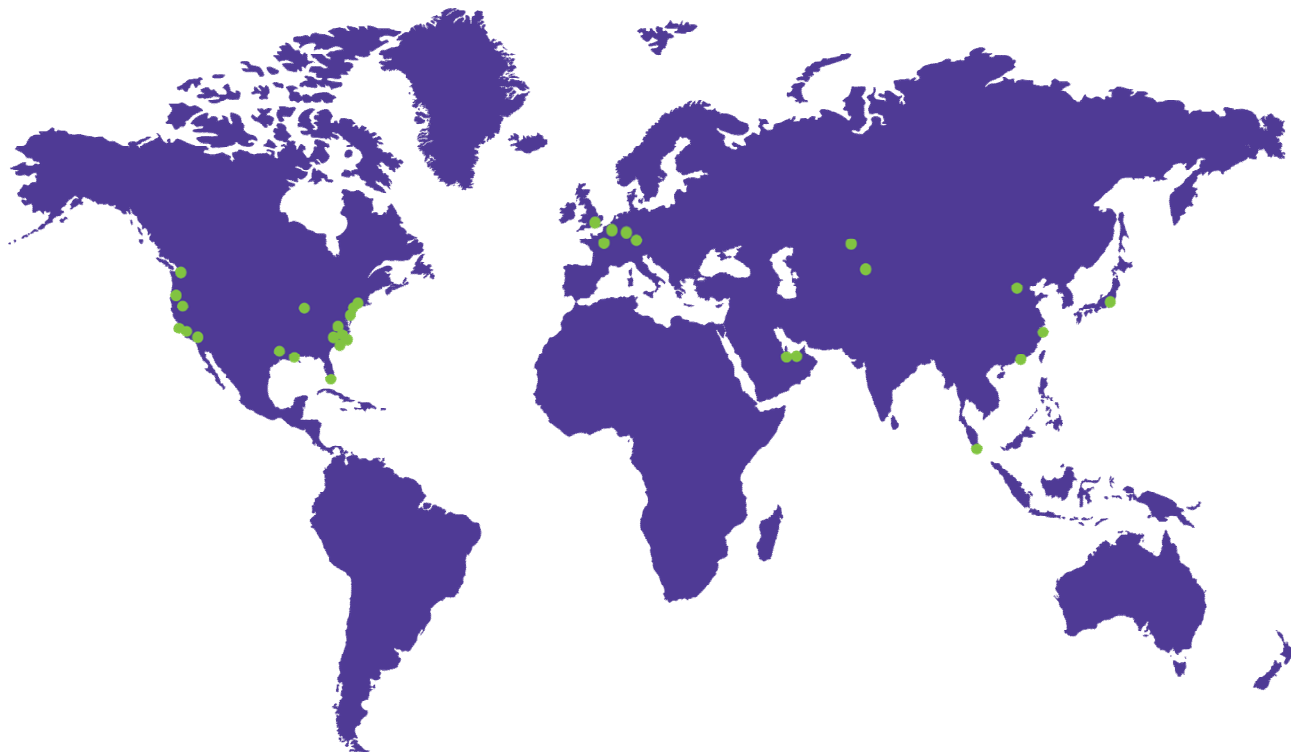
Debbie represents national and international clients in complex litigation and crisis management, focusing on environmental, toxic tort, and administrative law matters before federal courts, including appellate courts. As a former trial attorney and senior trial counsel for the Environmental Defense Section of the Environmental and Natural Resources Division at the US Department of Justice, Debbie's practice focuses on environmental litigation and matters requiring complex statutory and regulatory interpretation. She is adept at negotiating and litigating matters involving government agencies or flowing from government agency actions and rulemakings.

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