



Celebrating 60 Years Of Excellence

(1) EPA's Regulatory Agenda

(2) Cumulative Risk Assessment

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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 Ph.D. in Chemistry from Harvard University (1980) in addition to his US 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 an expert on the EU REACH regulation and has successfully argued numerous 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.



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 for 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. (SNURs). He also assists clients by negotiating the terms and conditions of TSCA Section 5(e) consent orders and Significant New Use Rules 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 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 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.



(1) LOOKING AHEAD IN 2023 - EPA'S REGULATORY AGENDA

Key Section 5 Rulemakings



- ◆ Fees Rule (final September 2023)
 - ◇ Major increases in new chemical fees
- ◆ Revisions to New Chemicals Regulations (NPRM July 2023)
- ◆ High Priority Substances SNURs (NPRM April 2023; four categories)
- ◆ Inactive PFAS SNURs (NPRM December 2022; final December 2023)

Key Section 6 Rulemakings (1)

- ◆ Proposed Risk Management Rules
 - ◇ Methylene Chloride (February 2023)*
 - ◇ Perchloroethylene (April 2023)
 - ◇ Carbon Tetrachloride (May 2023)
 - ◇ Trichloroethylene (June 2023)
 - ◇ 1-Bromopropane (September 2023)
 - ◇ N-Methylpyrrolidone (September 2023)
 - ◇ Section 6(h) PBT Rule revisions (November 2023)

- ◆ Statutory deadlines were 2021/2022 for the “first 10”

*Currently under OMB review

Key Section 6 Rulemakings (2)

- ◆ Fees Rule (final September 2023)
 - ◇ Major increases in risk evaluation fees
- ◆ Risk Evaluation Procedural Rule revisions (NPRM May 2023)
 - ◇ *SCHF v. EPA*; “whole chemical” approach; “regulatory nexus”
- ◆ Final Risk Management Rules
 - ◇ Asbestos (October 2023)

- ◆ Statutory deadline for asbestos §6 rule was December 2022

Rulemakings Under Other Sections



- ◆ PFAS §8(a) Reporting Rule (final March 2023)
 - ◇ 2020 National Defense Authorization Act
- ◆ Asbestos §8(a) Reporting Rule (final May 2023)
 - ◇ *ADAO v. EPA*
- ◆ Revised TSCA CBI Regulations (February 2023)

Not in the Reg. Agenda

- ◆ Proposed Risk Management Rules (Long-Term)
 - ◇ HBCD (February 2024)
 - ◇ Pigment Violet 29 (May 2024)
 - ◇ 1,4-Dioxane (no date)
- ◆ §8(a)/§8(d) Tiered Data Reporting Rule (Long-Term)
 - ◇ NPRM January 2024
- ◆ Test Orders
 - ◇ PFAS
 - ◇ High Priority Substances (?)
- ◆ Risk Evaluations for High Priority Substances

(2) CUMULATIVE RISK ASSESSMENT

What is Cumulative Risk Assessment?

- ◆ Cumulative risk is the combined risks from aggregate exposures to multiple agents or stressors
- ◆ Cumulative risk assessment is an analysis, characterization, and possible quantification of the combined risks to human health or the environment from multiple agents or stressors
- ◆ Addressing cumulative impacts from multiple sources is a top priority for Administrator Regan's efforts to prioritize protections for EJ communities
- ◆ Such communities often face a host of pollutants in multiple media and from a range of different sources -- factors that often overlap with the adverse effects of poverty and other socioeconomic factors

Cumulative Risk Assessment and TSCA



- ◆ TSCA does not explicitly require EPA to conduct cumulative risk assessment
- ◆ However, TSCA does require EPA to consider the reasonably available information, use the best available science, and make decisions based on the weight of scientific evidence
- ◆ For some chemicals, the best available science may indicate that the development of a cumulative risk assessment is appropriate to ensure that any risks to human health and the environment are adequately characterized

2008 NAS Report

- ◆ In 2008, the National Academy of Sciences (NAS) issued a report recommending that EPA pursue cumulative risk assessment of phthalates and other chemicals
 - ◇ NAS concluded that multiple human exposures to phthalates occur and exposure to different phthalates leads to similar outcomes in lab animals
 - ◇ NAS recommended that phthalates and other chemicals that affect male reproductive development in animals by a similar mechanism be considered in the cumulative risk assessment
- ◆ This conceptual approach should be considered further
 - ◇ For example, NAS suggested that EPA evaluate the risk of combined exposures to lead, methylmercury, and polychlorinated biphenyls because all contribute to cognitive deficits consistent with IQ reduction in children

EDF and Industry Reaction (1)

- ◆ On September 7, 2022, EDF released a model framework for EPA to consider cumulative risks from various chemicals and other stressors like poverty or discrimination in its TSCA risk evaluations
- ◆ EDF provided what they considered as “relevant examples”
- ◆ Halogenated flame retardants, such as polybrominated diphenyl ethers, and organophosphate pesticides both harm the developing brain, and co-exposure to these substances is known to occur
- ◆ Formaldehyde, ethylene dibromide, and particulate matter 2.5 (PM2.5) can cause or exacerbate respiratory effects and are of particular concern to communities that are disproportionately affected by asthma

EDF and Industry Reaction (2)

- ◆ EDF also suggested consideration of non-chemical stressors such as experiencing discrimination, having limited financial resources and limited access to education and health care, and being subject to other social inequities and marginalization
- ◆ Industry has argued that current scientific tools are not up to that task and any attempt to do so without new advances would be a “political experiment”
- ◆ There are significant scientific and research gaps on the subjects, including questions of how to identify and characterize factors that contribute to cumulative harms and methods of analyzing them

SACC Meeting

- ◆ In a Dec. 21, 2022 press release, EPA announced it is seeking 8 to 12 experts to augment its standing Science Advisory Committee on Chemicals (SACC) for review of two TSCA cumulative risk documents and expects to release the drafts for public comment in late February
- ◆ The first, titled, “Proposed Principles of Cumulative Risk Assessment Under [TSCA],” is intended to describe the fundamental principles of cumulative risk assessment of chemicals and how they may be applied within the regulatory requirements of TSCA to ensure TSCA risk evaluations are based on the best available science and are protective of human health
- ◆ The second is titled “Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under TSCA”

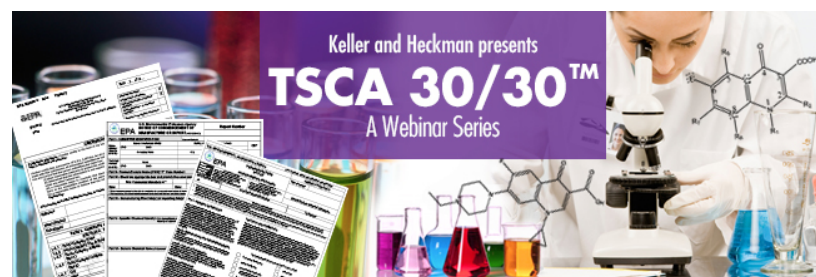
FINAL THOUGHTS



Please join us at 1:00 PM Eastern U.S.
Wednesday, January 25, 2023
www.khlaw.com/OSHA3030



Please join us at 10:00 AM Eastern U.S.
Wednesday, February 8, 2023
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, February 8, 2023
www.khlaw.com/TSCA-3030

Thank You



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