A Critical Review of the Application of Polymer of Low Concern and Regulatory Criteria to Fluoropolymers

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Overview  Per- and Polyfluoroalkyl Substances (PFAS)

Thousands of PFAS with a wide variety of properties

Similarities

1 fully fluorinated carbon

Differences

- **Stability**: seconds ↔ thousands of years
- **Toxicity**: low ↔ high
- **Mobility**: insoluble / non-volatile ↔ Highly mobile
- **Size**: MW less than 1,000 Daltons ↔ MW multi-million Daltons

- Gases
- Liquids
- Solids
Overview Per- and Polyfluoroalkyl Substances (PFAS)

1 Group

PFAS Per- and Polyfluoroalkyl substances

2 Categories

5 Classes

Non-Polymers

Perfluoroalkyl Substances
Compounds for which all hydrogens on all carbons (except for carbons associated with functional groups) have been replaced by fluorines

Polyfluoroalkyl Substances
Compounds for which all hydrogens on at least one (but not all) carbon have been replaced by fluorines

Polymers

Fluoropolymers
Carbon-only polymer backbone with fluorines directly attached

Polymeric Perfluoropolyethers
Carbon and oxygen polymer backbone with fluorines directly attached to carbon

Side-chain Fluorinated Polymers
Variable composition non-fluorinated polymer backbone with fluorinated side chains

PFOA, PFOS, PFHxS, Refrigerants
Regulatory Environment PFOS and PFOA

Overview

Regulatory assessment and management efforts in several countries curtail manufacture and use of PFOA, PFOS and substances that may degrade to form them (precursors)

- 2005: PFOS and related substances proposed for listing as POPs
- 2009: PFOS listed under Annex B of the Stockholm Convention
- 2011: PFOA and related substances proposed for listing as POPs
Mammalian Toxicity Tests to Address the Madrid Statement

<table>
<thead>
<tr>
<th>Endpoint of Concern for PFCs</th>
<th>Data Proposed to Address Endpoint of Concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>liver toxicity</td>
<td>acute, 28- and 90-day systemic toxicity studies</td>
</tr>
<tr>
<td>disruption of lipid metabolism</td>
<td>28- and 90-day systemic toxicity studies with enhanced lipid profiling</td>
</tr>
<tr>
<td>disruption of immune system</td>
<td>skin sensitization for cellular immunity, TDAR for humoral immunity with flow cytometry and NK cell work</td>
</tr>
<tr>
<td>disruption of endocrine systems</td>
<td>EDSP panel of tests</td>
</tr>
<tr>
<td>neurobehavioral effects</td>
<td>28- and 90-day systemic toxicity studies with neurotoxicity endpoints, extended 1-gen reproduction study with neurotoxicity group</td>
</tr>
<tr>
<td>neonatal toxicity/death</td>
<td>extended 1-gen reproduction study, 2-gen reproduction study, prenatal toxicity 2 species</td>
</tr>
<tr>
<td>tumors in one or more organs</td>
<td><em>in vitro</em> and <em>in vivo</em> genotoxicity studies, carcinogenicity (if genotoxicity weight of evidence is positive)</td>
</tr>
</tbody>
</table>

Would use ~7,000 mammals, take 3 years and $1.6 to $2.5 million.
Regulatory Environment Proposed New Criteria

Expanded Regulatory Interest

German Environment Agency (UBA)

Proposed new assessment criteria and procedures for identifying substances of very high concern under REACH, using the criteria persistent (P), mobile (M) and toxic (T) (PMT) or very persistent (vP) and very mobile (vM)(vPvM)

Swedish Chemicals Agency (KEMI)

Endorses German View
- all extremely persistent
- many are water soluble, mobile in soil
- likely to contaminate water
Regulatory Environment  no single globally harmonized system for PFAS classification exists

What is Needed

A clearer understanding of PFAS in the environment and assessment of their properties to be able to determine which classes of PFAS require management action.

Take into account differences in chemical, physical, thermal and biological properties.

Distinguish classes of PFAS to assure that regulations are appropriate in scope and proportionality.
Fluoropolymers in paper PTFE, FEP, ETFE, PFA

- PTFE, FEP, ETFE, PFA accounted for approximately 70-75% of the world fluoropolymer consumption in 2015 (IHS, 2016)
- PTFE made up 58% (by weight) of 2015 worldwide fluoropolymer consumption (IHS, 2016)

1938
PTFE discovery by Roy Plunkett

1969
ePTFE discovery by Bob Gore

Courtesy Hagley Museum and Library
Fluoropolymers

- Durability
- Inertness
- Mechanical strength
- Thermal stability
- Resistance to degradation
## Fluoropolymers

<table>
<thead>
<tr>
<th>Commercial Application</th>
<th>Durable</th>
<th>Inert</th>
<th>Functional</th>
<th>Stable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mechanical strength</td>
<td>low particulation</td>
<td>resistance to chemicals</td>
<td>non-toxic, biocompatible, biological degradation resistant</td>
</tr>
<tr>
<td>Aerospace</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Automotive Industry</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Medical Devices</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Pharmaceutical Manufacture</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Consumer Outdoor Apparel</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Technical Clothing (military, firefighters, first responders, medical personnel)</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Consumer Electronics</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Wireless Communications</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Satellite Navigation Systems</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Semiconductor Industry</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Building Construction</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Energy Production &amp; Storage</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Food and Beverage Production</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Food Protection &amp; Packaging</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Drinking Water Filtration</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Environmental Protection</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

W. L. Gore & Associates

60 years of improving lives
History Polymer Hazard Assessment

1976: Toxic Substance Control Act (TSCA)
- EPA assessed new chemicals for:
  - physical, chemical, biological effects & potential exposure to the environment and human populations

1984: EPA Polymer Exemption Rule
- Exempt low hazard polymers from certain notification requirements under the new chemicals program

1993: OECD Expert Group on Polymers
- Consensus Document identifying Polymer of Low Concern criteria & definition of polymer

2007: OECD Expert Group on Polymers
- “Polymers of low concern are those deemed to have insignificant environmental and human health impacts”

2015: EU Report on Global Polymer Regulation
- 9 of the surveyed nations agreed on polymer properties predictive of adverse health and environmental hazard
OECD Polymer of Low Concern Criteria

13 Criteria

- Polymer composition
- MW, M<sub>n</sub>, MWD
- wt% oligomer
- Electrical charge
- Reactive Functional Groups (RFG)
- Functional Group Equivalent Weight (FGEW)
- Low MW leachables
- Water / lipid solubility, octanol water partition
- Particle size
- Polymer stability
- Thermal stability
- Abiotic stability
- Biotic stability
OECD Polymer of Low Concern Criteria

13 Criteria

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- Polymer stability
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- Biotic stability
Fluoropolymers Considerations for Analyzing

Measuring Fluoropolymers

Standard MW methods (e.g., GPC) not applicable for insoluble fluoropolymers, like PTFE

- replaced by standardized indirect methods that use specific gravity and melt flow index to determine molecular weight
- Standard Specific Gravity (SSG) and Melt Flow Rate (MFR) are more conveniently and frequently used, rather than rheological and dynamic light scattering methods

Fluoropolymers don’t dissolve in water or octanol — can’t measure \( K_{ow} \)
Fluoropolymer Manufacture General Diagram

Monomers → Polymerization → Additives → Isolation → Aqueous/solvent removal → Recycle

Polymerization Aids → Polymerization

Initiators → Polymerization

Chain Transfer Agents → Polymerization

Recycle → Monomer Recovery

Thermal Treatment → Recycle

Treated Air Emissions → Finishing (Drying / Extrusion Stabilization)

Pellets, Powder, Dispersion

Additives

Aqueous/solvent removal → Treatment

Polymer Recycle

Land Fill (non-hazardous)

Thermal Treatment

Treated Effluent

Solid Waste
<table>
<thead>
<tr>
<th>Function</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulating agent</td>
<td>Acetone, Methanol, Potassium nitrate</td>
</tr>
<tr>
<td>Surfactant</td>
<td>4,9-dioxa-3H-perfluorononanoate, Ammonium, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy-) propionate, Perfluoro, 2-2-(methoxypropoxy)propanoic acid ammonium</td>
</tr>
<tr>
<td>Initiator</td>
<td>Ammonium carbonate, Ammonium persulfate, Borax, Hydrogen peroxide</td>
</tr>
<tr>
<td>pH adjuster</td>
<td>Ammonium hydroxide, Hydrochloric acid, Sodium hydroxide, Nitric acid</td>
</tr>
<tr>
<td>Anticoagulant stabilizer</td>
<td>Paraffin wax</td>
</tr>
<tr>
<td>Dispersant</td>
<td>Purified deionized water</td>
</tr>
<tr>
<td>Removes monomer inhibitor</td>
<td>Silica gel</td>
</tr>
</tbody>
</table>

Based on PTFE patents and publicly available information (no single PTFE uses all of these). Note: Initiator concentration depends on rate and degree of polymerization, from 0.01 wt% to 0.5 wt% of the water.
## Extractable/Leachable Analysis of PTFE

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>Nominal Sample Mass, g</th>
<th>Headspace GC/MS analysis</th>
<th>Ultrasonic IPA extraction GC/MS</th>
<th>Ultrasonic Hexane extraction GC/MS</th>
<th>Ultrasonic Extraction 55% H2O/45% IPA ESI(+) LC/MS</th>
<th>Ultrasonic Extraction 55% H2O/45% IPA ESI(-) LC/MS</th>
<th>Ultrasonic Extraction IPA ESI(+) LC/MS</th>
<th>Ultrasonic Extraction IPA ESI(-) LC/MS</th>
<th>72 hr IPA Leachable extraction ESI(+) LC/MS</th>
<th>72 hr IPA Leachable extraction ESI(-) LC/MS</th>
<th>72 hr Hexane Leachable extraction GC/MS</th>
<th>72 hr IPA Leachable extraction 55% H2O/45% IPA ESI(+) LC/MS</th>
<th>72 hr IPA Leachable extraction 55% H2O/45% IPA ESI(-) LC/MS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTFE Extract #1</td>
<td>1</td>
<td>trace</td>
<td>trace</td>
<td>trace</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>trace</td>
<td>trace</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
</tr>
<tr>
<td>PTFE Extract #2</td>
<td>1</td>
<td>trace</td>
<td>trace</td>
<td>trace</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>trace</td>
<td>trace</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
</tr>
<tr>
<td>Blank</td>
<td>1</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>trace</td>
<td>trace</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
<td>&lt; 1 ppm</td>
</tr>
</tbody>
</table>

* a - trace only from environmental contamination
* b - slight erucamide peak, a persistent system contaminant that was also detected in the blank.
* c - Hydrocarbon, fluorocarbon peaks but below identification threshold
* d - Hydrofluorocarbon fragmentation peaks ~MW=532
* e - A trace of 7H-perfluoroheptanoic acid, 9H-perfluorononanoic acid, ~600 ppb each.
* f - A trace of an unidentified compound likely formula is C_{27}H_{48}O_{8}

ESI(+) indicates positive ion mode acquisition
ESI(-) indicates negative ion mode acquisition

### Purpose

This analytical study was performed to develop and apply analytical approaches to generate the following PLC data for the fluoropolymer polytetrafluoroethylene, PTFE, with the sensitivity and selectivity needed. The specific properties that are not readily available and will be investigated in this work are: low molecular weight leachables and extractables, % oligomer, residual monomers.

### Conclusions

By all extraction and analytical techniques employed in this study, oligomer and residual monomer were not detected. In addition, an ambient air contaminant (Isopar K) adsorbed to the PTFE fine powder was detected at ≤ 2 ppb. Therefore, PTFE meets the Polymer of Low Concern criterion of < 2% wt/wt or 20,000 ppm of extractable oligomers.

John D. Jones, M.Sc.
Analytical Chemist
Fluoropolymers Food, Pharmaceutical and Medical Devices
### ePTFE tube, sheet, fiber data in Supplement

- Cytotoxicity (MEM)
- Sensitization
- Irritation
- Acute & 90-Day Subchronic Systemic Toxicity
- 2 In Vitro + 1 In Vivo Genotoxicity
- 4-Week Implantation
- Hemocompatibility

<table>
<thead>
<tr>
<th>Test Performed (Lab Report No.)</th>
<th>Extraction Vehicle(s)</th>
<th>Test Article(s) and Control(s)</th>
<th>Acceptance Criteria</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>ePTFE fiber, Code: SMR108316</td>
<td>No sign of cellular</td>
<td>PASS – non cytotoxic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(MEM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(MEM)</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

### Systemic Toxicity

- Acute systemic toxicity studies in mice
- Rabbit pyrogen study (Material Medicated)
- Local effects after implantation
- Mouse implantation study in rabbits
- Hemocompatibility
- Partial thromboplastin time (INR assay)
- C5a Complement Activation (Dias 2012)
- 12-week systemic toxicity assay in rabbits

### Local Effects after Implantation

- Mice's implantation study in rabbits
- Partial thromboplastin time (INR assay)
- C5a Complement Activation (Dias 2012)
- 12-week systemic toxicity assay in rabbits

### Hemocompatibility

- Direct contact: The test article was introduced directly to the test system at 0 cm3/mL.
- Negative control = HDFE
- Positive control = sterile water for injection.
- Percentage hemolysis must be < 2% to be non-hemolytic.
- PASS – Non-hemolytic.
- Direct contact: < 2% hemolysis.

### Partial Thromboplastin Time

- Direct contact: The test article was introduced directly to the test system at 0 cm3/mL.
- Negative control = HDFE
- Positive control = latex gloves, CVF
- Percentage hemolysis must be < 2% to be non-hemolytic.
- PASS – Non-hemolytic.
- Direct contact: < 2% hemolysis.

### C5a Complement Activation

- Direct contact: The test article was introduced directly to the test system at 0 cm3/mL.
- Negative control = HDFE
- Positive control = latex gloves, CVF
- Percentage hemolysis must be < 2% to be non-hemolytic.
- PASS – Non-hemolytic.
- Direct contact: < 2% hemolysis.

### 12-week Systemic Toxicity Test

- Direct contact: The test article was introduced directly to the test system at 0 cm3/mL.
- Negative control = HDFE
- Positive control = latex gloves, CVF
- Percentage hemolysis must be < 2% to be non-hemolytic.
- PASS – Non-hemolytic.
- Direct contact: < 2% hemolysis.
Fluoropolymers Toxicity and Clinical Data

PTFE, FEP, and a TFE/PAVE copolymer passed these GLP tests

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Standard Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity (MEM)</td>
<td>ISO 10993-5</td>
</tr>
<tr>
<td>Skin Sensitization</td>
<td>ISO 10993-10; OECD 406</td>
</tr>
<tr>
<td>Irritation</td>
<td>ISO 10993-10; OECD 406</td>
</tr>
<tr>
<td>Acute Systemic Toxicity</td>
<td>ISO 10993-11; OECD 408</td>
</tr>
<tr>
<td>90-Day Subchronic Systemic Toxicity</td>
<td>ISO 10993-11; OECD 408</td>
</tr>
<tr>
<td>Two In Vitro + One In Vivo Genotoxicity</td>
<td>ISO 10993-3; OECD 471, OECD 474, OECD 476</td>
</tr>
<tr>
<td>2- or 4-Week Implantation</td>
<td>ISO 10993-6</td>
</tr>
<tr>
<td>Hemocompatibility</td>
<td>ISO 10993-4; ASTM F756. ASTMF2382</td>
</tr>
</tbody>
</table>

Note: 90-Day Subchronic Toxicity Studies included hematology, urinalysis, clinical chemistry, gross pathology, microscopic histopathology, organ weights, clinical observations. Histopathology performed on: ovaries, testes, brain, heart, liver, kidneys, spleen, thymus, adrenal glands, lymph nodes.

Clinical studies of patients receiving permanently implanted PTFE, FEP or TFE/PAVE copolymer cardiovascular medical devices demonstrate no chronic toxicity, carcinogenicity, reproductive, developmental or endocrine toxicity.
## OECD Polymer of Low Concern Assessment Criterion

| Polymer Composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon) | yes | yes | yes | yes |
| Molecular Weight (MW) (Mₙ > 1,000 Da are not bioavailable; <1% oligomer content lower hazard potential) | 389,000 - 8,900,000** | 530,000 - 1,200,000*** | 241,000 - 575,000*** | 200,000 - 450,000*** |
| Molecular Weight Distribution (MWD) | 2.3^f | 1.4 - 2.7^a | 1.55 - 2.09^b | 1.7^c |
| w/ oligomer (<1% for <1,000 Da oligomers, <2% for <500 Da oligomers; lower hazard potential) | negligible | negligible | negligible | negligible |
| Ionic Character (not cationic or polycationic polymers are lower hazard potential) | neutral | neutral | neutral | neutral |
| Reactive Functional Groups (RFGs) (no functional groups associated with adverse effects, e.g., acrylates, isocyanates, aziridines, etc.) | < 1 (see text) | < 1 (see article) | < 1 (see text) | < 1 (see text) |
| Functional Group Equivalent Weight (FGEW) (typical value — the higher the FGEW, the lower polymer reactivity and lower hazard potential) | > 10^5 - 10^7 | > 10^5 - 10^7 | > 10^5 | > 10^5 |
| Low MW Leachables (low amount or none, lower hazard potential) | < 1 ppm | no active leachables by USP class VI (121°C) | no active leachables by USP class VI (121°C) | no active leachables by USP class VI (121°C) |
| Residual Monomers (less/no residual monomer has lower hazard potential) | < 1 ppm | < 50 ppb | < 50 ppb | < 50 ppb |
| Ratio of Residual Monomers to MW (higher ratio, lower hazard potential) | ~ 10^−1 - 10^−5 | ~ 10^−5 - 10^−10 | ~ 10^−10 | ~ 10^−10 |
| Structural Similarities to RFG of Concern (few/none, lower hazard potential) | none | none | none | none |

### Physical-Chemical Properties

| Water Solubility (per USP 34 NF29 General Notices, p6) (10 mg/L; lower hazard potential) | practically insoluble or insoluble (1x10^−6 mg/L) | practically insoluble or insoluble | practically insoluble or insoluble | practically insoluble or insoluble |
| Octanol/Water Partition Coefficient, Kᵪᵥ (Kᵪᵥ associated with lipophilicity & bioaccumulation or bioconcentration potential) | n/a | n/a | n/a | n/a |
| Particle Size (MMAD > 5µm, lower hazard potential) | 100-500 µm (powders) | 50-250 µm (powders) | 50-250 µm (powders) | 50-250 µm (powders) |
| Stability | stable | stable | stable | stable |
| Hydrolysis (not breaking down into Mₙ<1,000 Da lowers hazard potential) | stable | stable | stable | stable |
| Light (h) (not breaking down into Mₙ<1,000 Da lowers hazard potential) | stable | stable | stable | stable |
| Oxidation (not breaking down into Mₙ<1,000 Da lowers hazard potential) | stable | stable | stable | stable |
| Biodegradation (aerobic/anaerobic) (not breaking down into Mₙ<1,000 Da lowers hazard potential) | stable | stable | stable | stable |
| Thermal Stability at Normal Foreseeable Maximum Continuous Use Temp (°C) (not breaking down into Mₙ<1,000 Da lowers hazard potential) | 260 | 150 | 200 | 260 |


**Molecular Weight is number average molecular weight; **Molecular Weight is weight average molecular weight.

60 years of improving lives
OECD Polymer of Low Concern Criteria Applying to Fluoropolymers

**THE BIG CONCLUSION**

- Are distinctly different from other polymeric and non-polymeric per- and poly-fluoroalkyl substances
- Should be separated from them for hazard assessment or regulatory purposes
- Satisfy widely accepted assessment criteria to be considered as “Polymers of Low Concern”
- Vastly different — grouping PFAS for “read across” or structure activity relationship assessment is not scientifically appropriate
## Comparison of US, German, EU and Stockholm Convention Criteria

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Persistence (half-life)</strong></td>
<td></td>
<td></td>
<td></td>
<td>Same as REACH</td>
</tr>
<tr>
<td><strong>P</strong></td>
<td>water, soil, sediment: &gt;60 d</td>
<td>water: &gt;60 d</td>
<td>marine water: &gt;60 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td>soil, sediment: &gt;180 d</td>
<td></td>
<td>estuarine water: &gt;40 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>fresh or estuarine sediment or soil: &gt;120 d</td>
<td></td>
</tr>
<tr>
<td><strong>vP</strong></td>
<td>water, soil, sediment: &gt;180 d</td>
<td></td>
<td>marine, fresh, estuarine H2O: &gt;60 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>marine, fresh or estuarine sediment: &gt;180 d</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>soil: &gt;180 d</td>
<td></td>
</tr>
<tr>
<td><strong>Bioaccumulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>aquatic: BCF &gt;1,000</td>
<td>aquatic: BCF or BAF &gt;5,000</td>
<td>BCF: &gt;2,000</td>
<td></td>
</tr>
<tr>
<td></td>
<td>log Kow &gt;5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>vB</strong></td>
<td>BCF: &gt;5,000</td>
<td>BCF: &gt;5,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Low: &gt;10 mg/L</strong></td>
<td>Toxic or ecotoxic</td>
<td>Long-term aquatic NOEC or EC50 &lt;0.01;</td>
<td>1) carcinogenic, germ cell mutagenic or toxic for reproduction;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(no numeric criteria)</td>
<td>2) other evidence of chronic toxicity; and</td>
<td></td>
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</tr>
<tr>
<td><strong>Moderate: 0.1 mg/L-10 mg/L</strong></td>
<td></td>
<td>3) evidence for effects on or via lactation.</td>
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<tr>
<td><strong>High: &lt;0.1 mg/L</strong></td>
<td></td>
<td>4) DNEL: ≤ 9 µg/kg/d</td>
<td></td>
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</tr>
<tr>
<td><strong>Long-range transport (potential for)</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Long-range transport (potential for): Presence through monitoring or modelled data; t1/2 (air): 2 d</td>
<td></td>
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</tr>
<tr>
<td><strong>Mobility</strong></td>
<td></td>
<td></td>
<td></td>
<td>Mobility: water solubility at pH 6-8, 12 °C, must be ≥ 150 µg/L, and the log Kow at pH 6-8, 12 °C must be ≤4.5.</td>
</tr>
</tbody>
</table>

P = persistent; B = bioaccumulative; M = mobile; T = toxic; v = very; BAF: bioaccumulation factor; BCF: bioconcentration factor; DNEL: derived no adverse effect level

[6] Kalberlah et al., 2014; Barlow, 2005
Future Work Manufacture

- Manufacture & end of life phases are not the subject of paper.
- Perfluorocarboxylic acids (eg., PFOA, PFNA) no longer used by leading global fluoropolymer manufacturers.
Future Work End-of-Life

- Sufficient data to demonstrate fluoropolymers (eg., PTFE) do not degrade in environment or release substances of concern (Hintzer and Schwertfeger, 2014).

- Published studies on incineration of fluoropolymers under normal, foreseeable municipal waste incinerator conditions targeting specific analytes (Taylor, 2009).

- Most legislation addresses release of HF as the only critical parameter; limit values are for stack emissions.

- Gore incineration study underway to investigate incineration under a range of relevant foreseeable use conditions to determine more comprehensively the substances formed and their amounts.

- Open burning of fluoropolymers is unacceptable and unsafe.
Future Work Recycling

Recycling, reuse and closed loop systems

- Small scale ability to convert fluoropolymers back to their monomers for capture (Invertec, 2017; Schlipf, 2014).

- This approach to a closed loop economy for fluoropolymers merits additional work and discussion, as does the recycling and reuse of melt-processable fluoropolymers, such as FEP.
Conclusions

Fluoropolymer class of PFAS

- Is well defined.
- Meets polymer of low concern criteria.
- Should be considered as distinctly different from other classes of PFAS.
- The grouping of all PFAS together is not supported by the scientific data.

The grouping of all PFAS together is not supported by the scientific data.
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Questions
+ Supporting Slides