

Til: Toke Winther (████@mst.dk), DE (E1 (E1), P1
(E1), P2 (E2), P3
(E3))
Fra: P4 (E4)
Titel: Fluoropolymers - New scientific study demonstrates the insignificant risk fluoropolymers have on human health or the environment during the intended use phase, according to internationally recognized criteria
Sendt: 19-07-2022 14:16

Dear Madam, Dear Sir,

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

1. About the Study

The Fluoropolymers Product Group (FPG) members are committed to substantiating the safety to human health and the environment of its products during their intended use phase. As such, FPG members participated in the development of an in-depth assessment of its commercially available products against the 13 internationally recognized OECD polymer of low concern (PLC) criteria. This study was led by the American Chemistry Council's Performance Fluoropolymer Partnership (PFP).

The study looked specifically at the use phase of the life cycle and potential threats to human or environmental health during intended use.

2. Study Findings - The findings of the study in full can be found [here](#).

The outcome of this scientific study demonstrates that approximately 96% of the global commercial fluoropolymer market ^[1] meet or exceed the OECD PLC criteria ^[2]. They have been shown to be chemically and biologically stable, non-bio accumulative, non-bioavailable and non-toxic during their intended use phase. The results clearly demonstrate that the five most economically valuable fluoropolymers (by global market volume) pose insignificant threats to humans or the environment.

The conclusions of this study also provide further evidence that PFAS should not be grouped together as one for the purpose of regulation. Although fluoropolymers can be considered PFAS due to their structural makeup, they have unique physical, chemical, environmental, and toxicological properties which differentiate them from other PFAS. The authors of the study *"advocate for a segmentation based on properties before performing any grouping-based risk assessment, placing stable, non-hazardous fluoropolymers, that meet the criteria to be considered polymers on low concern, in a separate category."*

3. Next Steps

While the results of the study demonstrate, overwhelmingly, that fluoropolymers are safe during intended use phase, FPG members continue to look at the full cycle of its products.

All FPG Members have already committed voluntarily to responsible manufacturing principles in term of continuously improve and/or develop best available techniques in the manufacturing process, management of environmental emissions, development of R&D programs for the advancement of technologies allowing for the replacement of PFAS-based polymerization aids, and/or the increase recyclability and reuse of its products in line with the objectives of circular economy. Work is in progress regarding the possible implementation of a responsible manufacturing label.

4. What are fluoropolymers?

Fluoropolymers are a distinct subset of fluorinated polymers. They are polymers with fluorine atoms directly attached to their carbon-only backbone.

Fluoropolymers are critical for many uses in our daily lives as well as those integral to helping us achieve the European Green Deal objectives. Fluoropolymers provide exceptional functionality and benefits for multiple innovations and markets such as semiconductors, renewable energy, electronics, medical devices and aerospace and smart mobility solutions. In most applications, there are no suitable alternatives which can provide the same combination of functionality and performance.

5. About the Fluoropolymers Product Group

The Fluoropolymers Product Group represents Europe's leading fluoropolymer producers and experts. With a unique set of properties unobtainable by other polymers, fluoropolymers are non-replaceable across many key sectors and applications. Fluoropolymers ensure safety, reliability, durability and performance in numerous technologies, industrial processes and everyday products that are critical for human health, safety and the environment.

We are committed to promoting innovation, safe use of their products, sustainable manufacturing and stewardship across the industry for all our products. As the voice of the industry across Europe, the Fluoropolymers Product Group advocates for a balanced regulatory environment based on scientific facts to ensure that European industries remain competitive and sustainable.

Part of PlasticsEurope, the group's members are 3M, AGC, Arkema, Chemours, Daikin Chemicals, W. L. Gore & Associates and Solvay. Associate members are DuPont, Gujarat Fluorochemicals and Honeywell.

Do not hesitate to contact me if you need additional information.

Kind regards,

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[1] The substances included in this study are: polyvinylidene fluoride (PVDF) homopolymer; PVDF copolymer; ethylene-chlorotrifluoroethylene (ECTFE) copolymer; ECTFE terpolymer; polychlorotrifluoroethylene; fluoroethylene-vinyl ether copolymer; terpolymer of ethylene, tetrafluoroethylene, and hexafluoropropylene; terpolymer of chlorotrifluoroethylene, tetrafluoroethene, and perfluoroalkyl-vinyl-ether; and terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride, as well as specialty fluoroplastics amorphous fluoropolymers and fluorinated ionomers. The fluoroelastomers included in this study include tetrafluoroethylene-propylene co-polymer (FEP); three fluoroelastomers (FKM); and a perfluoroelastomer (FFKM).

[2] 13 OECD criteria were used to determine PLC status: polymer composition, molecular weight, weight percentage of oligomers, electrical charge, reactive functional groups, functional group equivalent weight, low molecular weight leachables, water solubility, particle size, polymer stability, thermal stability, abiotic stability, and biotic stability.

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Fluoropolymers Group

A product Group of Plastics Europe



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Transparency Register identification number : 454264611835-56

Plastics Europe is the pan-European association of plastics manufacturers with offices across Europe. For over 100 years, science and innovation has been the DNA that cuts across our industry. With close to 100 members producing over 90% of all polymers across Europe, we are the catalyst for the industry with a responsibility to openly engage with stakeholders and deliver solutions which are safe, circular and sustainable. We are committed to implementing long-lasting positive change.

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Aktdetaljer

**Akttitel: Fluoropolymers and the PFAS REACH
Restriction**

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Dato: 05-01-2023 08:44:12

Type: Indgående

Dokumenter:

- [1] Fluoropolymers and the PFAS REACH Restriction.eml
- [2] Fluoropolymer Letter 5 January 2023 - PFAS REACH Restriction.pdf

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Cc: (████████████████████), P3 P4 (████████████████████), (████████████████████), E5 (████████████████████),
(████████████████████), P5 (████████████████████),
Fra: P6 (████████████████████)
Titel: Fluoropolymers and the PFAS REACH Restriction
Sendt: 05-01-2023 08:44
Bilag: Fluoropolymer Letter 5 January 2023 - PFAS REACH Restriction.pdf;

Dear Competent Authorities of Denmark, Germany, Netherlands, Norway, Sweden,

On behalf of the [Fluoropolymers Product Group](#) (FPG) of Plastics Europe, an association representing Europe's leading fluoropolymer producers and experts, please find enclosed an open letter co-signed by the FPG and 21 EU and national stakeholders, manufacturing and using fluoropolymers.

With the expectation your PFAS REACH restriction dossier will shortly be submitted to ECHA, we encourage you to put forward a proposal for a restriction in a way that differentiates between fluoropolymers and other PFAS groups, taking into account the different risk profiles and uses of each group separately. Recognition of the safe uses of fluoropolymers, as determined by prior rigorous evaluation and of their importance for many applications, should result in an exemption for fluoropolymers from any regulatory action under the REACH restriction.

FPG has been and will continue to be open and transparent in its exchanges on fluoropolymers and the restriction and we would be delighted to provide you with further information on fluoropolymers and to discuss the PFAS restriction.

The FPG very much appreciate your time and consideration of our views, and we look forward to cooperating with you on this vitally important issue over the coming months.

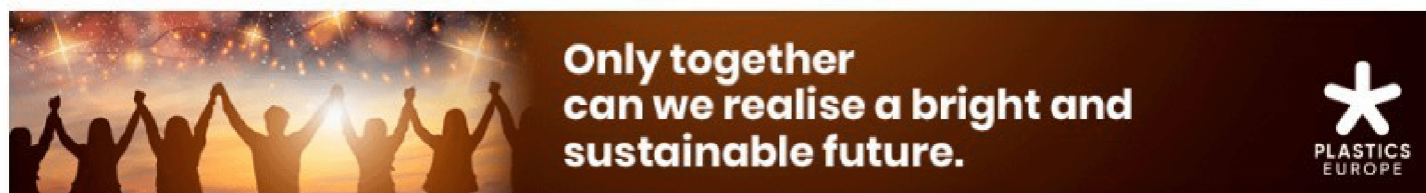
Yours sincerely,

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5 January, 2023

Dear Competent Authorities of Denmark, Germany, Netherlands, Norway, Sweden,

Cc: Commissioner Breton, Commissioner Sinkevičius

We, the undersigned manufacturers and users of fluoropolymers encourage you to put forward a proposal for a per- and polyfluorinated alkyl substances REACH restriction in a way that differentiates between fluoropolymers and other PFAS groups, taking into account the different risk profiles and uses of each group separately. Recognition of the safe uses of fluoropolymers, as determined by prior rigorous evaluation and of their importance for many applications, should result in an exemption for fluoropolymers from any regulatory action under the REACH restriction.

Fluoropolymers have been categorized as PFAS¹ when based solely on their molecular structure. However, their environmental and toxicological profiles are distinctly different to the majority of other lower molecular weight PFAS:

- In general, the properties of many fluoropolymers (fluoroplastics and fluoroelastomers) are such that they do not display the environmental and toxicological profiles associated with some PFAS that could be considered of concern;
- Specifically, recent [studies](#)²³ have shown that 16 unique families of commercially popular fluoropolymers meet the OECD Polymer of Low Concern criteria.⁴ They are chemically stable, non-toxic, non-bioavailable non-water soluble and non-mobile materials and they are deemed to have no significant environmental and human health impacts.

Significant benefits are generated along the value chain via the use of fluoropolymers. They have unmatched chemical and temperature resistance and unique electrical performance. Their stability in combination with these properties, translates to unique, durable, lasting performance in applications and contributes to extension of product life. Additionally, the durability of fluoropolymers makes them ideal materials that enable the development of innovative technologies.

Assessments of alternative materials have shown that, when available, they frequently cannot meet the critical performance characteristics of fluoropolymer-based materials and lack the combinations and ranges of properties required for applications that sets the fluoropolymer-based materials apart.

A broad PFAS restriction which includes fluoropolymers could result in:

- Environmental, health and safety implications such as higher safety risks to employees, medical patients and consumers; and increased emissions from modes of transport due to technical regression;

¹ Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance Series on Risk Management No.61, 9 July 2021.

[https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO\(2021\)25&docLanguage=En](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/CBC/MONO(2021)25&docLanguage=En)

² A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and Fluoroelastomers, Stephen H. Korzeniowski et al, 2022.

<https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646?af=R>

³ A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Barbara Henry et al, 2018. <https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035>

⁴ Data Analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern, OECD 2009. <https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf>

- Applications having lower durability and reliability resulting in higher maintenance and replacement frequency and increased waste;
- Negative impacts for emerging and growing technology markets such as energy storage, electrification, renewable energies and hydrogen;
- Constraints for products needing to meet stringent standards requirements (e.g. safety standards), in addition to the need to re-design products.

A PFAS REACH restriction proposal that differentiates between the diverse PFAS groups according to their respective risk profiles and properties and that acknowledges the safe use of fluoropolymers and their importance for applications should result in an exemption from any regulatory action under the REACH restriction.

