PFAS TSCA Workshop: Overview of the National PFAS Testing Strategy

February 13th, 2024

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Outline

- Toxic Substances Control Act
- Overview of the National PFAS Testing Strategy
- Chemical curation
- Chemical grouping
- Data gathering
- Candidate selection
- Issued Test Orders

Toxic Substances Control Act (TSCA)

The federal statute that provides EPA with the authority to require testing, reporting of data, and record-keeping and mandates EPA's review of chemicals and imposing of restrictions relating to chemical substances and/or mixtures, as appropriate.

- TSCA section 4 – Test Rules and Orders to require development of new information
- TSCA section 5 – New Chemicals
- TSCA section 6 – Existing Chemicals
- TSCA section 8 – Data Reporting of extant information such as uses, production volumes, processes, etc.

TSCA Section 4

- Authorizes EPA to require chemical manufacturers (including importers) and processors to develop new information on chemicals and submit such information to EPA via Test Order, Rule, or Enforceable Consent Agreement
- Per TSCA section 4(a)(1) the following findings must be made:
  - Insufficient information exists, testing is necessary to get that information, and
  - The chemical substance **may present unreasonable risk**, or
  - The chemical substance is produced in substantial quantities and may cause substantial or significant exposures to the environment or humans.
- **PFAS Test Orders have been using section 4(a)(1)** as the basis for the actions
- TSCA section 4(a)(2) has other provisions for which EPA can issue a Test Order
  - For example, to inform TSCA section 5 or 6 activities
- Other considerations required in section 4 actions include:
  - Using a tiered testing approach
  - Reducing testing on vertebrates

Overview of National PFAS Testing Strategy (NTS)

The Problem: Per- and polyfluoroalkyl substances (PFAS) are an extremely large, diverse class of chemicals with large data gaps, making these substances challenging to regulate.

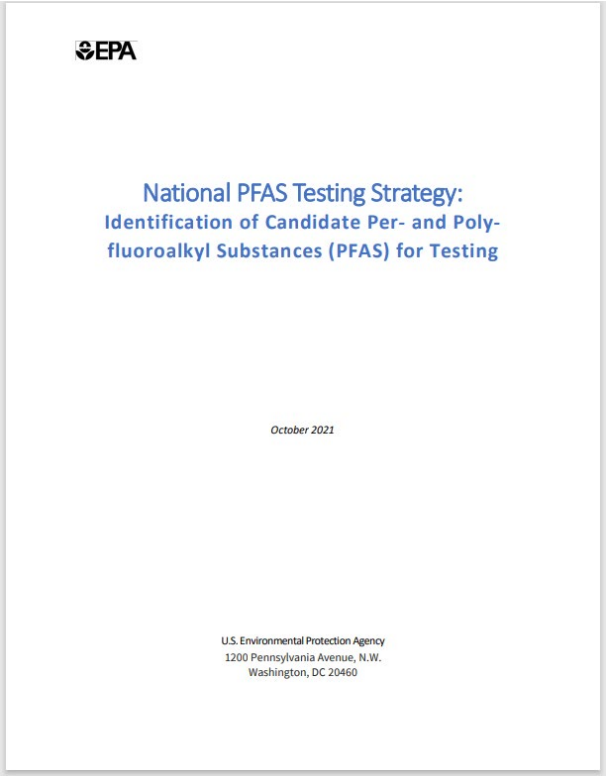
- Depending upon the definition, PFAS class can include 10,000+ substances
- Manufactured and used since the 1940s for a variety of uses
- Many PFAS are extremely persistent in the environment and can bioaccumulate
- A few have been well-studied (e.g., perfluorooctanoic acid [PFOA] and perfluorooctanesulfonic acid [PFOS]), and these provide evidence that exposure to these substances can lead to acute and chronic health outcomes
- **The majority of substances lack toxicity data**
- Limited monitoring data contributes to uncertainty in the understanding of exposure

Overview of NTS

Purpose of the National PFAS Testing Strategy (NTS)

- Group similar PFAS into categories
- Identify representative substances within those categories
- Compile available information on all PFAS
- Use EPA's authority under Section 4 of TSCA to require testing on representative substances of the data-poor categories

The information will be used to inform the Agency's future research, monitoring and regulatory efforts and support the use of read-across to other substances within a category, where appropriate.

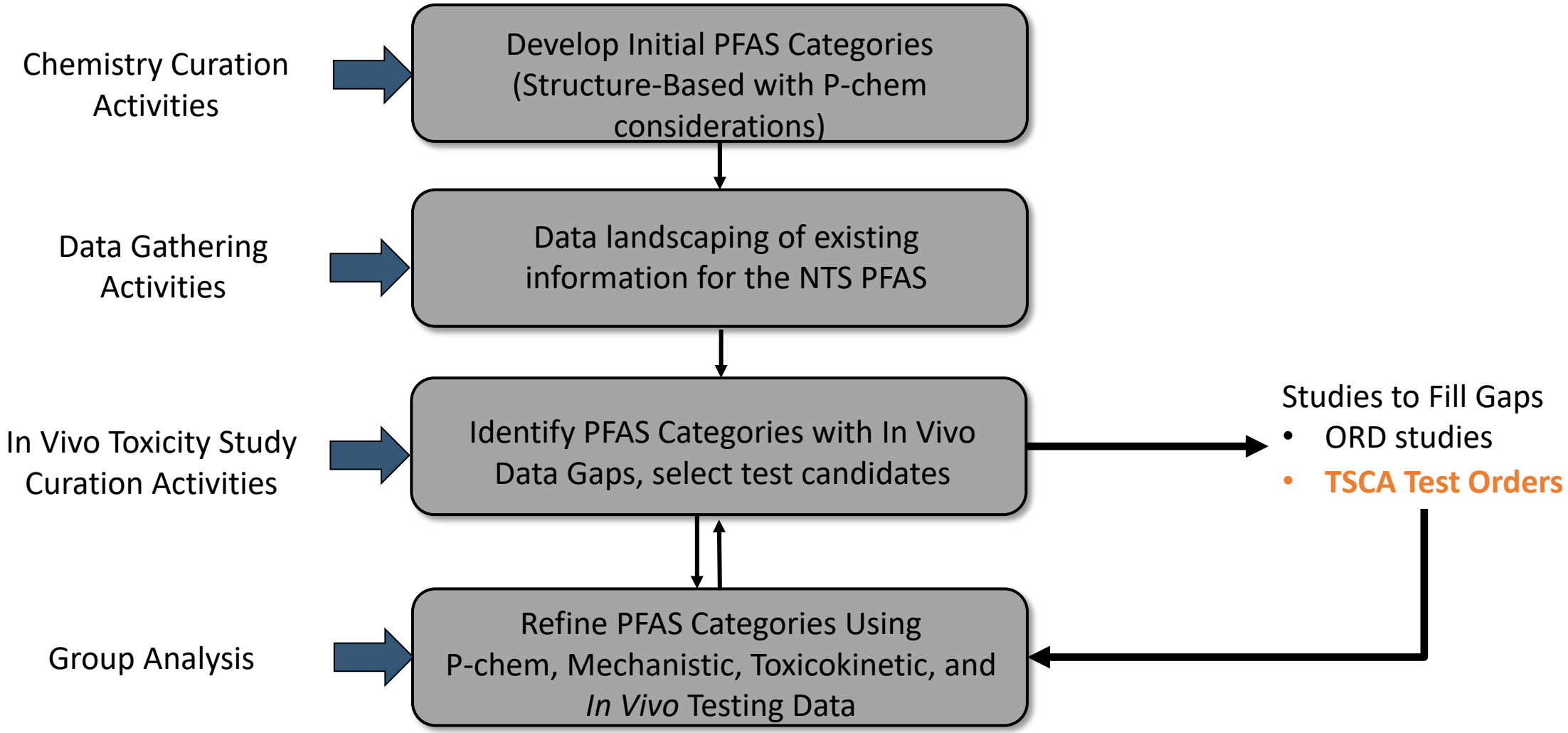

EPA

National PFAS Testing Strategy:
Identification of Candidate Per- and Poly-fluoroalkyl Substances (PFAS) for Testing

October 2021

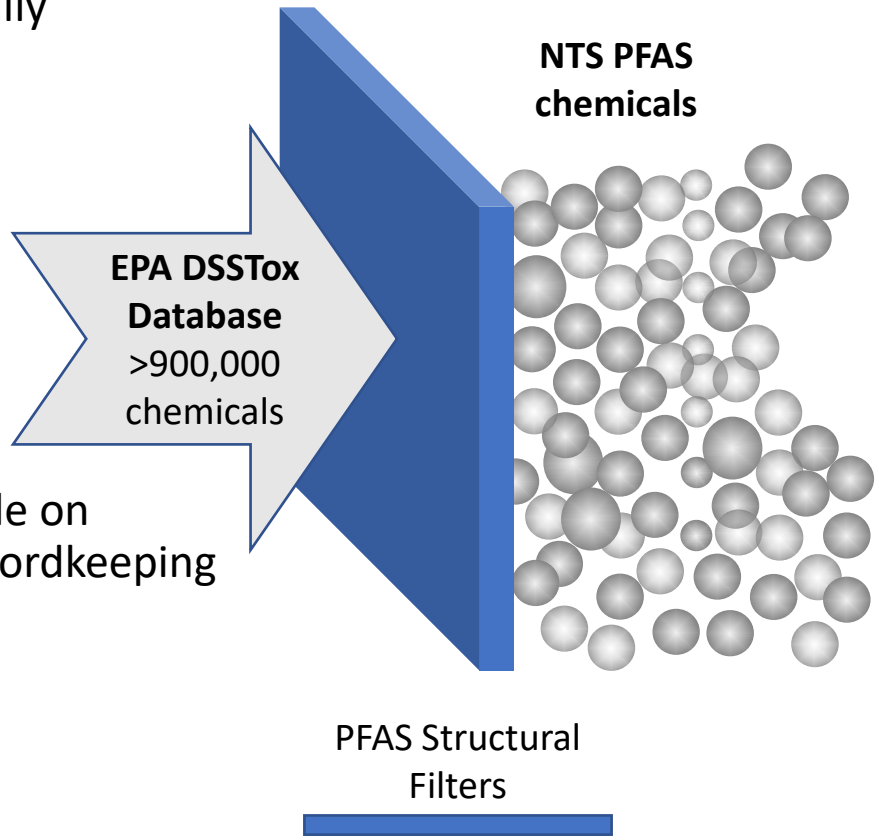
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Overview of the NTS Process



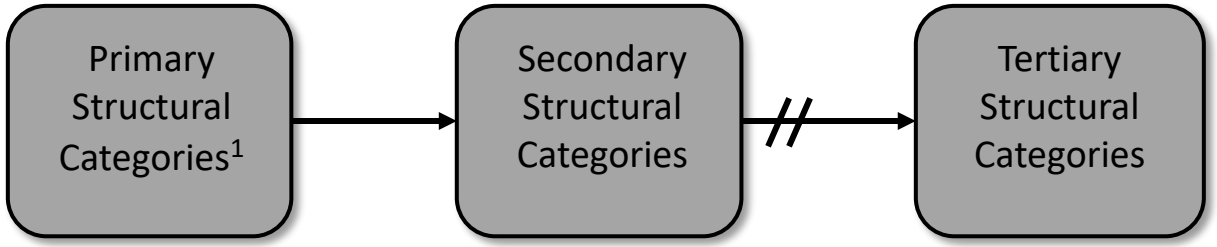
Chemistry curation – PFAS included in the NTS

- Initial NTS PFAS **~6,500**
  - 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
  - Chemicals with at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated
- Updated TSCA / NTS PFAS **~12,500 + ~3,000 predicted degradants**
  - Substances that meet any of the following criteria:
    (i) R-(CF_2)-CF(R')R", where both the CF_2 and CF moieties are saturated carbons
    (ii) R-CF_2OCF_2-R', where R and R' can either be F, O, or saturated carbons
    (iii) $CF_3C(CF_3)$R'R", where R' and R" can either be F or saturated carbons
  - Consistent with the recent definition proposed in a Significant New Use Rule on inactive TSCA inventory PFAS (88 FR 4937) and the TSCA Reporting and Recordkeeping Requirements for PFAS rule (88 FR 70516)
- Filtering for NTS
  - Did not include substances with undefined structures
  - Eliminated substances where toxicity was likely not due to the fluorination



Chemical Grouping– development of the PFAS categories

- Detailed presentation by Dr. Grace Patlewicz on Day 2
- EPA used computer software developed by Su and Rajan[1] to assign the starting list of PFAS into **nine primary categories** based on their structure
- PFAS that did not meet the conditions of membership for one of the primary categories were placed into an "**Others**" category
- Additional structural filters further grouped similar compounds
- Result was 90 terminal categories
- Numbers of PFAS in each terminal category ranges



1. PFAS derivatives
2. PFAAs
3. Perfluoro PFAA precursors
4. Non-PFAA Perfluoroalkyls
5. FASA-based PFAA Precursors
6. Fluorotelomer PFAA precursors
7. Silicon PFAS
8. Side-chain fluorinated aromatic PFAS
9. Other aliphatic PFAS

(10. Others)

Carbon chain length cutoff

Tertiary categorization performed only on Secondary Categories with structural diversity greater than a defined threshold

[1]Su, A., Rajan, K. A database framework for rapid screening of structure-function relationships in PFAS chemistry. Sci Data 8:14, 2021

Data Gathering Activities– data landscaping of existing information

- For all discrete substances identified for the NTS grouping effort, two primary sources were searched to compile available information relevant to human health hazard
- Additional effort to compile physical-chemical property information- experimental and predicted by OPERA[2]

Data sources

a. ToxValDB[3] - public

b. TSCA Chemical Information System

Human Health-relevant study categories

a. Acute
b. Subchronic
c. Chronic including Cancer Bioassays
d. Developmental
e. Reproductive
f. Immunotoxicity
g. Neurotoxicity
h. Toxicokinetics
i. Genotox/Mutagenicity
j. Sensitization/Irritation
k. (biomonitoring)

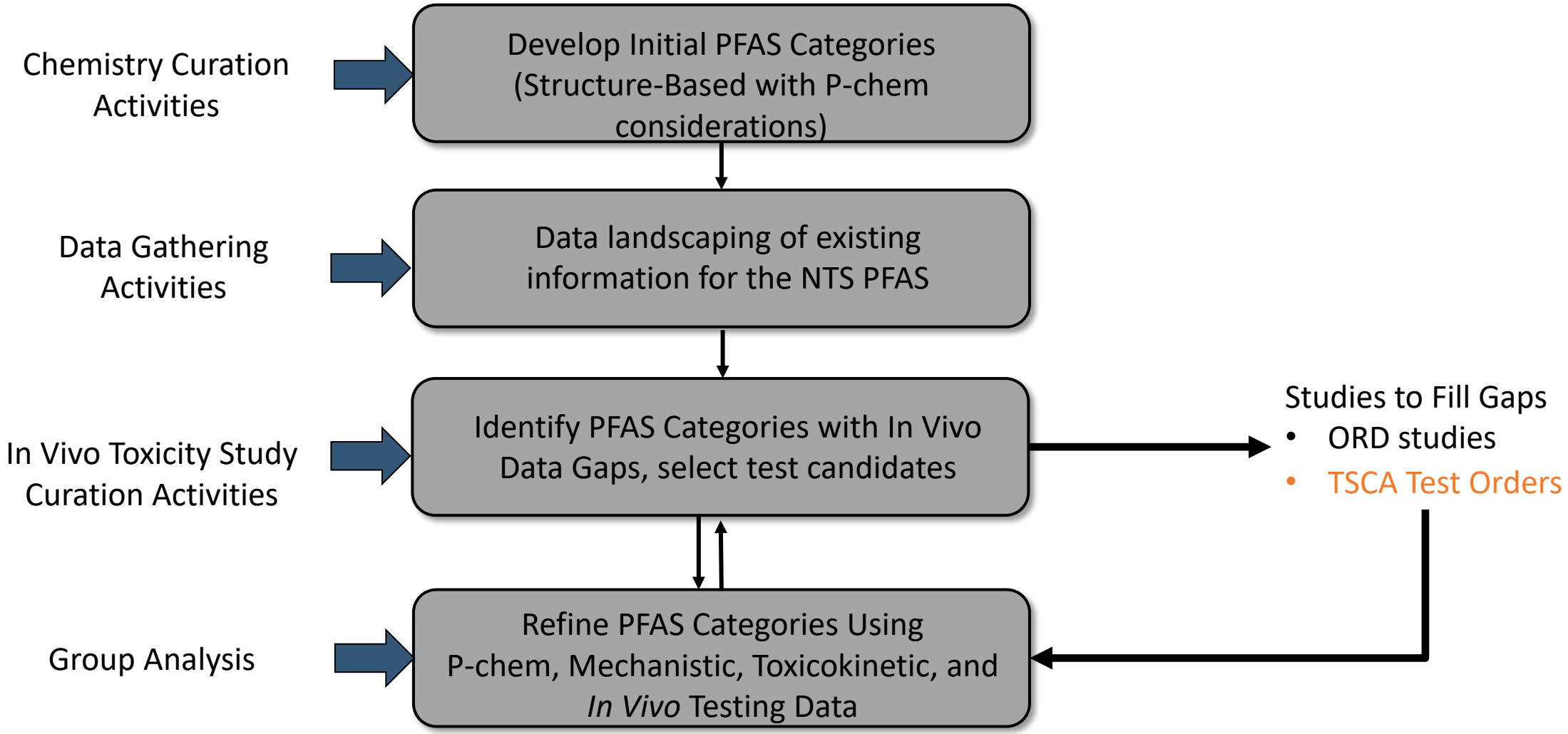
Physical Chemical property information

a. Boiling point
b. Melting point
c. Vapor Pressure
d. pKa
e. Water solubility
f. Kow
g. Hydrolysis

[2] Mansouri K, Grulke CM, Judson RS, Williams AJ. OPERA models for predicting physicochemical properties and environmental fate endpoints. J Cheminform. 2018 Mar 8;10(1):10

[3] Data is accessible from EPA's CompTox Chemicals Dashboard www.epa.gov/comptox-tools/comptox-chemicals-dashboard

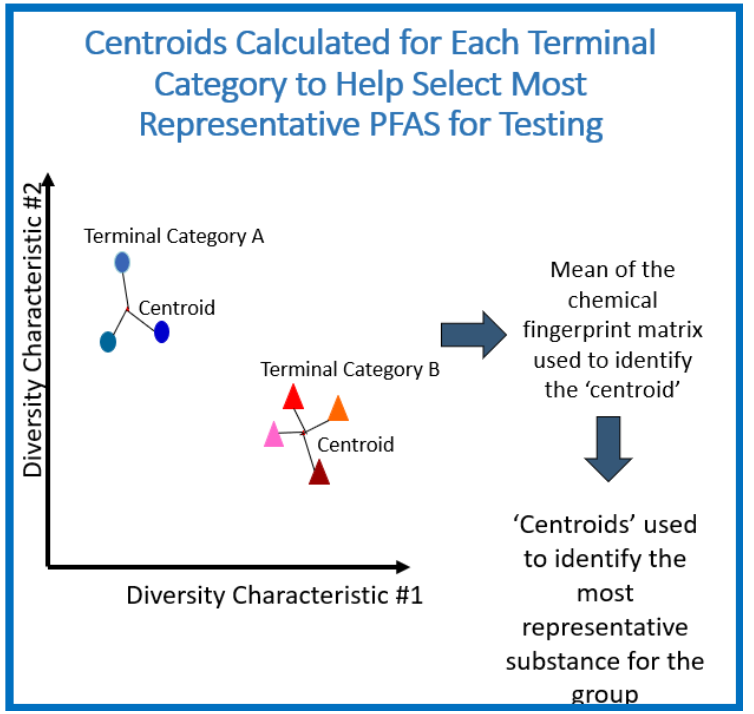
Overview of the NTS Process



Candidate Selection

Factors considered in selecting PFAS for Testing (TSCA Section 4 Test Orders)

- Inventory status / availability of a recipient
- Data poorness of terminal category
  - First phase of NTS is focused on human health-related toxicity concerns
  - Looked at availability of in vivo rodent study information
- Known or suspected exposure concerns
  - Chemical Data Reporting (CDR)
  - Monitoring information
- Representativeness of members of its structural category
  - To be described in detail in later presentation by Dr. Patlewicz
- Other EPA program data needs
- Predicted or known physical state

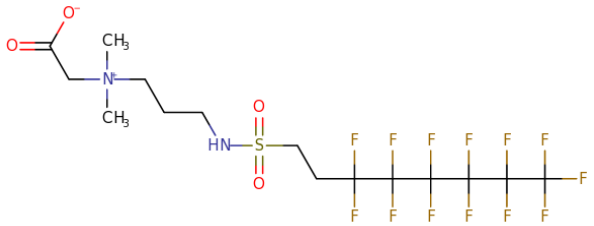


Test Orders

EPA has issued 3 PFAS Test Orders (and another is imminent):

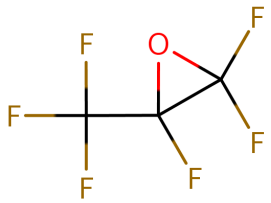
6:2 Fluorotelomer sulfonamide betaine (6:2 FTSB)

- CASRN 34455-29-3
- Surface-active agent
- Used in fire-fighting foams
- Yearly production > 25,000 lbs



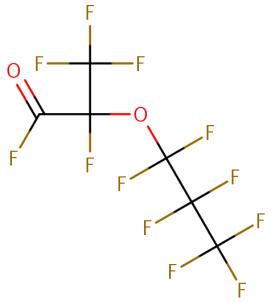
Trifluoro(trifluoromethyl)oxirane (HFPO)

- CASRN 428-59-1
- Epoxide gas
- Reaction intermediate
- Yearly production > 1M lbs



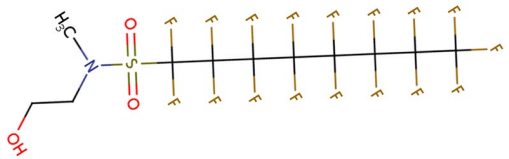
2,3,3,3-tetrafluoro-2-heptafluoropropoxy) propanoyl fluoride (HFPO-DAF)

- CASRN 2062-98-8
- Precursor for GenX
- Yearly production > 1M lbs



1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-Heptadecafluoro-N-(2-hydroxyethyl)-N-methyloctane-1-sulfonamide (NMeFOSE)

- CASRN 24448-09-7
- Found in biosolids, environmental media, indoor dust



Testing details for these test order PFAS be discussed in the next presentation by Dr. Martin Phillips