



Fixing TSCA

December 4, 2024

Herb Estreicher

Partner

Washington, DC

+1 202.434.4334

estreicher@khlaw.com

David B. Fischer

Counsel

Washington, DC

+1 202.434.4224

fischer@khlaw.com



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 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 US-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.



David B. Fischer

- ◆ David Fischer counsels clients on environmental, policy, and health and safety matters, with a concentration on the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Having served as the Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention as well as having held senior level positions at the American Chemistry Council, David advocates for clients before the U.S. EPA and provides strategic advice to them regarding issues before Congress.
- ◆ In addition to TSCA and FIFRA, he has experience with numerous other statutes, including the Clean Air Act (CAA), Clean Water Act (CWA), Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), Safe Drinking Water Act (SDWA), Emergency Planning and Community Right-to-Know Act (EPCRA), and the Food Quality Protection Act (FQPA).
- ◆ David's clients include domestic and international industrial and specialty chemical manufacturers, and the trade associations which represent them. Clients seek his assistance on new chemical approvals, and chemical and pesticide risk evaluations and risk management rulemakings because of his deep understanding of EPA, its internal science policy apparatus, and its many organizational pieces that collectively are responsible for all aspects of TSCA and FIFRA.



Why Does TSCA Need Fixing (Again)? (1)

- ◆ Two key TSCA implementation challenges impacting the chemical industry:
 - ◇ Section 5: the need for EPA to make an affirmative determination **before** a new chemical can enter commerce.
 - Many months (sometimes years) vs. statutory 90-180 days
 - Fees have increased, but so has the PMN review timeframe

Why Does TSCA Need Fixing (Again)? (2)



- ◆ In 2016, Congress added a hammer provision to penalize EPA if it fails to meet the statutory deadlines in its review of new chemicals:
 - ◇ “If the Administrator fails to make a determination ... by the end of the applicable review period ..., the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice ..., and the Administrator shall not be relieved of any requirement to make such determination.”
 - To date, this provision has been ineffective.
 - Has anyone asked for a refund or received a refund?

Why Does TSCA Need Fixing (Again)? (3)

- ◆ Updating the New Chemicals Regulations could help, but none of EPA's proposed regulatory changes would move the needle.
 - ◆ OIRA completed its review on December 2nd
 - ◆ EPA likely will issue amended regulations soon
 - ◆ New EPA administration could further amend the rule
 - ◆ The Part 720 petition for rulemaking would be a helpful roadmap
- ◆ Statutory changes are still needed because regulatory fixes may change with different administrations, and those fixes can't fully address the underlying challenges with TSCA itself

Why Does TSCA Need Fixing (Again)? (4)



- ◆ Section 6: “Unreasonable risk” is not defined by TSCA or by EPA, but as applied, it essentially means little if any risk.
- ◆ Once unreasonable risk is determined, EPA must issue a rule to eliminate that risk, even if costs greatly outweigh the benefits of the rule.
- ◆ EPA must “consider” costs and benefits but those considerations don’t override the mandate to eliminate unreasonable risk.

Why Does TSCA Need Fixing (Again)? (5)



- ◆ EPA should revise the risk evaluation procedural rule and develop a new risk management procedural rule in which EPA could explicitly define unreasonable risk, but...
 - ◆ A rule could not address TSCA's unreasonable risk elimination provision
 - ◆ Amending TSCA would still be needed

Fixing TSCA

- ◆ It is not too soon for statutory fixes:
 - ◇ TSCA was amended nearly 10 years ago
 - ◇ We have years of experience with all the amended sections of TSCA through multiple administrations
- ◆ The new Congress presents an opportunity to initiate constructive dialogue to:
 - ◇ Cast the spotlight on TSCA implementation challenges
 - ◇ Develop solutions that facilitate U.S. based manufacturing
 - ◇ Enable EPA to meet its statutory deadlines in an efficient and scientifically sound manner

TSCA Improvement Coalition (1)



- ◆ An informal group of companies and organizations formed in 2024 to discuss and draft legislative fixes to TSCA
 - ◇ Meetings are held virtually
- ◆ Sections 5 and 6 have been the initial focus, but we are amending other provisions as well.

TSCA Improvement Coalition (2)



- ◆ The Coalition will continue to meet throughout next year and potentially longer
- ◆ We are seeking additional company participation
 - ◇ Especially if your company has been actively engaged with TSCA and you have ideas on how TSCA could be amended
- ◆ Please reach out to David Fischer with questions about joining the Coalition



Please join us at 1:00 PM Eastern U.S.
Wednesday, December 11, 2024
www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, January 8, 2025
www.khlaw.com/TSCA-3030



Please join us at 10:00 AM Eastern U.S.
Wednesday, February 12, 2025
www.khlaw.com/REACH-3030

Thank You

Any questions?



Herbert Estreicher, Ph.D.
Partner

Washington, DC

+1 202.434.4334

estreicher@khlaw.com



David B. Fischer, M.P.H.
Counsel

Washington, DC

+1 202.434.4224

fischer@khlaw.com

