A Critical Review of the Application of Polymer of Low Concern Regulatory Criteria to Fluoropolymers II: Fluoroplastics and Fluoroelastomers

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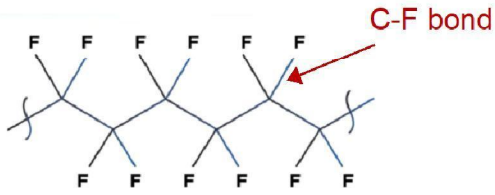
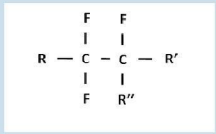
Fluoropolymers: **A distinct class of per- and poly-fluoroalkyl substances (PFAS) - high molecular weight polymers with fluorine (F) attached to their car only backbone.**



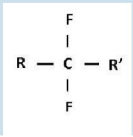
Polytetrafluoroethylene (PTFE)

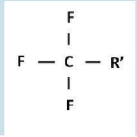
PFAS: A *universe* of substances with widely diverse properties includes FPs as "DISTINCT" class. However, PFAS lacks a single, globally harmonized definition.

USEPA: at least two adjacent carbon atoms, where one carbon is fully fluorinated and the other is at least partially fluorinated



OECD: PFAS is a fluorinated substance that contains in its structure at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)





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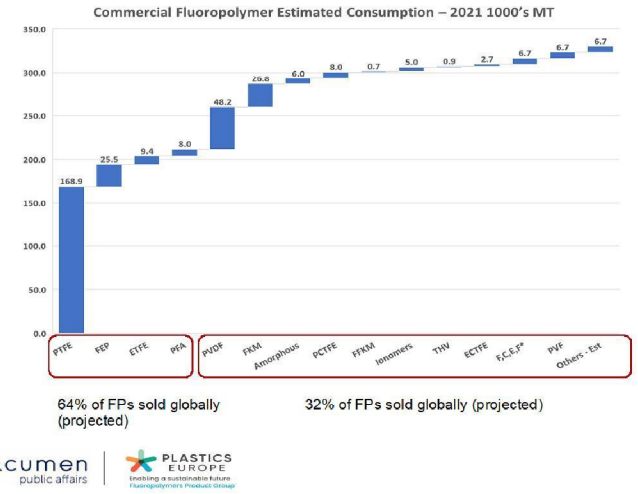
In-depth assessment of commercially available fluoropolymers against the 13 internationally recognized OECD polymer of low concern (PLC) criteria



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In 2018,Henry et al. demonstrated that four major fluoropolymers meet the polymers of low concern criteria.

The new study presents data for 14 additional fluoropolymers. The two studies represent approximately 96 % of the global commercial fluoropolymer market.

Why use Polymers of Low Concern (PLC) criteria for our assessment and where do the PLC come from?

Polymers of Low Concern (PLC) criteria have been discussed and elaborated globally for decades to ensure international consistency.

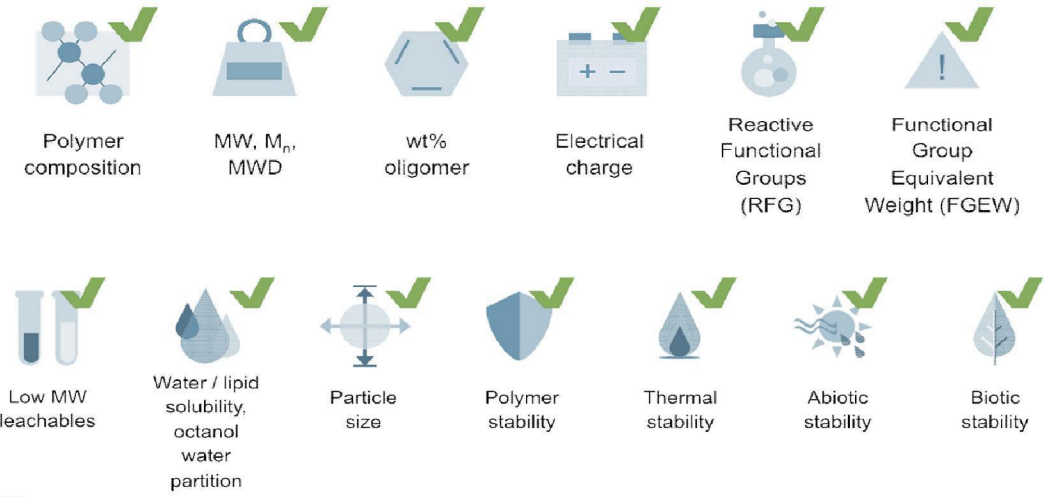
The PLC criteria were created to facilitate polymer hazard assessment that identifies low risk polymers that in turn assists in prioritizing regulatory activity on high-risk substances.

1993 OECD: Consensus on these criteria and their respective metrics, documenting the data required for a polymer to qualify as a PLC.

2009 OECD: PLC have "insignificant environmental health and human health impacts".

2015 Several member countries agreed on the polymer properties predictive of adverse human health and environmental hazard. The report outlined eligibility criteria for a polymer to be considered a PLC (BIO by Deloitte).

In-depth assessment of commercially available fluoropolymers against the 13 internationally recognized OECD polymer of low concern (PLC) criteria



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Studied FPs and PLC criteria (for the polymers in use)

All 14 studied FPs fulfill the PLC criteria.

Stability and lack of solubility indicates that FPs are relatively inert.

- Polymer composition → All FPs fulfil the criterion of polymer composition (either fluorine (F) and/or chlorine (Cl) must be covalently bound to the carbon-only polymer backbone)
- Molecular Weight (MW and Molecular Weight Distribution (MWD) → FPs are high MW solid polymers with narrow MWD→ Not bioavailable with low hazard potential
- wt% oligomer →low (or even negligible) wt% oligomer → Not bioavailable with low hazard potential
- Electrical charge → Absence of cationic character → Low hazard potential
- Reactive functional groups → do not contain RFG set forth in the PLC criteria → Demonstrates absence of reactivity
- Functional Group Equivalent Weight (FGEW) → Due to the lack of functional groups the term “equivalent weight” is not applicable.
- Low MW leachables → No active leachables or negligible < 1 ppm → Not be expected to significantly contribute to landfill leachate
- Water solubility and octanol/water partition coefficient → practically insoluble in both water and n-octanol. → No potential for bioavailability or bioconcentration. Lack of solubility confirms that FPs are not mobile in the environment.
- Particle size → Greater than 5 **µm** (MMAD) → Cannot cross cell membranes
- Polymer stability (thermal, biotic, abiotic) → All studied FPs met the PLC criteria for hydrolysis, light stability, oxidative stability and aerobic and anaerobic biodegradability →Stable and thermally, chemically and biologically inert

Persistence, Bioavailability and Toxicity of the studied fluoropolymers

FPs are:
- ✓ Solid
- ✓ Stable
- ✓ Durable

Persistent→ Persistence is **not** considered an intrinsic hazard and does not justify risk management measures (REACH)

Under REACH persistence is combined with bioaccumulation and toxicity (vPvB/vPvM)

- ✓ Not expected to degrade under environmental conditions or normal use/processing conditions
- ✓ Thermally, chemically and biologically inert

FPs:
- ✓ Persistent
- × Bioaccumulative
- × Mobile
- × Toxic

× NOT a Substance of Very High Concern (SVHC) from a regulatory perspective

Persistence, Bioavailability and Toxicity of the studied fluoropolymers

Bioavailability

FPs cannot be absorbed through a cell membrane via passive or active transport and do not bind or interact with the cell surface. Fluoropolymers are neither bioavailable nor bio-accumulative.

Toxicity

Toxicity studies on FPs are difficult to conduct due to lack of solubility and their high MW. In Annex VII of REACH guidance is stated that **toxicity is unlikely to occur "if a substance is highly insoluble in water or the substance is unlikely to cross biological membranes**."

FPs **are not subject** to passive transport into the cell because:

- **Of size, the lack of lipid solubility to penetrate the cell membrane**, the lack of oxygen and nitrogen atoms or groups accepting of hydrogen atoms.
- They are hydrophobic and lipophobic and have little or no hydrogen bond donating potential because they have few hydrogen bonds
- They are **not** structurally similar to steroids, peptides, natural compounds, etc.

Active Transport and Cell Surface Binding

- Is dependent on shape, volume/size, rotational bonds, etc. and requires interaction with the cell surface. **Fluoropolymers have none of the required properties to interact with the cell surface**.
- Fluoropolymers **do not "fit" into cell surface receptors to signal events within the cell. They are insoluble solids**.
- The types of high molecular weight compounds that can be bioavailable through active transport or cell surface binding/signaling are "natural compounds"

Outcome of the In-Use PLC Fluoropolymer Study

96% of the global commercially assessed fluoropolymers meet or exceed the "polymers of low concern" criteria.

They have been shown to be chemically and biologically stable, non-bio accumulative, non-bioavailable and non-toxic during their intended use phase.

The study demonstrates the insignificant risk fluoropolymers have on human health or the environment during the intended use phase, according to internationally recognized criteria.

The studied FPs contain **low levels of impurities, are thermally, biologically and chemically stable, negligibly soluble in water, non-mobile, non-bioavailable, non-bio-accumulative and non-toxic.**

Segmentation that clearly differentiates the broad PFAS family according to their properties is needed for a **scientifically sound, risk-based regulatory approach.**

Grouping of all PFAS is **not** supported by the scientific data. FPs possess **distinct physical, chemical and biological properties** and fluoropolymer class **is well defined**. Therefore, FPs **should not be grouped with other PFAS for hazard assessment or regulatory purposes**.

Fluoropolymers **should be derogated** from the PFAS REACH restriction.

A broad derogation for fluoropolymers supplemented by a Voluntary Industry Initiative during the manufacturing and an update of existing EU regulations on waste **will guarantee** that industry address stakeholders' concerns during the fluoropolymer life cycle.

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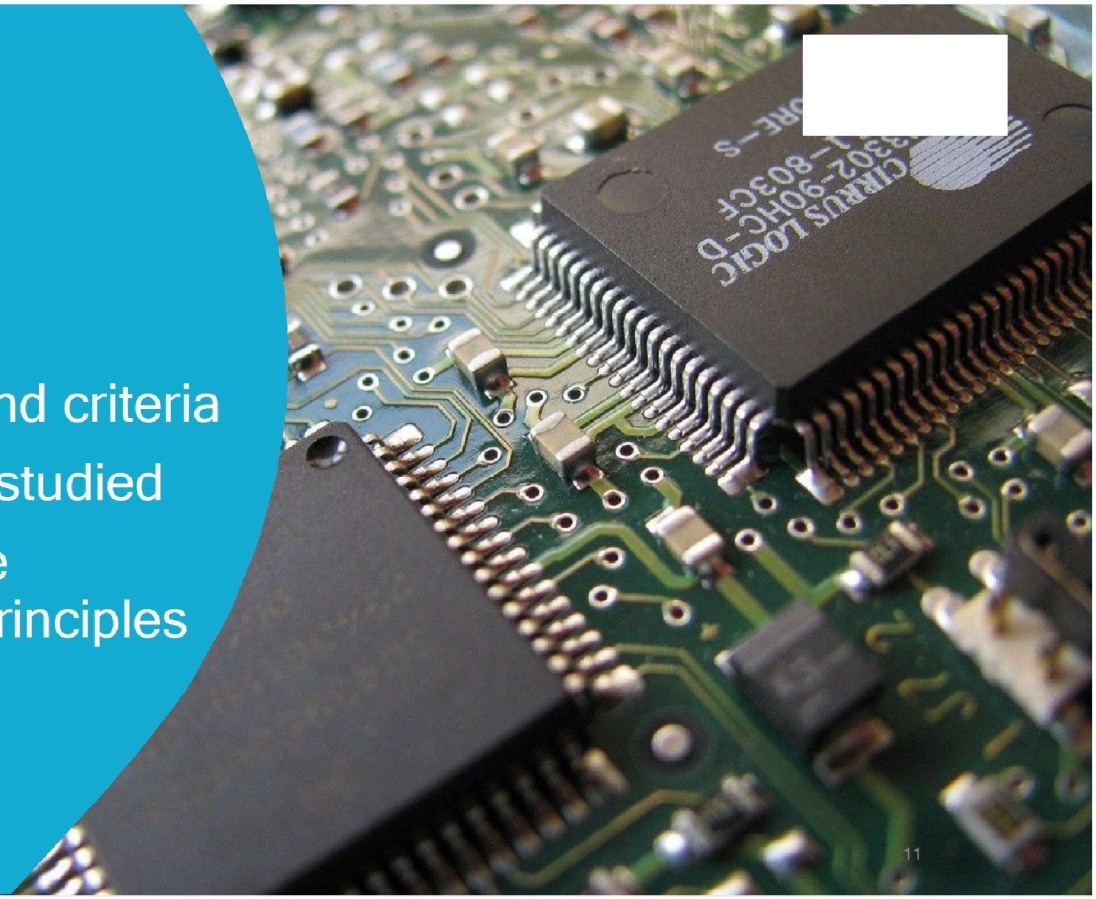
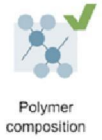
Annexes

1. PLC definition and criteria
2. Fluoropolymers studied
3. FPG responsible manufacturing principles

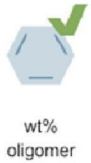


PLC criteria explained



Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to carbon)

Molecular Weight Distribution (MWD)
Mw ÷ number average Mn (Mn and heterogeneity of MW distribution indicate if most oligomers > 1,000 Da and not bioavailable)



wt% oligomer (<5% for <1000 Da oligomers, <2% for <500 Da oligomers; lower hazard potential)

Electrical charge

Ionic Character (not cationic or polycationic polymers are lower hazard potential)

Reactive Functional Groups (RFGs)

Functional Group Equivalent Weight (FGEW)

Polymers with <1% MW <1000 Da and low water extractability are not able to cause systemic effects which are toxicologically or ecotoxicologically relevant."

PLC criteria explained

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Water / lipid solubility, octanol water partition

According to the Stockholm Convention, a bioconcentration factor of >5000 and a log Kow >5 is used as a criterion for bioaccumulation.

Particle size

Median mass aerodynamic diameter, MMAD, should be > 5µm

Polymer stability

Stability is resistance to physical, chemical, or biological transformation.

Thermal stability

Thermal stability

Abiotic stability

Abiotic degradation may involve sunlight, water, or oxygen.

Biotic stability

Polymer degradation by microorganisms under oxygenated (aerobic) or anoxic (anaerobic) conditions

Fluoropolymers in the study: Chemical names and key properties

- Fluoropolymers demonstrate extraordinary combined set of property. It is this combination of properties which is governing the use of fluoropolymers.
- Fluoropolymers are an important driver of the European Green Deal and UN Sustainability Development Goals, supporting smart mobility, clean energy and sustainable industry.

Fluoroplastics
PVDF homopolymer
PVDF copolymer
ECTFE copolymer
ECTFE terpolymer
PCTFE
FEVE
EFEP terpolymer
CPT terpolymer
THV terpolymer

Fluoroelastomers
FEPM
FKM
FFKM

Specialty Fluoroplastics
Amorphous
Ionomer

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Overview of the studied FPs and key properties

Fluoroplastics

PVDF homopolymer and copolymer

ECTFE copolymer and terpolymer

PCTFE

FEVE

EFEP terpolymer

CPT terpolymer

THV terpolymer

Specialty Fluoroplastics

Amorphous

Ionomer

Fluoroelastomers

FEPM

FKM

FFKM

Mechanical strength
Heat resistance
High transparency
Radiation resistance
Ionic conductivity
Low moisture absorption
Thermal stability
Chemical resistance
Weather resistance
Low permeability

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THE FLUOROPOLYMER PRODUCTS GROUP COMMITS TO RESPONSIBLE MANUFACTURING PRINCIPLES

The fluoropolymer industry, represented by the **PlasticsEurope Fluoropolymer Products Group**, is committed to develop and implement innovative solutions to minimize the environmental footprint associated to fluoropolymer production and to reduce their potential emissions, based on the Best Available Techniques (BATs).

The fluoropolymer industry has adopted and will continue to develop new technologies and to invest in R&D to reach this goal. Therefore, the Fluoropolymer Products Group member companies commit voluntarily to the following **responsible manufacturing principles.**

FPG'S PRINCIPLES

1 BEST AVAILABLE TECHNIQUES

Continue to maintain, improve and/or develop Best Available Techniques in the manufacturing processes and management of environmental emissions related to fluoropolymers.

2 CONTAINMENT, CAPTURE & RECYCLE TECHNOLOGIES

Maintain and continuously improve and develop containment, capture, and recycle technologies to minimize emissions into the environment from PFAS substances intentionally and non-intentionally occurring during fluoropolymer manufacturing processes including fluorinated raw materials, fluorosurfactants, monomers, solvents, intermediates, and process chemicals as well as by-products.

3 SAFE SUBSTITUTION OF PFAS-BASED POLYMERIZATION AIDS

Intensify our efforts to investigate and develop R&D programs for the advancement of technologies for the replacement of PFAS-based polymerization aids during fluoropolymer production. Where proven technically feasible, environmentally sound, and viable at an industrial and commercial scale, FPG commits to replace the use of PFAS as polymerization aids.

4 ENHANCED RECYCLABILITY AND REUSABILITY

Continue to proactively work with its downstream users to increase recyclability and reuse of its products and develop R&D programs in line with the objectives of a circular economy.

5 ENSURE WORKERS MINIMAL EXPOSURE TO CHEMICALS

Continue to minimize the exposure levels for workers to chemicals used in the fluoropolymers manufacturing process.

6 MONITOR COMMITMENTS THROUGH THIRD-PARTY ASSESSMENT SYSTEMS

Introduce or expand already existing third-party assessment programs to help verify progress in members' commitments.

FPG COMMITMENTS

Each member company takes actions to implement these responsible manufacturing principles. In addition, the Fluoropolymer Products Group members aim to demonstrate progress on these actions by reporting on their achievements. As a first step, the Fluoropolymer Products Group is currently working on a review of wastewater related monitoring activities. The objective is the identification of best practices and possibly recommendations for procedural changes.

7 OPEN AND TRANSPARENT DIALOGUE WITH KEY STAKEHOLDERS

Continue to engage in an open and transparent dialogue with policymakers, employees, NGOs and other key stakeholders.