



# PFAS Test Orders, SNURS, Litigation, and Other Challenges

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Herb Estreicher

Partner

Washington, DC

202.434.4334

[estreicher@khlaw.com](mailto:estreicher@khlaw.com)

David B. Fischer

Counsel

Washington, DC

202.434.4224

[fischer@khlaw.com](mailto: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 an 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.



# EPA's PFAS Roadmap



- ◆ Administrator Regan created a PFAS Council, comprised of representatives from EPA's program and regional offices
- ◆ The Council developed a PFAS Roadmap to guide the Agency's activities in 2021-2024 to research, restrict, and remediate harmful PFAS
- ◆ Under former EPA Administrators Pruitt and Wheeler, EPA issued the first PFAS Strategy document, which set the stage for the subsequent Roadmap

# PFAS Roadmap

Includes regulatory and administrative actions and enforcement approaches to address PFAS Goals

## 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

# PFAS Definition (1)

- ◆ The Roadmap does not delineate a single EPA-wide PFAS definition
  - ◇ EPA offices can develop their own definitions:
    - EPA's Office of Water issued the Contaminant Candidate List 5 (CCL5), a list of contaminants that are not currently subject to any proposed or promulgated national primary drinking water regulations but are known or anticipated to occur in public water systems



# PFAS Definition (2)

- ◆ CCL5 PFAS definition:
  - ◆  $R-(CF_2)-CF(R')R''$ , where both the  $CF_2$  and  $CF$  moieties are saturated carbons, and none of the  $R$  groups can be hydrogen
  - ◆  $R-CF_2OCF_2-R'$ , where both the  $CF_2$  moieties are saturated carbons, and none of the  $R$  groups can be hydrogen or
  - ◆  $CF_3C(CF_3)RR'$ , where all the carbons are saturated, and none of the  $R$  groups can be hydrogen

# PFAS Definition (3)

- ◆ EPA's Office of Pollution Prevention and Toxics (within the Office of Chemical Safety and Pollution Prevention (OCSPP)) has a "working definition" when identifying PFAS: a structure that contains the unit  $R-CF_2-CF(R')(R'')$ , where R, R', and R'' do not equal "H" and the carbon-carbon bond is saturated
- ◆ But note that the recently proposed SNUR for inactive PFAS on the TSCA Inventory uses a broader PFAS definition (88 Fed. Reg. 4937)



# EPA's National PFAS Testing Strategy (1)



- ◆ Congress directed EPA in the 2020 National Defense Authorization Act to develop a process for prioritizing which PFAS or classes of PFAS should be subject to additional research efforts based on potential for human exposure to, toxicity of, and other available information
- ◆ The National PFAS Testing Strategy describes EPA's approach for identifying candidate PFAS for which EPA plans to require companies to perform testing using its TSCA section 4 authority

# EPA's National PFAS Testing Strategy (2)



- ◆ The Strategy is based on an approach that groups similar PFAS into categories based on structure
  - ◇ EPA's application of the category approach is consistent with the TSCA mandate to reduce and replace the use of vertebrate animals in the testing of chemicals under section 4(h)
  - ◇ The use of a tiered approach to identify specific testing for the candidate PFAS is also consistent with section 4(h)
- ◆ To date, two test orders have been issued:
  - ◇ Trifluoro (trifluoromethyl) oxirane (HFPO)
  - ◇ 6:2 Fluorotelomer sulfonamide betaine

# EPA's National PFAS Testing Strategy (3)



- ◆ EPA anticipates issuing 75 test orders per year in FY 2023 – 2025; 45 of these test orders per year will be PFAS
- ◆ Note that the White House Office of Science and Technology Policy (OSTP) established an interagency working group to coordinate federal activities related to PFAS research and development
  - ◇ Tasked with developing a strategic plan for federal support for PFAS research

# Abridged Appendix A: List of PFAS Candidates for Testing (1)



<b>CASRN</b>	<b>Candidate PFAS Name</b>
422-05-9	2:1 Fluorotelomer alcohol
306-94-5	Perflunafene
115-25-3	Octafluorocyclobutane
335-42-0	Perfluorohexane
3330-14-1	2H-Perfluoro-5-methyl-3,6-dioxanonane
2062-98-8	Perfluoro(2-methyl-3-oxahexanoyl) fluoride
355-80-6	1H,1H,5H-Perfluoropentanol
27619-88-1	3,3,4,4,5,5,6,6,6-Nonafluorohexane-1-sulphonyl chloride
376-90-9	Hexafluoroamylene glycol
1682-78-6	2,3,3,3-Tetrafluoro-2-(perfluoroethoxy)propanoyl fluoride

# Abridged Appendix A: List of PFAS Candidates for Testing (2)



<b>CASRN</b>	<b>Candidate PFAS Name</b>
1623-05-8	Perfluoropropyl trifluorovinyl ether
42532-60-5	2,3,3,3-Tetrafluoro-2-(trifluoromethyl)propanenitrile
475678-78-5	3-Methyl-3-[[[(3,3,4,4,5,5,6,6,6-nonafluorohexyl)oxy]methyl]-oxetane
38565-52-5	3-(Perfluorohexyl)-1,2-epoxypropane
382-28-5	Perfluoro(N-methylmorpholine)
428-59-1	Trifluoro(trifluoromethyl)oxirane
15290-77-4	1H, 1H,2H-Perfluorocyclopentane
307-35-7	Perfluorooctanesulfonyl fluoride
69116-72-9	Methyl perfl oro-3-[(perfluoro-3-oxop ropan-2-yl)oxy]propanoate

# Abridged Appendix A: List of PFAS Candidates for Testing (3)



<b>CASRN</b>	<b>Candidate PFAS Name</b>
16090-14-5	Perfluoro(4-methyl-3,6-dioxaoct-7-ene)sulfonyl fluoride
423-39-2	Nonafluoro-1-iodobutane
375-72-4	Perfluorobutanesulfonyl fluoride
76-13-1	1,1,2-Trichloro-1,2,2-trifluoroethane
34455-29-3	6:2 Fluorotelomer sulfonamide betaine

# TSCA Inventory Reset

- ◆ TSCA requires EPA to designate chemical substances on the TSCA Inventory as either “active” or “inactive” in U.S. commerce
- ◆ To accomplish that, EPA finalized a rule requiring reporting of chemicals manufactured (including imported) or processed in the U.S. over a ten-year period ending on June 21, 2016
- ◆ There are approximately 45,500 inactive chemicals on the TSCA Inventory
- ◆ Inactive chemicals can be reactivated by filing a simple notice (Form B) with EPA prior to manufacture/import or processing
- ◆ The reactivation notice does not trigger a Section 5 review



# EPA Proposed SNUR for Inactive PFAS Substances



- ◆ On Jan. 26, 2023, EPA proposed a Significant New Use Rule (SNUR) to block companies from manufacturing, importing, or processing over 300 PFASs listed on the TSCA Inventory as inactive (88 Fed. Reg. 4937)
- ◆ EPA is accepting comments on the proposal until March 27, 2023
- ◆ The category of PFAS that would be covered by the rule as those that are: (1) listed on the TSCA Inventory as inactive as of Jan. 26, 2023, (2) not already subject to another individual or categorical PFAS SNUR (e.g., 40 C.F.R. §§ 721.9582 (certain perfluoroalkyl sulfonates) and 721.10536 (long-chain perfluoroalkyl carboxylate chemical substances), and (3) containing one or more of the following structures:
  - ◆  $R-(CF_2)-CF(R')R''$ , where both the  $CF_2$  and  $CF$  moieties are saturated carbons;
  - ◆  $R-CF_2OCF_2-R'$ , where  $R$  and  $R'$  can either be  $F$ ,  $O$ , or saturated carbons; or
  - ◆  $CF_3C(CF_3)R'R''$ , where  $R'$  and  $R''$  can either be  $F$  or saturated carbons

# Exemptions

- ◆ Even if a PFAS meets the definitional criteria, a company's specific use may still be exempt from the proposed SNUR if it meets any of the standard SNUR exemptions
- ◆ These include substances:
  - ◆ Manufactured for R&D
  - ◆ Manufactured as impurities, or as a byproduct that is burned as fuel or disposed of as waste, or solely for export
  - ◆ Imported or processed as part of an article

# Areas for Comment

- ◆ Comments about ongoing uses of inactive PFAS including activities exempt from the Active-Inactive Rule that entities believe would not be covered by the general SNUR exemptions
- ◆ The Active-Inactive Rule includes an exemption from notification for the manufacturing or processing of any byproduct that is not used for commercial purposes
  - ◇ There is no such broad exemption for byproducts in the SNUR regulations
- ◆ 30 of the inactive substances are on the confidential inventory and the generic names do not contain “fluor” or “fluorine”
- ◆ What is the best way to identify these?

# What is the Problem?

- ◆ EPA justifies the proposed SNUR because the substances are not currently in commerce and any reintroduction would increase exposure
- ◆ In principle, that same rationale could justify SNURS for all 45,500 inactive chemicals on the TSCA Inventory
- ◆ Congress specifically provided that a chemical on the inactive inventory could not be delisted and a reactivated chemical could not be subject to PMN review by reason of a change to active status
- ◆ However, Congress said nothing about SNURing such chemicals
- ◆ NGOs now want EPA to extend the SNUR to also include products that 3M recently announced it will phase out

# PFAS TSCA Litigation

- ◆ EPA filed an action under TSCA Section 17(a) and the Declaratory Judgment Act, 28 U.S.C. § 2201, to obtain declaratory and injunctive relief against a manufacturer alleged to violate TSCA by fluorinating containers in violation of a SNUR
- ◆ NGOs filed a Section 20 citizen's suit against the same manufacturer
- ◆ One issue is: whether the PFAS formed are exempt impurities or non-exempt byproducts
- ◆ Another issue is: what is a new use?
- ◆ We discussed this issue at length in our [October 2022 TSCA 30/30](#)

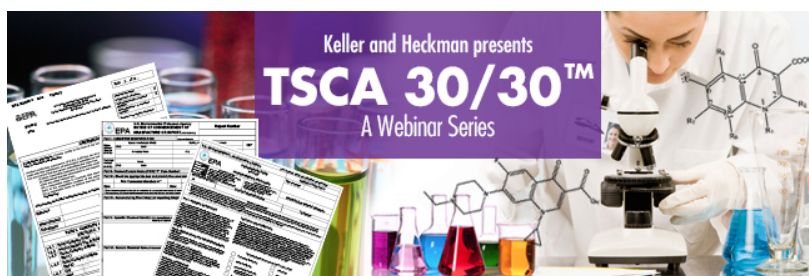
# Further Thoughts



Please join us at 10:00 AM Eastern U.S.  
Tuesday, February 14, 2023  
[www.khlaw.com/REACH-3030](http://www.khlaw.com/REACH-3030)



Please join us at 1:00 PM Eastern U.S.  
Wednesday, February 22, 2023  
[www.khlaw.com/OSHA3030](http://www.khlaw.com/OSHA3030)



Please join us at 1:00 PM Eastern U.S.  
Wednesday, April 12, 2023  
[www.khlaw.com/TSCA-3030](http://www.khlaw.com/TSCA-3030)



Thank You



Herbert Estreicher  
Partner

Washington, DC

202.434.4334

[estreicher@khlaw.com](mailto:estreicher@khlaw.com)



David B. Fischer  
Counsel

Washington, DC

202.434.4224

[fischer@khlaw.com](mailto:fischer@khlaw.com)

