



The Global Regulatory Posture of Per-and-Poly Fluorinated Chemicals

September 21, 2022

James Eggenschwiler, JD, Esq.

Principal, Global Trade & Chemical Regulation Services



SafeBridge® Regulatory
& Life Sciences Group

PFAS Industry Usage



- ▶ **Pulp and Paper:**
 - Adds grease and water resistance
- ▶ **Firefighting foam:**
 - Usage of foam at airports, terminals, refineries, chemical manufacturing, etc.
- ▶ **Semiconductors:**
 - Mainly in photolithography, other usages exist
- ▶ **High performance coatings**
- ▶ **Aerospace and automotive components**
- ▶ **Plastics, resins, rubber, adhesives**

What constitutes “PFAS” in the U.S.?

- ▶ Pursuant to recent EPA publications and staff comments, any molecule that contains:
 - (i) at least two per-fluorinated carbons;
 - (ii) that are adjacent to each other;
 - Constitutes “PFAS” for EPA regulatory purposes.
- ▶ However, the “adjacency” of the two perfluorinated carbons is an essential factor

What constitutes “PFAS” in the U.S.?

- ▶ Example 1: Illustrating EPA’s comments

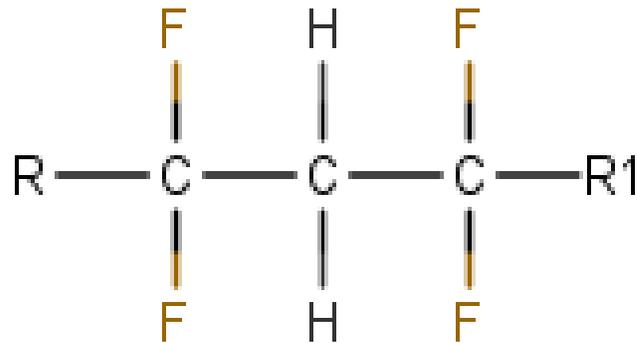
PFAS: if R2 = F



What constitutes “PFAS” in the U.S.?

- ▶ Example 2: Illustrating EPA’s comments

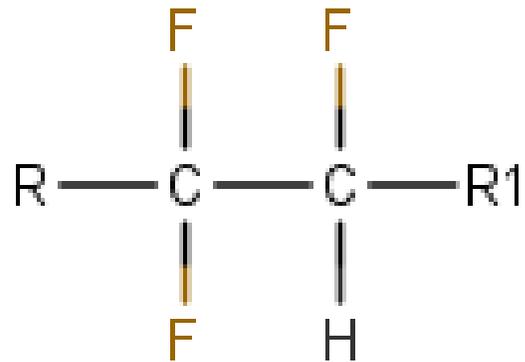
Not PFAS: No Adjacency



What constitutes “PFAS” in the U.S.?

- ▶ Example 3: Illustrating EPA’s comments

Not PFAS: Only one Fluorinated Carbon



What constitutes “PFAS” in Europe and OECD Jurisdictions?

► Contrast with Europe/OECD

- In Europe, a single perfluorinated carbon appearing in a chemical structure meets the definition of “PFAS” for regulatory purposes
- Using the same example structures, Example 1 using the European definition:

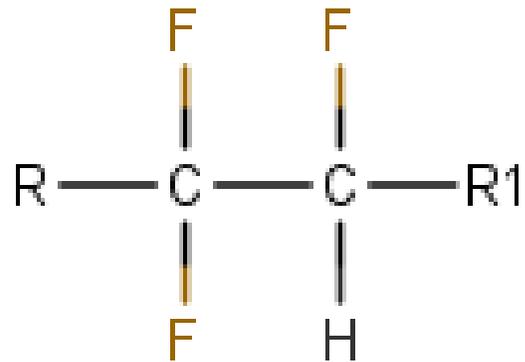
PFAS: Regardless of R2 Identity



What constitutes “PFAS” in Europe?

- ▶ Example 3: Illustrating European/OECD definition

PFAS: Only one perfluorinated carbon is needed



PFAS Categorized: Chain Length & Properties

- ▶ “Long Chain” = 6 fluorinated carbons or more
 - ▶ “Short Chain” = 7 fluorinated carbons or less
 - ▶ Solubility decreases as carbon-chain length increases.
- **Shorter-chain:** more likely to dissolve in water and to be more mobile in the environment.
 - **Longer-chain:** attach better to organic carbons (soils) and can accumulate and be transported by particulate matter.

Perfluorinated Polymers

- ▶ So far, EPA holds that a single perfluorinated carbon structure in the polymer, or chains with the absence of adjacency, do not constitute "PFAS" for EPA regulatory purposes
- ▶ The European and OECD view is that a single perfluorinated carbon structure in polymers **do** cause the polymers to constitute "PFAS"

EPA “Requested Withdrawal” of PFAS LVEs

- In **July of 2021** EPA separately “encouraged” the “voluntary” withdrawal of more than **600** approved Low Volume Exemptions (LVEs) by US manufacturers that hold them, and EPA is “encouraging” these manufacturers to submit Pre-Manufacture Notices (PMNs) for these substances;
- EPA ultimately offered an incentive to allow sell-off of remaining inventories.
- U.S. EPA New Chemicals Division implemented a new policy in 2021 that no PMNs will receive a “not likely to present unreasonable risks” determination, and that all new chemical determinations will result in a Consent Order (CO) and Significant New Use Rule (SNUR);
- U.S. manufacturers who voluntarily withdraw current LVEs will likely experience an eight (8) to twelve (12) month PMN process (**NOW 12 to 18+ months**), in addition to related data development time needed prior to PMN submittal.

Global Trade Implications Posed by Differing Regulatory Definitions Concerning “PFAS”

- ▶ Other U.S. Commercial Impact Based on U.S. vs. EU/OECD “PFAS” Definition
 - Based on TSCA Inventory and Federal Register information, there are more than 1,500 “PFAS” substances in the U.S.;
 - Europe reports more than 4,700 discreet PFAS substances, not counting PFAS polymers;
 - Based on the differences in “PFAS” regulatory standards, European “PFAS” export products are more likely to qualify for US market eligibility, than will U.S. “PFAS” export products exported to Europe.

Global Trade Implications Posed by Differing Regulatory Definitions Concerning “PFAS”

- ▶ Other U.S. EPA Newly Announced Regulatory Requirements Concerning “PFAS” Substances Released to Water:
 - On September 8, 2021, EPA separately announced that it will be initiating three new rulemakings (two of which concern “PFAS” substances) after concluding several studies that were discussed in Effluent Guidelines Program Plan 14.
 - The new Effluent Guidelines Program Plan 15 will address the following “PFAS” categories:
 - ❖ (i) Organic Chemicals, Plastics and Synthetic Fibers category to address per- and polyfluoroalkyl substances (PFAS) discharges from facilities manufacturing PFAS; and,
 - ❖ (ii) Metal Finishing category to address PFAS discharges from chromium electroplating facilities.

The EPA Proposed Recordkeeping and Reporting Rule

- ▶ If and when adopted and effective, the Rule will apply independently and **without regard to** the current TSCA section **8(a)(1) (Recordkeeping and Reporting)**;
- ▶ “**Small**” manufacturers are not exempt from reporting;
- ▶ Reporting of information is required to the extent that the information is known to or **reasonably ascertainable by** the manufacturer;
- ▶ “Known to or reasonably ascertainable by” is defined to include “all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know”;
- ▶ Manufactured “byproducts” **are included**;
- ▶ Includes **articles** containing PFAS (including imported articles).

EPA adds PFAS to TRI Reportable Chemicals

- ▶ Action in [Dec. 2019 and Feb. 2020](#) added [172 new](#) PFAS chemicals. Reportable in RY2020.
- ▶ De minimis concentrations:
 - 0.1% for PFOA (CAS 3335-67-1)
 - 1% for all other PFAS
- ▶ Manufacturing, processing, otherwise use threshold of 100 lbs for each individual PFAS
- ▶ **All TRI chemicals are required to be on the SDS per 40 CFR 372.45(a) and §372.45(c)(5)**
 - New SDS or supplier documentation may need to be requested to contain new reportable chemicals, or have the supplier declare that the chemicals are not present.

QUESTIONS?

Contact Us for More Insight or Regulatory Assistance



James Eggenschwiler, J.D., Esq.

Principal, Global Trade and Chemical Regulations
Services – Westerville, Ohio

James.Eggenschwiler@safebridge.com

P: 614.568.8854 M: 614.599.8250

U.S. TSCA Compliance, Risk Evaluations

Global REACH Product Stewardship

Supply Chain & 3rd Party Risk Mitigation



SafeBridge® Regulatory
& Life Sciences Group