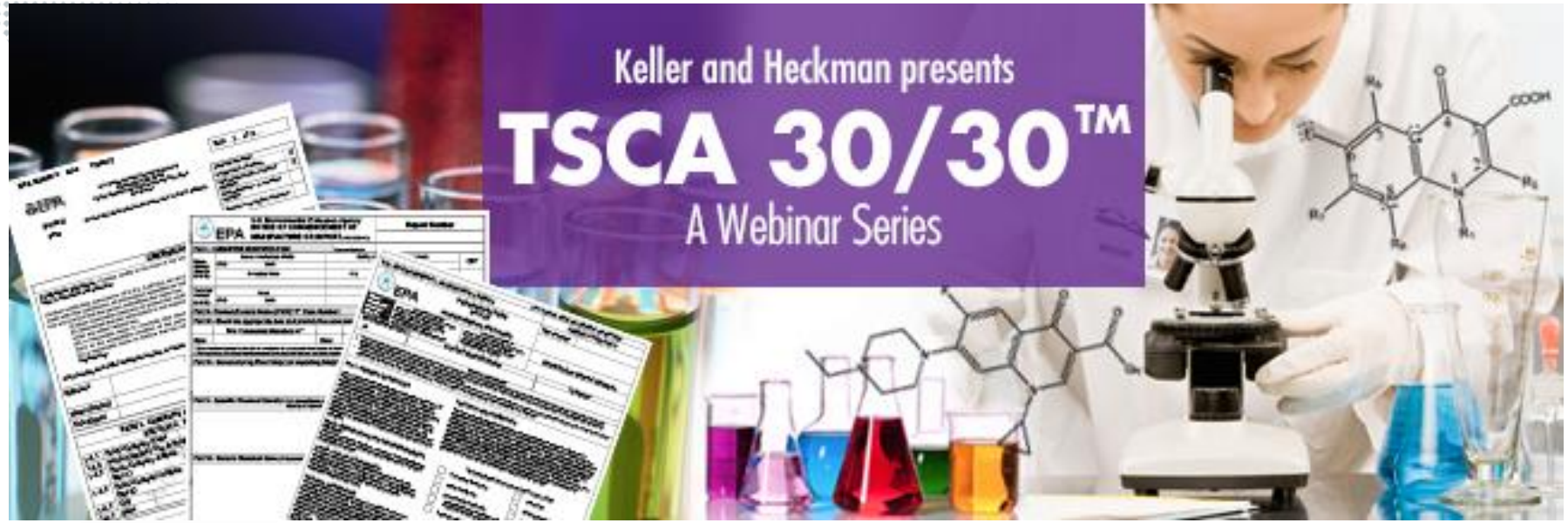

Tiered Data Reporting and More PMN Transparency
August 18, 2021

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Herb Estreicher

- Herbert (Herb) Estreicher is a prominent environmental lawyer who is listed in Who's Who Legal: Environment and in Marquis Who's Who in America. Herb holds a PhD in Chemistry from Harvard University (1980) in addition to his U.S. law degree (1988). He is also listed as a foreign lawyer (B List) with the Brussels legal bar. Herb is recognized as a leading expert on the Toxic Substances Control Act (TSCA) and is frequently quoted in Inside EPA, Chemical Watch, and BNA Environmental Law Reporter. He is one of the few U.S.-based lawyers that is expert on the EU REACH regulation and has successfully argued a number of cases before the European Chemicals Agency (ECHA) Board of Appeal and has briefed cases before the EU General Court and the European Court of Justice.

- Herb represents leading manufacturers of chemicals, pesticides, and consumer products. His broad practice in international environmental regulatory law allows him to take an interdisciplinary approach with his clients and their needs. His extensive background in organic chemistry, risk assessment, and bioengineering is valued highly by his clients in the chemical, nanotechnology, and biotechnology industries.

- Herb provides advice on product liability risk control and assists his clients with crisis management for embattled products, including wood preservatives and persistent, bioaccumulative, and toxic (PBT) chemicals. He helps his clients secure and maintain chemical approvals and pesticide registrations in Canada and Europe, advises clients on matters involving the Canadian Environmental Protection Act and on European chemical directives such as the EU Registration, Evaluation and Authorization of Chemicals (REACH) regulation, the Classification, Labelling and Packaging (CLP) regulation, and the Biocidal Products Regulation. Herb also represents clients in matters involving the Stockholm Convention on persistent organic pollutants (POPs) and has participated in the Canadian Strategic Options Process (SOP). He counsels clients on matters concerning sustainability and the circular economy.

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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) 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 allows 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 on 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

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Tiered Data Reporting Rule for Existing Chemical Substances

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EPA Announcement and Webinar

- July 14, 2021: EPA published a Federal Register notice announcing July 27, 2021 webinar
- EPA also opened a public comment period for 30 days
- Create tiered data reporting (TDR) to support the review of existing chemicals
- Potentially reduce CDR requirements

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What Reporting Could Be Required

- Limited to existing information for section 8
  - Reporting standard: known to or reasonably ascertainable (for most)
- Section 4 authority
  - Generate data for prioritization (limited) or risk evaluation
  - Previous test rule authority ("may present unreasonable risk…" or "substantial quantities…")

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How Does EPA Currently Collect Data and Information?

- §8(a) Chemical Data Reporting Rule: every four years → next in 2024
- §8(b) Inventory Reset → one-time in 2017-2018, ongoing for "inactive" substances
- §8(c) Allegations of significant adverse reactions → ongoing
- §8(d) Unpublished health and safety studies → 20 High Priority Substances added in July 2021
- §8(e) Substantial risk reporting → ongoing
- §4(a)(2) → test orders issued to 9 High Priority Substances in January 2021

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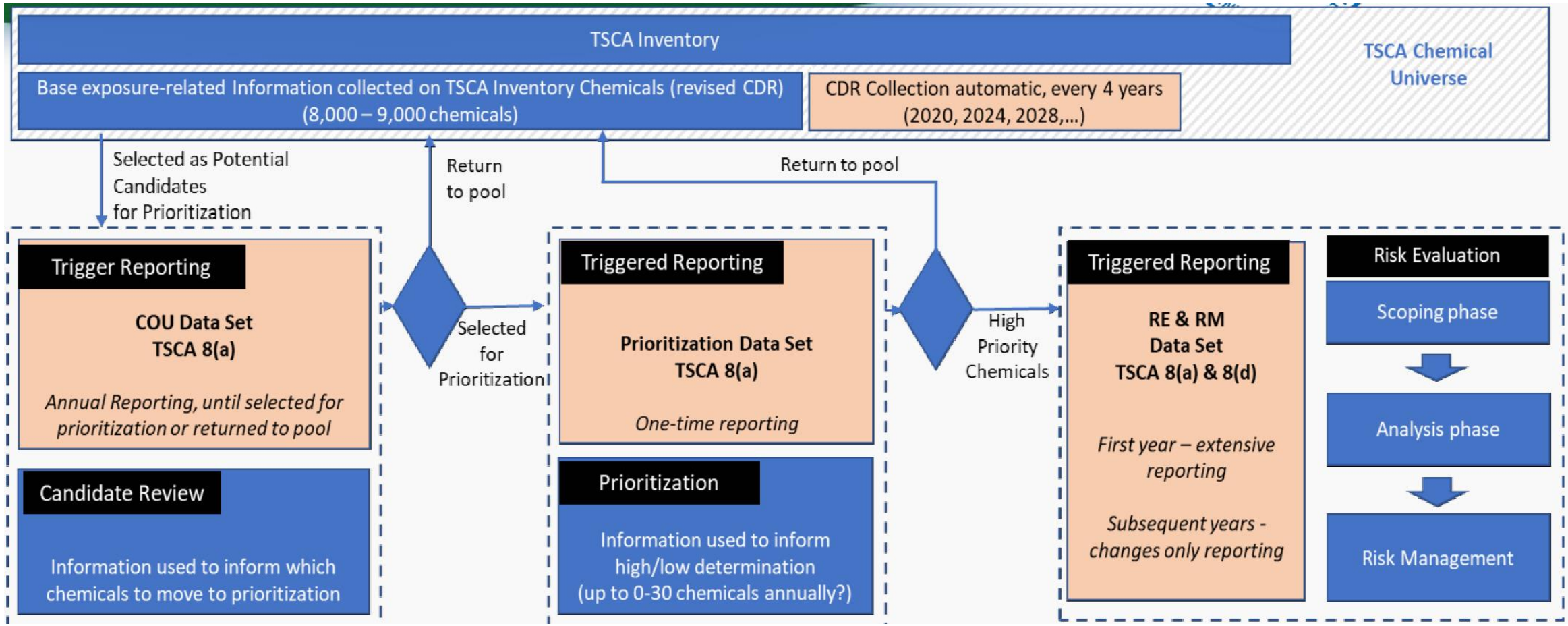
Section 6 and EPA Information Needs



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Information Needs at Each Stage

Pre-Prioritization ("COU")

- Active/Inactive
- Sufficient information to make the prioritization finding
- "CDR+"
- *Annual reporting – 8(a)*

Prioritization

- Potential hazard(s)
- Potential route(s) of exposure
- Uses
- *One-time reporting – 8(a)*

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Information Needs at Each Stage

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Risk Evaluation

- Phys-chem properties
- All uses and industrial sectors
- Hazards
- Exposure monitoring data
- Engineering controls
- Other regulations

- *First year reporting – 8(a) & 8(d)*

Risk Management

- Changes since R.E.
- Essential uses
- Available substitutes

- *When information changes – 8(a) & 8(d)*

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Public Comments

- EPA rejected multiple requests to extend the comment period
- Comment: EPA would exceed its §4(a)(2) authority if it issued test orders/rules prior to initiating prioritization
- Comment: under 8(d), EPA should require submission of information from New Approach Methodologies, bioinformatics, computational toxicology
- Comment: EPA needs hazard and exposure data earlier than R.E. stage
- Comment: all data collection should occur before prioritization

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Outstanding Questions and Principles

- Is any additional data in fact necessary for the prioritization stage?
- Will CDR requirements be reduced?
- What substances will be subject to the pre-prioritization stage?
- How much will be required of processors? Distributors?
- How far will EPA stretch its authorities?
- Will there be a post-risk management stage?
- Industry engagement on remaining Work Plan chemicals is critical

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PMN Transparency

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EDF et al. v. EPA

- Complaint filed in U.S. District Court for the District of Columbia
- Trump Era Case
- NGO's allege that EPA operates the PMN review process as a "black box", "thwarting" the ability of the public to be informed and to provide input.
- They state they have requested information about hundreds of new chemicals being reviewed by EPA.
- But EPA has repeatedly denied these requests.

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NGOs allege there is no transparency

- They note that TSCA requires that EPA conduct its review of new chemicals transparently.
- TSCA requires that notice of EPA's receipt of PMNs be published in the Federal Register within 5 business days; EPA routinely fails to disclose that it has received an application within the mandated time frames.
- TSCA mandates that EPA disclose to the public any health and safety studies and all other non-confidential information submitted in support of a new chemical application; EPA routinely withholds such information from the public.
- EPA's regulations require that EPA publish the applications in an online docket; yet, EPA fails to do so.

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What do NGO's want the Court to Do?

- Declare EPA to be in violation of TSCA's disclosure mandates
- Order EPA to publish full and complete notices of its receipt of new chemical applications in a timely fashion
- Order EPA to disclose all non-confidential information, including health and safety studies, supporting such applications.
- Require EPA to disclose previously requested information on new chemicals that EPA refused to disclose.
- Request that the Court declare that EPA engages in a pattern and practice of violating TSCA's numerous disclosure mandates and enjoin EPA's black-box approach to reviewing new chemicals on a prospective basis

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Where is this case going?

- During the Trump Administration Parties stated we “do not believe there is a realistic possibility of settling the case.”
- Now in the Biden Administration:
  - In an Aug. 6, 2021, joint case update the Parties say they held “an initial discussion to evaluate the potential for settlement of some or all” of the claims and are engaged in “further discussions regarding the potential for settlement.”

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Final Thoughts

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Wednesday, October 20, 2021
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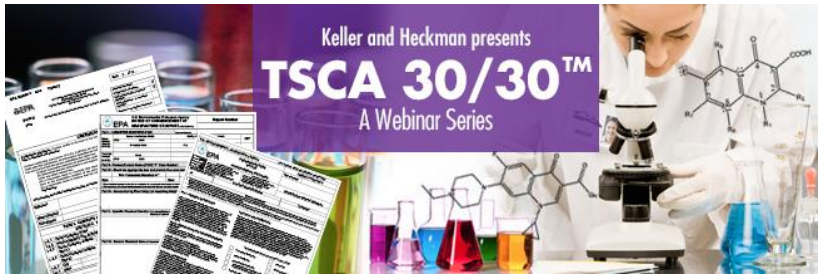

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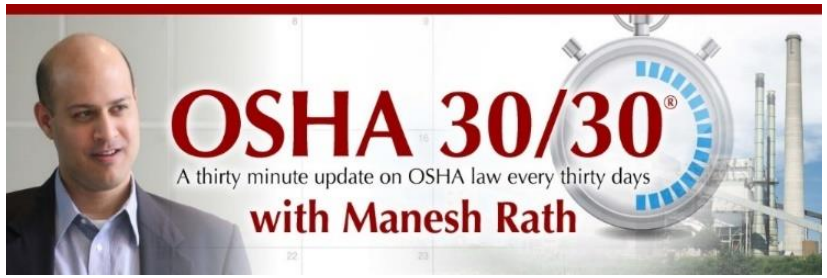

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The Next TSCA 30/30:
Wednesday, October 20, 2021

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Thank You

Any questions?

Herb Estreicher

Partner

Washington, DC and Brussels

202-434-4334

Estreicher@khlaw.com

Greg A. Clark

Partner

Washington, DC
202-434-4302

clarkg@khlaw.com

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