



U.S. Goes to War Against Forever Chemicals

November 10, 2021

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



David B. Fischer

- ◆ David Fischer advises 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). In addition, he has extensive 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), the 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. Having held senior level positions with the U.S. Environmental Protection Agency (EPA) and the American Chemistry Council (ACC), clients look to David for his insight and perspective when navigating the myriad of complex environmental regulations
- ◆ Prior to joining Keller and Heckman, David was the Deputy Assistant Administrator (DAA) for the Office of Chemical Safety and Pollution Prevention (OCSPP). During his tenure as DAA, he was deeply involved in TSCA implementation, with a particular focus on risk evaluation and risk management of existing chemicals, and all aspects of FIFRA implementation
- ◆ During his tenure at the American Chemistry Council, David co-managed the Chemical Products and Technology Division (CPTD) where he led the implementation of the Lautenberg Chemical Safety Act



AGENDA

- ◆ Congressional Action
- ◆ EPA's PFAS Roadmap
- ◆ National PFAS Testing Strategy
- ◆ PFAS Section 8 Rulemaking
- ◆ Section 21 PFAS Testing Petition

Congressional Action (1)

- ◆ During the 116th Congress (2019-2021), Congress used the annual processes around the Department of Defense's authorization bill (the National Defense Authorization Act or "NDAA") and government-wide appropriations bills to adopt PFAS-related programs and provisions
- ◆ Congress included in the 2020 NDAA direction to EPA to develop a process for prioritizing which PFAS or classes of PFAS should be subject to additional research efforts

Congressional Action (2)

- ◆ On December 21, 2020, both the House and Senate passed the appropriations spending package for fiscal year 2021, which included several PFAS-related provisions. The legislation was signed into law by President Trump on December 27, 2020
- ◆ The legislation includes a \$44 million appropriation to EPA for PFAS priority actions

EPA'S PFAS Roadmap (1)



- ◆ The risks posed by PFAS demand that the Agency attack the problem on multiple fronts at the same time
- ◆ EPA must leverage the full range of statutory authorities to confront the human health and ecological risks of PFAS

EPA'S PFAS Roadmap (2)

- ◆ Integrated approach to PFAS is focused on three central directives:
 - ◆ **Research** - Invest in research, development, and innovation to increase understanding of PFAS exposures and toxicities, human health and ecological effects, and effective interventions that incorporate the best available science
 - ◆ **Restrict** - Pursue a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment
 - ◆ **Remediate** - Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems

Objectives Relevant to TSCA's Mission (1)



◆ RESEARCH

- ◆ Build the evidence base on individual PFAS and define categories of PFAS to establish toxicity values and methods
- ◆ Increase scientific understanding on the universe of PFAS, sources of environmental contamination, exposure pathways, and human health and ecological effects
- ◆ Expand research on current and emerging PFAS treatment, remediation, destruction, disposal, and control technologies
- ◆ Conduct research to understand how PFAS contribute to the cumulative burden of pollution in communities with environmental justice concerns

Objectives Relevant to TSCA's Mission (2)



◆ RESTRICT

- ◆ Use and harmonize actions under all available statutory authorities to control and prevent PFAS contamination and minimize exposure to PFAS during consumer and industrial uses
- ◆ Place responsibility for limiting exposures and addressing hazards of PFAS on manufacturers, processors, distributors, importers, industrial and other significant users, dischargers, and treatment and disposal facilities
- ◆ Establish voluntary programs to reduce PFAS use and release
- ◆ Prevent or minimize PFAS discharges and emissions in all communities, regardless of income, race, or language barriers

TSCA Specifics in or related to the Roadmap (1)



- ◆ In April 2021, the Agency announced that it would generally expect to deny pending and future LVE submissions for PFAS based on the complexity of PFAS chemistry, potential health effects, and their longevity and persistence in the environment
- ◆ EPA recently launched a stewardship program to encourage companies to voluntarily withdraw previously granted PFAS LVEs

TSCA Specifics in or related to the Roadmap (2)



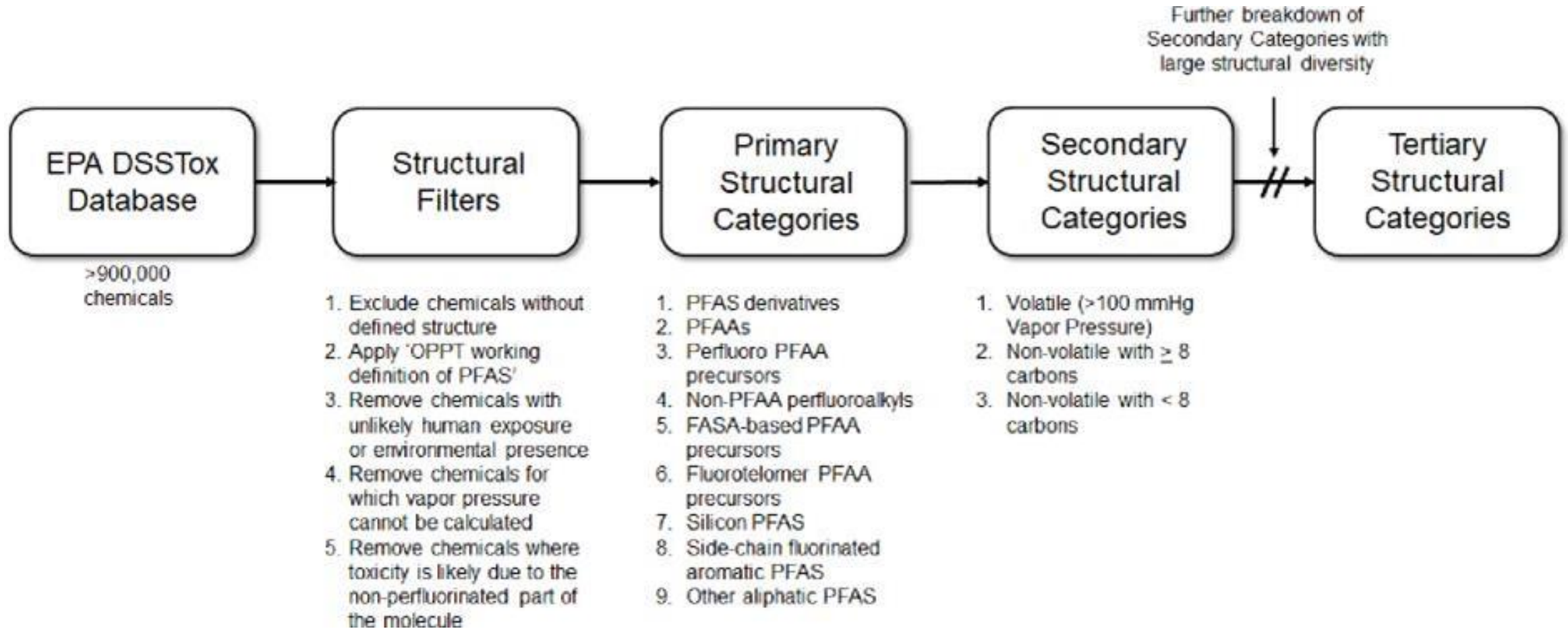
- ◆ EPA plans to issue TSCA Section 5(e) orders for existing PFAS for which significant new use notices have recently been filed with EPA. The orders would impose rigorous safety requirements as a condition of allowing the significant new use to commence
- ◆ EPA is considering how it can apply its SNUR authority to help address abandoned uses of PFAS as well as future uses of PFAS on the inactive portion of the TSCA Inventory

National PFAS Testing Strategy (Published in October 2021)



Candidate PFAS Name
2:1 Fluorotelomer alcohol
Perfluonafene
Octafluorocyclobutane
Perfluorohexane
2H-Perfluoro-5-methyl-3,6-dioxanonane
Perfluoro(2-methyl-3-oxa hexanoyl) fluoride
1H,1H,5H-Perfluoropentanol
3,3,4,4,5,5,6,6,6-Nonafluorohexane-1-sulphonyl chloride
Hexafluoroamylene glycol
2,3,3,3-Tetrafluoro-2-(perfluoroethoxy)propanoyl fluoride
Perfluoropropyl trifluorovinyl ether
2,3,3,3-Tetrafluoro-2-(trifluoromethyl)propanenitrile
3-Methyl-3-[[[(3,3,4,4,5,5,6,6,6-nonafluorohexyl)oxy]methyl]-oxetane
3-(Perfluorohexyl)-1,2-epoxypropane
Perfluoro(N-methylmorpholine)
Trifluoro(trifluoromethyl)oxirane
1H, 1H,2H-Perfluorocyclopentane
Perfluorooctanesulfonyl fluoride
Methyl perfluoro-3-[(perfluoro-3-oxopropan-2-yl)oxy]propanoate
Perfluoro(4-methyl-3,6-dioxaoct-7-ene)sulfonyl fluoride
Nonafluoro-1-iodobutane
Perfluorobutanesulfonyl fluoride
1, 1,2-Trichloro-1,2,2-trifluoroethane
6:2 Fluorotelomer sulfonamide betaine

How EPA got to those 24 PFAS candidates for testing



TSCA Section 8(a)(7) Proposed Rule (1)

- ◆ NDAA FY 2020:

“Not later than January 1, 2023, the Administrator shall promulgate a rule in accordance with this subsection requiring each person who has manufactured a chemical substance that is a perfluoroalkyl or polyfluoroalkyl substance in any year since January 1, 2011, to submit to the Administrator a report that includes, for each year since January 1, 2011, the information described in subparagraphs(A) through (G) of paragraph (2).”

- ◆ EPA has stated that it intends to finalize the rule before the end of 2022

TSCA Section 8(a)(7) Proposed Rule (2)



- ◆ EPA interpreted the statutory language as a “stand alone” provision, unfettered by any of the standard reporting exemptions (e.g., articles, small business)
- ◆ As currently proposed, the rule would subject an unquantified number of manufacturers (including importers) to furnish an unprecedented amount of data, starting from 2011, on an unknown number of PFAS
- ◆ The proposed rule attracted comments from a large swath of affected stakeholders, including chemical companies and numerous trade associations, as well as:
 - ◆ Small Business Administration
 - ◆ Environmental organizations, water utilities and states

TSCA Section 8(a)(7) Proposed Rule (3)



- ◆ Comment themes of Industry:
 - ◇ Exemptions should apply
 - ◇ Limit the scope of reportable PFAS
 - ◇ De minimis reporting threshold
 - ◇ Expand time for reporting
 - ◇ Phase in reporting

TSCA Section 8(a)(7) Proposed Rule (4)



- ◆ Comment themes of ENGOs and Water Utilities:
 - ◇ Supportive of the rule
 - ◇ Expand definition of PFAS to reflect OECD definition
- ◆ Comment themes of the Small Business Administration:
 - ◇ EPA improperly certified the proposed rule as **not** having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA)
 - ◇ EPA must conduct a small business advocacy review panel, pursuant to the RFA

TSCA Section 21 PFAS Testing Petition

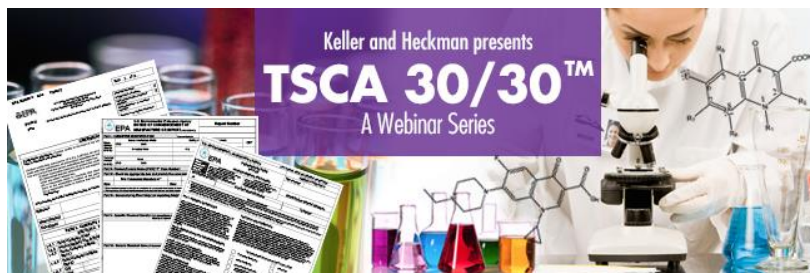


- ◆ Petition filed by Center for Environmental Health and numerous North Carolina based organizations requesting that EPA compel Chemours to:
 - ◆ Initiate health and environmental effects testing under TSCA section 4 on 54 PFAS manufactured by Chemours at its Fayetteville, NC facility
 - ◆ Initiate an epidemiological study on the potential impacts of PFAS
 - ◆ Fund and carry out the testing under the direction of the National Academy of Sciences

TSCA Section 21 PFAS Testing Petition



- ◆ EPA denied the petition because petitioners failed to “set forth the facts which it is claimed establish that it is necessary” to initiate testing
- ◆ Petitioners filed a request for reconsideration of the denial
- ◆ Petitioners filed suit against EPA for its initial denial in the U.S. District Court for the Northern District of California
- ◆ EPA granted the request for reconsideration
- ◆ The Parties to the litigation stipulated to holding the case in abeyance for 90 days – until the end of December 2021 - while EPA completes its reconsideration of the petition’s denial and decides whether to grant or deny the petition



Please join us at 1:00 PM Eastern U.S.
Wednesday, December 8, 2021
www.khlaw.com/TSCA-3030



Please join us at 1:35 PM Eastern U.S.
Wed. December 8, 2021
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, Nov. 17, 2021
www.khlaw.com/OSHA3030

Thank You

**NEXT TSCA 30/30
and REACH 30/30
December 8, 2021**

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