PUBLIC CONSULTATION | SUBMITTED ON 27.06.2023

Berghof Fluoroplastic Technology

Section III – General and specific information

Summary

We decided to submit a non-confidential and confidential report (attachments section IV an section V) to elaborate in detail on all the important topics addressed in the ECHA public consultation request. It is recommended to ECHA examiners to evaluate the confidential report, since more detailed and business related data could be provided. Please note that due to time constraints, this document may not include all detailed information about the 'missing uses – Analysis of alternatives and socio-economic analysis', but further submissions by *Berghof Fluoroplastic Technology* will provide this information during the course of the public consultation. A summary is given below, but note that all detailed information with supporting references and data is presented in the attachments!

Scope or restriction option analysis:
The scope of our contribution is the processing of fluoropolymers in general, PTFE in particular and more specifically: suspension PTFE. It should be noted that *Berghof Fluoroplastic Technology* solely processes PTFE manufactured by suspension polymerization (i.e. sPTFE) to obtain sintered PTFE products to serve i) high-density/solid PTFE, ii) porous PTFE, iii) optical PTFE. It is known and confirmed by multiple sPTFE suppliers, that sPTFE does not require PFAS-based processing aids in their manufacturing process. *Berghof Fluoroplastic Technology* endeavor a supply chain, from raw material to shipped products, without PFAS-of-concern.
The consumption of all PTFE types worldwide and in western Europe is 190 and 35 Mio. kg respectively. The suspension PTFE market size is estimated to reach 1.500 Mio US$ by 2027 after growing at a CAGR of 7,2% from 2022 to 2027.
PTFE is a high performance polymer with a unique set of properties, e.g. temperature range from -250 to +260°C, universal chemical resistance, hydrophobic properties, excellent dielectric properties, amongst many others. This makes it an extremely valuable materials for the use in many different industries.

Hazard or exposure:
PTFE is a polymer of low concern (PLC) in terms of its potential environmental and human health impacts. To this, it is important that suspension PTFE is manufactured without the use of PFAS-of-concern. To confirm this, two other information sources are given related to hazard or exposure, i.e. i) safety data sheets and ii) statements of compliance (e.g. food contact material, USP class VI).

Environmental emissions:
During PTFE processing, emissions of PFAS-of-concern due to heating of the PTFE in the sintering process does not occur.
Berghof Fluoroplastic Technology has taken measures to further optimize the use of resources to meet the criteria of 'Operation Clean Sweep'. *Berghof Fluoroplastics Technology* is an official partner of the 3M's worldwide unique Fluoropolymer Up-Cycling Project. More than 95% of the generated waste of the production process is reused or recycled! Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. It is shown in scientific studies that municipal incineration of fluoropolymers using best available technologies is not a significant source of PFAS and should be considered an acceptable form of waste treatment. The relation between PTFE and its global impact as microplastic (MP) in marine environment was investigated and it was concluded that PTFE plays a medium role when it concerns microplastics. sPTFE at *Berghof Fluoroplastic Technology* is used for industrial and high tech products only and is not directly applied as consumer goods. Therefore, the contribution of sPTFE to microplastics is estimated very low. PTFE has a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS.

BERGHOF

Baseline:
Berghof Fluoroplastic Technology processes PTFE to make a wide variety of PTFE components consisting of high-density/solid PTFE, porous PTFE and optical PTFE for various industries: Semiconductor industry, laboratory equipment/technology, automotive, aerospace, chemical industry, industrial processing, electronics and electrical equipment, photonics (optical industry / light measurement), food & beverage, medical technology.

Information on alternatives:
PTFE is a high performance material and has many beneficial properties, especially the combination of these properties makes the difference in comparison to alternative materials. High performing polymers permit exceptional end-use-applications, specialized products at high costs. In general, it can be stated, that PTFE will only be applied, when this is really required for the application, otherwise a less costly material will be chosen. PTFE is not used for conveniency, but for high-end products where a certain combination of properties is really necessary (essential use!).

Other socio economic analysis (SEA) issues:
As soon as the restriction takes effect, it is expected that *Berghof Fluoroplastic Technology* will lose a very large share of the total revenue which is related to European business. Customer and industry/application demands cannot be met anymore and no competitive products can be offered. Relocating the production of *Berghof Fluoroplastic Technology* to outside Europe is the only alternative for the company to remain. This will result in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. It will be a challenge (or an impossible mission) to compensate the revenue of the European market outside of Europe.
This does not have an impact solely on *Berghof Fluoroplastic Technology* but on whole Berghof Group as well. The existence of the total Berghof Group is highly endangered because of the entanglement of the PTFE products in the Berghof Group. Other subsidiaries, i.e. *Berghof Products + Instruments* and *Gigahertz Optik* cannot apply these high-quality products with fit-to-purpose properties anymore. The high-value products cannot be offered in the market anymore in a fair and competitive way. *Berghof Fluoroplastic Technology* is a significant pilar for the Berghof Company. It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubtful.

Request for exemption:
Berghof Fluoroplastic Technology cannot comprehend the possible ban of fluoropolymers in general, PTFE in particular and more specifically: suspension PTFE. This fluoropolymer type is a polymer-of-low-concern and can be manufactured without using fluorinated production aids, like fluorosurfactants. It is already confirmed by various sPTFE manufacturers that PTFE applied at *Berghof Fluoroplastic Technology* is manufactured with no such production aids. *Berghof Fluoroplastic Technology* endeavor a supply chain, from raw material to shipped products, without PFAS-of-concern.
We are not against a restriction/limitation of hazardous, persistent and mobile PFAS-of-concern, and support a scientific approach differentiating high and low risk substances based on risk assessment. In that way, it should be concluded that fluoropolymers should not be treated in a similar way as other PFAS and should be removed from the ECHA restriction dossier.
In general, it can be stated, that PTFE will only be applied, when this is really required for the application, otherwise a less costly material will be chosen. Furthermore, it is no discussion that the fluorine loop should be closed. This is manageable for PTFE applied in industrial applications or in high tech products. These products are traceable and/or recyclable. The application of PTFE in consumer goods should be minimized and only applied if really necessary.
The socio-economical impact of a possible restriction or a ban of PTFE on *Berghof Fluoroplastic Technology* is severe. Relocating the production of *Berghof Fluoroplastic Technology* to outside Europe is the only alternative for the company to remain. This will result in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. The existence of the total Berghof Group in Europe is highly endangered because of the entanglement of the PTFE products in the Berghof subsidiaries. It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubtful. The uncertainty among various stakeholders, which is already evident in the initial reluctance to invest after the publication of the restriction dossier, already suggests how dramatically and quickly the Berghof Group would be hit by a possible fluoropolymer ban.

General: Fluoropolymers should be exempted from any regulatory action under the REACH restriction!!

Specified: Exemption for PTFE used in high tech products and products and production aids for industrial applications!!

Contents

1. General information

1.1. Scope on restriction option analysis

PFAS type: General: Fluoropolymer
Group: polytetrafluoroethylene (PTFE)
Subgroup: suspension polytetrafluoroethylene (sPTFE)
(Note: in our public consultation reply, PTFE comprises modified sPTFE and sPTFE compounds)

General

PFAS definition

Per- and polyfluorinated chemicals (PFCs)c, or more specifically per- and polyfluoroalkyl substances (PFASs), are a large group of chemicals that have been used since the 1950s as ingredients or intermediates of surfactants and surface protectors for assorted industrial and consumer applications [OECD/UNEP 2013]. The PFAS terminology was proposed by Buck et al. [Buck 2011]. This is a widely accepted and used terminology for PFAS which divides them basically into two sub-groups: non-polymeric and polymeric PFASs. The polymeric PFASs are subdivided into i) fluoropolymers, ii) side-chain fluorinated polymers and iii) perfluoropolyethers. Our contribution focusses on fluoropolymers in general and PTFE in particular. The environmental and toxicological profiles of these polymers are distinctly different to the majority of other PFAS.

Fluoropolymers have very high molecular weight (usually > 10,000 Da) and show excellent thermal, chemical, photochemical, oxidative, hydrolytic and biological stability with low flammability, neutral electrical charge and resistance to degradation. Fluoropolymers do not bioaccumulate, are not mobile and no reactive groups are present in the structure of fluoropolymers. They are characterized by a carbon-only polymer backbone with F atoms directly attached to it, a unique feature in the chemical space.

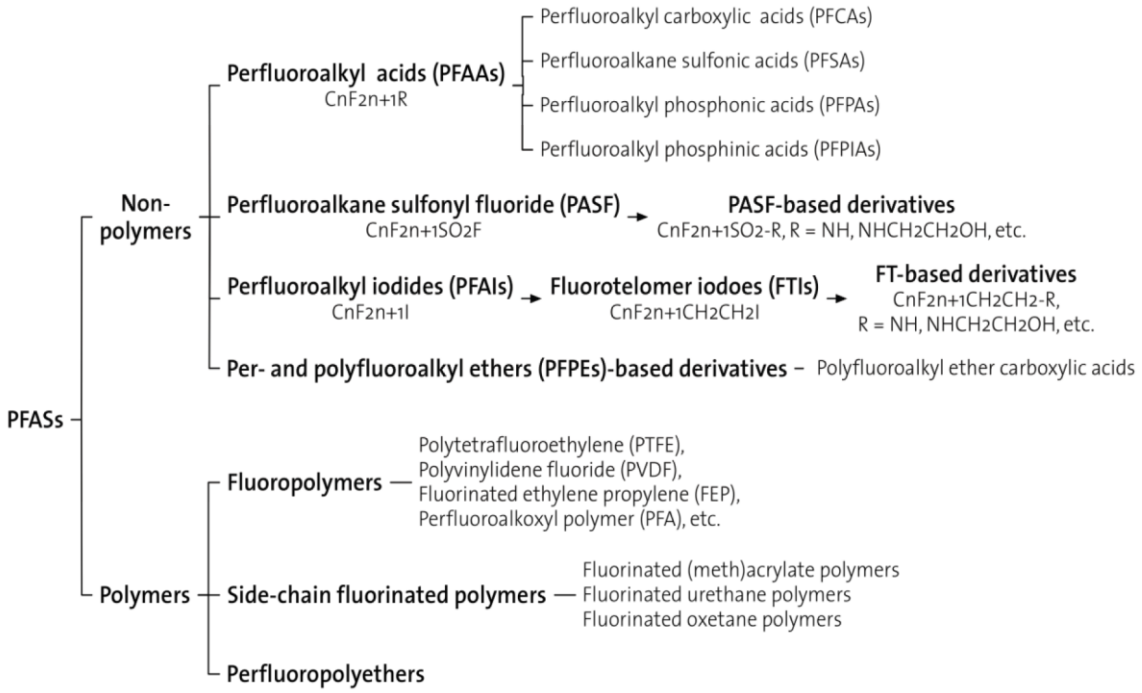

Figure 1: general classification of per- and polyfluoroalkyl substances (PFAS) as proposed by Buck et al. [OECD/UNEP 2013]

PTFE – manufactured types

According to Lohmann et al. [Lohmann 2020], there are many different processes of making fluoropolymer products. For example, some fluoropolymers do not require PFAS-based processing aids in their manufacture by *suspension polymerization* (e.g. granular PTFE), whereas other fluoropolymers (e.g. fine powder PTFE and PVDF) are manufactured using PFAS-based processing aids during *emulsion polymerization*. The developments in Fluoropolymer Manufacturing Technology with the focus on removing PFAS as polymerization aids was assessed by Ameduri et al. [Ameduri 2023]. It is expected that most of the fluoropolymer production will be developed completely free from PFAS polymerization aids in a relatively short time frame. Thus, it appears reasonable to claim that fluoropolymers that are manufactured without the use of PFAS polymerization aids should be exempted from any regulatory initiative, and that their uses should be allowed without any unjustified restriction. Additionally, a detailed overview from polymerization (addressing additionally e.g. supercritical CO_2 polymerization or γ-radiation-induced polymerization) to recycling and disposal of PTFE was given in the scientific review on PTFE porous membrane technology by Guo et al. [Guo 2022].

In suspension polymerization, the TFE is polymerized in water, since PTFE is insoluble in water; the polymerized product is precipitated from water to form primary particles. If there is no dispersant in the water, the primary particles will aggregate into coarse particle or grain, which is commonly known as suspension polymerization. These grains can be molded after they have been processed into pellets. [Chemservice 2021]

PTFE – Polymer of Low Concern (PLC)

PTFE is a Polymer of Low Concern (PLC) → the study by Henry et al. [Henry 2018] has presented data demonstrating that PTFE satisfy the widely accepted polymer hazard assessment criteria and that this polymer is to be considered PLC [OECD 2009].

Fluoropolymer market overview

A comparison between the global market and European market was given in the presentation of M. Schlipf [Schlipf 2023]. It concerns fluoropolymer consumption data of 2018 (Figure 2). Similar ratios between the different kind of fluoropolymers are still valid today.

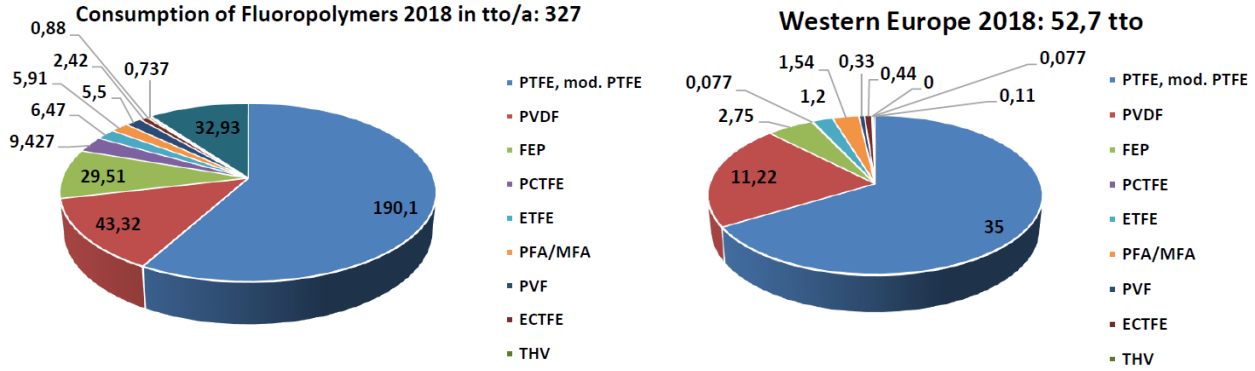

Figure 2: Consumption of fluoropolymers: left: global numbers of 2018; right: western Europe numbers of 2018 (unit tto = mio. kg]

Conversio presented the fluoropolymer market by industry segments as can be seen in the figure below [Conversio 2023]. It is very clear that fluoropolymers, of which 56% concerns PTFE (in 2020), find its use in industries with very high requirements and standards, i.e. electronics & semiconductors, chemical industry, automotive, medical & pharma. Therefore it is not understood why these extremely important industries seemed to be inferior to the industries addressed in the restriction proposal, like TULAC, food contact materials and packaging, consumer mixture, cosmetics, ski wax etc. **Sophisticated and high demanding high tech products and industrial applications were therefore underrated and overshadowed by consumer products**.

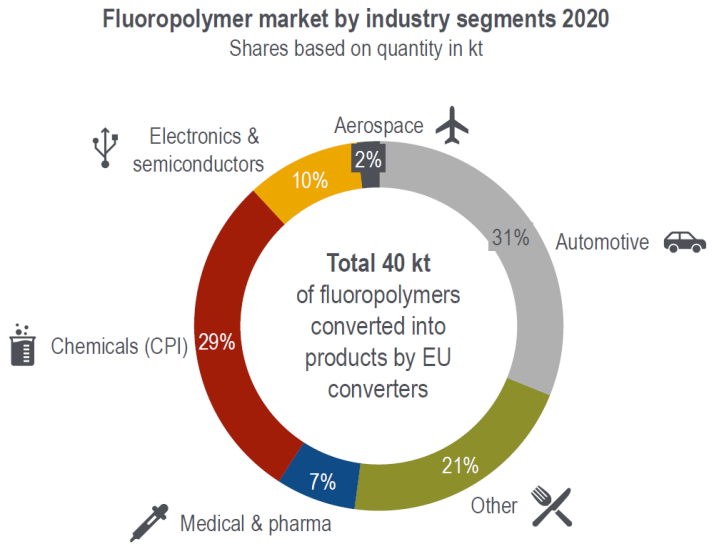

Figure 3: Fluoropolymer market by industry segments 2020 [Conversio 2023]

sPTFE market overview [IndustryARC 2023]

The suspension PTFE Market size is estimated to reach 1.500 Mio US$ by 2027 after growing at a CAGR of 7,2% from 2022 to 2027. Generalities of the market overview of sPTFE can be given by

Molding Process	–	PTFE Extrusion Molding, PTFE Isostatic Molding, PTFE Compression Molding
Application	–	Coatings, Seals, Gaskets, Valves, Expansion Joints, Pipes, Protective Liners, Electrical Insulators, Electrical Tapes and Others
End-Use Industry	–	Automotive and Transportation, Oil and Gas, Chemical Processing, Electrical and Electronics, Medical (Implants, Surgical Instruments and Others), Cookware (Pan, Baking Trays and Others), Building and Construction (Residential, Commercial and Industrial), Consumer Goods, Paints and Coatings and Others.

Scientific relevance

The scientific relevance can be demonstrated by means of yearly amount of publications. As an example, this is shown for porous PTFE with following searching criteria ‘PTFE membrane’ by Dimensions [Dimensions 2023]:

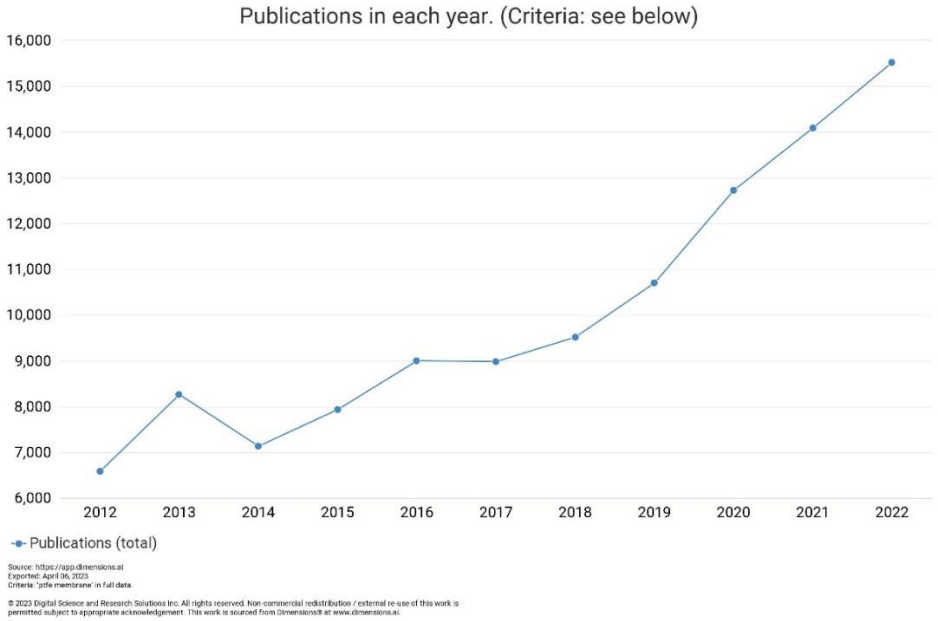

Figure 4: Yearly amount of publications on ‘PTFE membrane’ by Dimensions [Dimensions 2023]

The scientific review paper of Guo et al. [Guo 2022] aims to provide updates on the recent developments of PTFE porous membranes based on the PTFE polymer, with significant attempts to improve PTFE porous membranes. To this, 221 references were addressed in this paper, indicating the relevance, actuality and the technologically need for PTFE porous materials. Following topics were described in detail:

- introduction to PTFE material, including the polymerization process, structure and properties, processing, recycling and disposal, and applications.
- recent progress in the preparation method and procedure of PTFE flat-sheet membrane, hollow fiber membrane as well as the tubular membrane
- strategies to control membrane pore structure and the functionalization of PTFE porous are assorted and illustrated in detail.
- an overview of PTFE membranes for various applications.

It should be noted that in this section, the need for PTFE membrane or porous PTFE is given exemplarily and similar relevance and trends are expected for other PTFE applications (i.e. sealings, optical applications, applications where low dielectric constant is required, low abrasion uses, amongst many others).

PTFE properties

PTFE is a high performance polymer with a unique set of properties:

- High-molecular weight and a high melting point
- Temperature range from -250 to +260°C
- Universal chemical resistance
- Anti-adhesive surface, extremely low coefficient of friction
- Hydrophobic properties
- Porous properties available by special treatment
- Excellent dielectric properties
- High UV resistance and resistance to weathering
- High purity
- High flame resistance according to UL94 V-0
- Physiologically harmless

There are no materials showing this set of properties. The search for alternative materials always ends up in a compromise, which could be sufficient for certain products and applications. The majority of high-end products demand a certain uncompromising combination of properties in order to assure efficiency, stability, durability, health and safety! That is what it makes PTFE irreplaceable.

PTFE at Berghof Fluoroplastic Technology

It should be noted that *Berghof Fluoroplastic Technology* solely processes PTFE manufactured by suspension polymerization (i.e. sPTFE) to obtain sintered PTFE products.

PTFE product supply chain

PTFE supply:	Detailed information from the suppliers of PTFE is given in 'confidential documents' in Section V. The suppliers confirm that the PTFE is produced without PFAS-of-concern* (see 'confidential attachments'). The PTFE is of high purity and is free of PFAS-of-concern*
PTFE processing:	The process for obtaining solid or porous sintered PTFE parts consist of hydraulic or isostatic molding of PTFE granulate. After demolding, the PTFE parts are sintered and cooled down. Subsequently parts are shaped by machinery post-processing. Isostatic molding gives the opportunity make optimal use of resources by molding with almost precise contours leading to extreme raw material reduction.

Product: sPTFE form parts or sPTFE porous sheets or porous 3D-parts

Downstream users: 1. The customers are mainly original equipment manufacturers (OEMs),
2. System integrators
3. Endusers

Product groups at *Berghof Fluoroplastic Technology*

- High-Density/solid PTFE
- Porous PTFE
- Optical PTFE

PTFE geometry

- machined parts
- sheets

Industries and products/applications

Industries	**Product / Applications**
Aerospace	Bushings, antenna-parts for WIFI-communication, reflectors / thermal shielding of exposed space craft surfaces, liquid tanks for space craft propellant
Automotive	Pressure compensation of high voltage batteries, elements with bursting function for passenger safety, high performance membranes that repel water and oil, painting-robot parts, parts for crankcase pressure regulation, diaphragms,
Chemical and industrial processing	Pump housings, containment shells, process tanks, bellows, pump impellers, can inserts for pumps, filters for liquid processing, hollow cylinders, guiding strips,
Electronics and Electrical	Sensor protection caps, insulations caps, high-voltage parts, parts for level-sensors,
Food & Beverage	Bellows, sealings/gaskets
Laboratory Equipment/Technology	Digestion reactors, pressure vessels
Medical	Vents and filters for various applications
Optical industry / Light measurement	Reflection standards, interior of Ulbricht integrating spheres, diffuse reflectors, projection screens, display backdrops, reflectors for highly intensive radiation sources.
Semiconductor industry	Etching tanks, bubbling systems, stirrers, heaters, clamps shells, bellows,

*** Definition of PFAS-of-concern**

a subset of per- and polyfluoroalkyl substances (PFAS) that are considered to be particularly problematic due to their potential adverse effects on human health and the environment (in terms of persistence, bioaccumulation, and toxicity), like short-chain non-polymeric PFAS or fluorosurfactants (e.g. fluorinated production aids).

References

[OECD/UNEP 2013] OECD/UNEP Global PFC Group, Synthesis paper on per- and polyfluorinated chemicals (PFCs), Environment, Health and Safety, Environment Directorate, OECD, 2013. (https://wedocs.unep.org/bitstream/handle/20.500.11822/32445/SPPPC.pdf?sequence=1)

[Buck 2011] Buck et al., Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. Integr. Environ. Assess. Manag. 7(4), 2011, 513-541. (https://doi.org/10.1002/ieam.258)

[Lohmann 2020] Lohmann et al., Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?, Environ. Sci. Technol. 54(20), 2020, 12820–12828 (https://doi.org/10.1021/acs.est.0c03244)

[Ameduri 2023] Ameduri et al., Developments in Fluoropolymer Manufacturing Technology to Remove Intentional Use of PFAS as Polymerization Aids, International Chemical Regulatory and Law Review (ICRL) 6(1), 2023, 13-23 (https://icrl.lexxion.eu/data/article/18899/pdf/icrl_2023_01-006.pdf)

[Guo 2022] Guo et al., PTFE porous membrane technology: A comprehensive review, J. Membr. Sci. 664, 2022, article 121115 (p. 1-21) (https://doi.org/10.1016/j.memsci.2022.121115)

[Chemservice 2021] Chemservice, report prepared for Fluoropolymers Group of PlasticsEurope, Regulatory Management Option Analysis For Fluoropolymers, 2021 (https://fluoropolymers.plasticseurope.org/application/files/5416/5104/8333/20211104_FP_RMOA_Final_3.pdf)

[Henry 2018] Henry et al., a critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integr. Environ. Assess. Manag. 14(3), 2018, 316-334 (https://doi.org/10.1002/ieam.4035)

[OECD 2009] Organization for Economic Co-operation and Development (OECD), Task Force on New Chemicals Notification and Assessment, Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern, 2009 (https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf)

[Schlipf 2023] M.Schlipf, Title: Fluoropolymers Global Market Overview; Conference: Innovations using Fluoropolymers, SKV, 3-4 Mai 2023 in Würzburg (given in 'confidential documents' in Section V)

[Conversio 2023] Conversio – Market & Strategy, Fluoropolymer waste in Europe 2020 – final report, elaborated for pro-K, published January 2023 (given in 'confidential documents' in Section V)

[IndustryARC 2020] Industry ARC, Suspension Polytetrafluoroethylene Market - Forecast(2023 - 2028), Report Code: CMR 29235, https://www.industryarc.com/Research/Global-Suspension-Ptfe-Market-Research-511461, visited on 21.04.2023

[Dimensions 2023] Dimensions website, https://app.dimensions.ai, visited on 06.04.2023

1.2. Hazard or exposure

Toxicology studies on PTFE demonstrate the absence of acute or subchronic systemic toxicity, irritation, sensitization, local toxicity on implantation, in vitro and in vivo genotoxicity, hemolysis, complement activation, or thrombogenicity [Henry 2018]. It was also concluded that PTFE is a polymer of low concern (PLC) including its low potential environmental and human health impacts. It is not considered to be a carcinogen, mutagen, or reproductive toxin.

Two other information sources can be given related to hazard or exposure, i.e.:

- safety data sheet; the safety data sheet of PTFE does not include any hazard statements or precautionary statements. The safety data sheets from two PTFE suppliers are exemplary given in 'confidential documents' in Section V.
- Statement of Compliance: PTFE passes all relevant human health (i.e. hazard and exposure) related approvals, shown by e.g. migration tests. Compliance documents of various suppliers are given in 'confidential documents' in Section V. Following standards are generally met:
    - Food contact materials (e.g. Bedarfsgegenständeverordnung)
    - FDA-compliance (21 CFR 177:1550)
    - TSCA
    - Drinking water approval
    - USP class VI
    - Sanitary standards

It should be noted, that the used suspension PTFE is manufactured without using fluorinated production aids, like fluorosurfactants. This is already confirmed in section 1.1. So, the argument of environmental emissions related to manufacturing aids **does not apply** here!

Finally, we want to emphasize that Article 68 (1) of REACh (Introducing new and amending current restrictions) phrases that there must be an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances [REACh 2023].
It is shown in this section, that this is not the case!

References

[Henry 2018] Henry et al., a critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers, Integr. Environ. Assess. Manag. 14(3), 2018, 316-334 (https://doi.org/10.1002/ieam.4035)

[REACH 2023] REACH online, https://reachonline.eu/reach/en/title-viii-chapter-2-article-68.html, visited on 05.05.2023

1.3. Environmental emissions

Emissions

Granular PTFE is processed and one of the process steps is sintering. To this, PTFE parts are heated up in an oven with recirculated air to a certain temperature for a certain time. The only production exit for gases is via the production ventilation system. The impact of the exhaust air was determined by measuring the PFAS concentration at the exhaust of the production. The applied raw materials are free of PFAS-of-concern*. This is proven by:

- Confirmation of the manufacturer (no use of fluorinated production aids, like fluorosurfactants), see section 1.1.
- PFAS measurements of PTFE materials by accredited test laboratory (certificates are given in 'confidential documents' in Section V).

The New York State Department of Environmental Conservation (DEC) requested the US Environmental Protection Agency (EPA) Office of Research and Development (ORD) qualitatively characterize the emissions from polytetrafluoroethylene (PTFE) sintering ovens [Gentile 2019]. The overall results indicate extremely low emissions from PTFE sintering oven process operations at their facility. They identified shorter chain fluoropolymer aide replacements, perfluoroethanoic acid (C2), perfluoropropanoic acid (C3), and perfluorobutanoic acid (C4), that have been phased in. Since we can confirm that *Berghof Fluoroplastic Technology* has no such aids in their raw material or as production aid during the manufacturing, it is unlikely that short-chain PFAS is emitted during the sintering process.

Production waste, reuse and recycling

Production waste is not included in the definition of emission as defined by German law [BImSchG 2022].

Since waste management is a very important part of the whole production process, numbers regarding production and waste (in terms of reuse and recycling, upcycling and incineration) are given in the 'confidential document' in Section V. *Berghof Fluoroplastic Technology* has taken measures to further optimize the use of resources to meet the criteria of 'Operation Clean Sweep' [OCSweep 2023]. It is no discussion that the fluorine loop should be closed. To this, *Berghof Fluoroplastics Technology* is an official partner of the 3M worldwide unique Fluoropolymer Up-Cycling Project [3M 2015]. Furthermore *Berghof Fluoroplastics Technology* contributes to recycling and reusing the PTFE material. More than **95%** of the generated PTFE scraps are collected, milled, purified and processed to manufacture new, highly qualitative PTFE products. Just a very small portion is too much contaminated (e.g. dirt) and leaves the factory for incineration. Following input is given in the 'confidential document' in Section V:

- Total amount of PTFE used for 2022:
- Total amount of PTFE scraps for 2022:
    - Amount of PTFE for reuse/recycling:
    - Amount of PTFE for upcycling:
    - Amount of PTFE for incineration:

Conversio performed a detailed analysis regarding the fluoropolymer waste in Europe in 2020. The most relevant industry segments were chemicals (~29% incl. energy), automotive (~31%) and others (~21% incl. coated metals, cookware, lubricants, textiles, food & beverage etc.), which are also depicted in Section 1.1. The scheme in Figure 5 presents the treatment route of post-consumer fluoropolymer waste showing that approx. 84% of fluoropolymers are mainly recycled for energy or thermally separated from other materials [Conversio 2023]. It is therefore highly assumable that the proportion of landfilled fluoropolymers related to industrial applied PTFE is very small.

The thermal degradation of PTFE by incineration was investigated thoroughly and summarized by Sales [Sales 2022]. For PTFE, it was concluded that complete thermal decomposition is achieved at a temperature of about 800°C. In more detail, incineration was studied by Aleksandrov et al. [Aleksandrov 2019]. The conclusion was that no significant evidence could be found of PFAS creation (of the 31 studied PFAS species) during the incineration of PTFE. Therefore, it can be expected that municipal incineration of PTFE using best available technologies (BAT) is not a significant source of studied PFAS and should be considered an acceptable form of waste treatment. This study was further intensified by Karlsruhe Institute of Technology (KIT) in cooperation with Société Générale de Surveillance (SGS), initiated by Gujarat Fluorochemicals Limited (GFL) [GFL 2023]. They confirmed complete thermal destruction of fluoropolymers during incineration and no organic fluorides and more specifically PFAS substances were present in incineration flue gas.

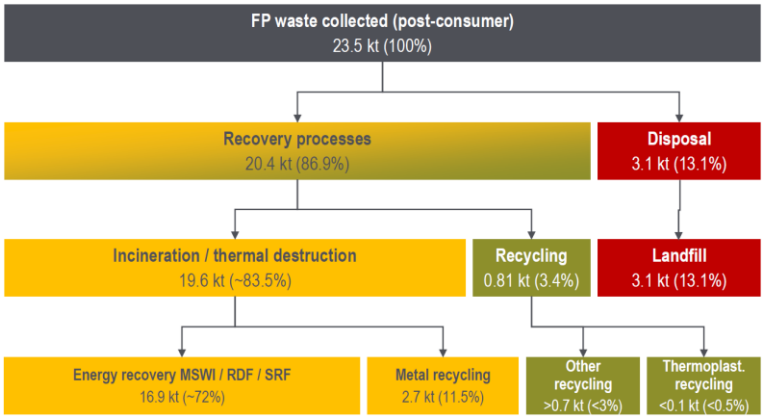

Figure 5: (Co-)treatment route of post-consumer fluoropolymer waste in the EU in 2020 [Conversio 2023]

Degradation to Microplastics

The relation between PTFE and its global impact as microplastic (MP) in marine environment was investigated by means of the risk screening method [Yuan 2022]. 36 different polymers were evaluated on global level by five different risk factors covering the probability of human exposure to MP and the potential impact. PTFE was ranked 17/36 with a risk score of 22! This, in comparison to e.g. polyurethane (PUR) ranked 1/36 with a risk score of 150 or polyvinylchloride (PVC) ranked 2/36 with a risk score of 135. Remarkable is the annual production of these latter polymers: 27 and 38 Mio. tonnes respectively in comparison to 0,1 Mio. tonnes in case of PTFE. The recovery rate of PUR and PVC were 40% and 60% respectively. They assumed that PTFE cannot be recovered (recovery rate of 0%!), this is in contradiction what is described in this section. With the right assumptions, PTFE should have been ranked lower! The persistency, density and particle size were the main contributors to the PTFE-score. The sPTFE at *Berghof Fluoroplastic Technology* is used for technical products only and is not directly applied as consumer goods. Therefore, the contribution of sPTFE in technical products to microplastics is estimated very low.

Degradation to PFAS-of-Concern*

Finally, fluoropolymers are substantially different from the other polymeric PFAS in terms of potential emissions due to degradation into small PFAS molecules during intended use or under environmental conditions and, for this reason, they have no environmental impact. Fluoropolymers have a high molecular weight, no water solubility and volatility, therefore they are not expected to degrade to lower molecular weight PFAS. Also, they are not expected to lead to the formation of long-chain PFAS as a result of degradation. [Sales 2022]

Fluorosurfactant-free manufacturing

It should be noted, that the used suspension PTFE is manufactured without using fluorinated production aids, like fluorosurfactants. This is already confirmed in section 1.1. So, the argument of environmental emissions related to manufacturing aids **does not apply** here!

*** Definition of PFAS-of-concern**

a subset of per- and polyfluoroalkyl substances (PFAS) that are considered to be particularly problematic due to their potential adverse effects on human health and the environment (in terms of persistence, bioaccumulation, and toxicity), like short-chain non-polymeric PFAS or fluorosurfactants (e.g. fluorinated production aids).

References

[Gentile 2019] Gentile, EPA – Air Toxics Section, Results of PTFE Sintering Oven Emissions Characterization Study, 2019, https://www.dec.ny.gov/docs/remediation_hudson_pdf/finalcoverordrept121719.pdf, visited on 06.06.2023

[BImSchG 2022] Bundesministerium der Justiz, Gesetz zum Schutz vor schädlichen Umwelteinwirkungen durch Luftverunreinigungen, Geräusche, Erschütterungen und ähnliche Vorgänge (Bundes-Immissionsschutzgesetz - BImSchG), last revision in 2022, https://www.gesetze-im-internet.de/bimschg/, visited on 24.04.2023

[OCSweep 2023] Operation Clean Sweep, https://www.opcleansweep.org/, visited on 05.05.2023

[3M 2015] 3M™ Dyneon™ Fluoropolymer Up-Cycling, https://www.3m.co.uk/3M/en_GB/design-and-specialty-materials-uk/products/full-story/?storyid=bfc8cfed-72ac-4982-8f5e-79b7cbb4fc62, visited on 05.05.2023

[Conversio 2023] Conversio – Market & Strategy, Fluoropolymer waste in Europe 2020 – final report, elaborated for pro-K, published January 2023

[Aleksandrov 2019] Aleksandrov et al., Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas, Chemosphere 226, 2019, 898-906 (https://doi.org/10.1016/j.chemosphere.2019.03.191)

[GFL 2023] Gujarat Fluorochemicals Limited (GFL), Incineration study on Fluoropolymers at their End-of-Life https://www.gfl.co.in/upload/pages/64ca54ee691b6f4a8b2649ec9c7b291f.pdf, , visited on 02.06.2023

[Yuan 2022] Yuan et al., Ranking of potential hazards from microplastics polymers in the marine environment, J. Hazard. Mater. 429, 2022, 1–19 (https://doi.org/10.1016/j.jhazmat.2022.128399)

[Sales 2022] Sales et al., Fluoropolymers: The Safe Science That Society Needs, International Chemical Regulatory and Law Review (ICRL) 5(1), 2022, 13-23 (https://icrl.lexxion.eu/data/article/18600/pdf/icrl_2022_01_2022-11-02-12.39.059.pdf)

1.4. Baseline

Berghof Fluoroplastic Technology processes PTFE to make a wide variety of PTFE components consisting of high-density/solid PTFE, porous PTFE and optical PTFE.

Group:	Polytetrafluoroethylene (PTFE)	
Subgroup:	suspension polytetrafluoroethylene (sPTFE)	
Materials:	sPTFE	CAS No. 9002-84-0 (Poly(tetrafluorethylene))
	Modified sPTFE	
	sPTFE compounds	
Consumption of raw materials:	Total processed tonnage is given in the ‘confidential document’ in Section V	
Industries:	Semiconductor industry, laboratory equipment/technology, automotive, aerospace, chemical industry, industrial processing, electronics and electrical, photonics (optical industry / light measurement), food & beverage, medical technology.	

1.5. Description of analytical methods

Sintered PTFE **does not emit PFAS-of-concern** during life-cycle which can be proven by analytical measurements process by analytical laboratories as mentioned in 'confidential documents' in Section V.

As written in all Safety Datasheets of PTFE: "This product is not classified as hazardous substance / hazardous mixture according to Regulation (EC) No 1272/2008", or: "Regulation (EC) No 1272/2008 is not applicable".
We have taken measures to underline this by the analysis of several of our products. In the 'confidential documents' (Section V) certificates are attached that show the harmlessness of the fluoropolymers. To this, also the applied test method is described.

1.6. Information on alternatives

PTFE is a high performance material and has many beneficial properties, especially the combination of these properties makes the difference in comparison to alternative materials. Compared to standard plastics, like polyolefins (e.g. LDPE, HDPE or PP) or PVC, PTFE is rather expensive, but thermally stable (Relative Temperature Index (RTI) > 150°C [Haghani 2021]). Engineering plastics, like polyamides, POM or PMMA, are less costly then PTFE but are thermally inferior. High performing polymers permit exceptional end-use-applications, specialized products at high costs. In general, it can be stated, that PTFE will only be applied, when this is really required for the application, otherwise a less costly material will be chosen. PTFE is not used for conveniency, but for high-end products where a certain combination of properties is really necessary (essential use!). This is also expressed by the annual production of fluoropolymers, i.e. 0,1% of the total plastic production worldwide (380 Mio.t in 2022). [Schlipf 2023]
Alternative materials can also be glass, ceramic or other inorganic materials. Still, the combination of certain properties will make PTFE irreplaceable.

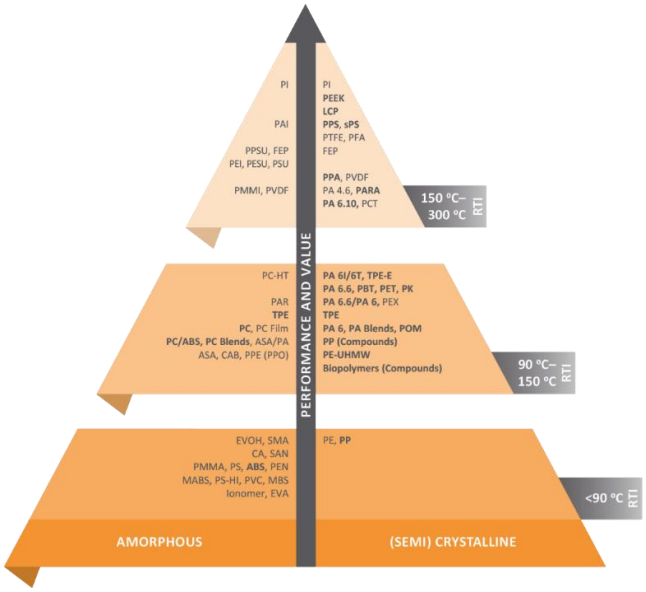

Figure 6: Thermoplastics classification [Haghani 2021]

Currently, many different PFAS (on the order of several thousands) are used in a wide range of applications, and there is no comprehensive source of information on the many individual substances and their functions in different applications.

A broad overview of many use categories where PFAS have been employed and for which function was given by Glüge et al. [Glüge 2020]. They also specified which PFAS have been used and discuss the magnitude of the uses. Despite being non-exhaustive, this study clearly demonstrates that PFAS are used in almost all industry branches and many consumer products. In total, more than 200 use categories and subcategories are identified for more than 1400 individual PFAS. The search for alternatives is therefore a challenging and extensive task and is important in all use categories.

Chemservice provided an analysis of alternatives to fluoropolymer and evaluated many case studies in many different sectors [Chemservice 2022]. The case studies that are described in that report are based on specific applications as reported by a selection of downstream users of fluoropolymers. The applications should be considered as a reduced sample of the broad industrial sectors that rely on fluoropolymers today. The conclusion was that fluoropolymers are currently irreplaceable for many critical applications, and existing potential alternatives would be associated with significant trade-offs that could compromise safety of workers, general population, or the environment, either due to direct hazardous properties of the alternative, or by downgrading performance of key applications.

The possibility to apply alternative materials depends strongly on the application and the technical and safety requirements. There is no general alternative material for PTFE and in many cases there is simply no alternative for PTFE. In section 2.6, possible alternatives accompanied with the compromises and drawbacks are described for the missing uses not addressed in the restriction proposal.

References

[Haghani 2021] M. Haghani, Relative thermal index (RTI), https://www.linkedin.com/pulse/rti-relative-temperature-index-mohamadreza-haghani/, visited on 05.06.2023

[Schlipf 2023] M. Schlipf, Title: Fluoropolymers Global Market Overview; Conference: Innovations using Fluoropolymers, SKV, 3-4 Mai 2023 in Würzburg (see section 1.1)

[Glüge 2020] Glüge et al., An overview of the uses of per- and polyfluoroalkyl substances (PFAS), Environ. Sci.: Processes Impacts, 2020, 22, 2345-2373 (https://doi.org/10.1039/d0em00291g)

[Chemservice 2022] Chemservice, technical report - analysis of alternatives to fluoropolymers and potential impacts related to substitution in different sectors of use, Version 1, 19.7.2022, confidential document

1.7. Information on benefits

There are no benefits for NOT using PTFE in industrial applications or in high tech products in case the required combination of properties can only be provided by PTFE material.

1.8. Other socio economic analysis (SEA) issues

Berghof Group

Berghof is a technology and family-owned company with 400 employees and 71 million EUR revenue (both numbers from 2021). Berghof Group consists of six different subsidiaries, i.e.:

- Berghof Fluoroplastic Technology GmbH
- Berghof Membrane Technology GmbH
- Berghof Products + Instruments GmbH
- Gigahertz-Optik GmbH
- Berghof Automation GmbH
- Berghof Environmental Engineering GmbH

The contribution of Berghof Fluoroplastic Technology to the turnover of the whole Berghof Group is clearly above average. Furthermore, it can be stated, that the EBIT of Berghof Fluoroplastic Technology is positive and contributes significantly to the welfare of the Berghof Group.

Berghof Fluoroplastic Technology

Employees
Employee numbers of *Berghof Fluoroplastic Technology* are presented in the 'confidential document' in Section V; all employees are located in Germany.

Revenue
As already stated in section 1.1, the three main product groups at *Berghof Fluoroplastic Technology* are:

- High density PTFE (solid PTFE)
- Porous PTFE; brand name: Permeaflon®
- Optical PTFE; brand name: OptoPolymer®

The total revenue and revenue shares related to the product groups of *Berghof Fluoroplastic Technology* in 2021 and 2022 is presented in the 'confidential document' in Section V.

Berghof Fluoroplastic Technology distributes its products internationally. This is schematically represented in Figure 7. A very significant revenue share is related to the European market and the Germany market is the largest within Europe. It can be stated that *Berghof Fluoroplastic Technology* is highly dependent on producing and distributing its products in Europe.
As the restriction proposal is accepted as submitted, the only alternative is, that the production of *Berghof Fluoroplastic Technology* is transferred to outside Europe resulting in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. Since revenue contribution to the European market is very significantly, it will be a challenge (or an impossible mission) to compensate the revenue of the European market outside of Europe.

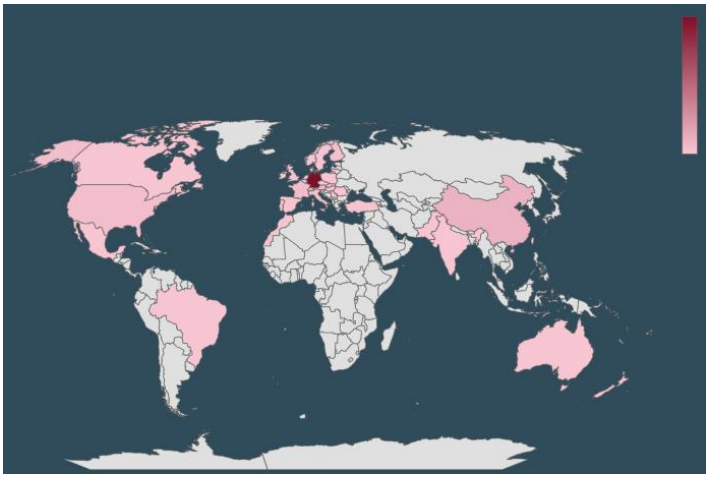

Figure 7: worldwide revenue distribution in 2022.

Investments and recruitment
It has to be mentioned, that the consequence of this proposal is the uncertainty it accompanies. This uncertainty results in stopping investments (or at least putting them on hold) and delaying recruitment activities. Instead of moving forward, we are standing still. More regulatory obligations for producers of fluoropolymers will result in decline of production in Europe in the transition period and a full production stop after a possible ban. Materials become scarce, supply chain is endangered, reliable delivery times are on stake, leading to higher costs and customer dissatisfaction. This has a significant impact on the competitiveness of *Berghof Fluoroplastic Technology*.

Influence on the Berghof Group
This does not have an impact solely on *Berghof Fluoroplastic Technology* but on whole Berghof Group as well. *Berghof Fluoroplastic Technology* is a significant pilar for the Berghof Group in terms of revenue and EBIT. The existence of the Berghof Group is highly endangered when PTFE products cannot be manufactured anymore (in Europe).

Berghof Fluoroplastic Technology is also a PTFE product supplier for the subsidiary *Berghof Products + Instruments*. The revenue share of the laboratory technology directly related to *Berghof Products + Instruments* is significant. The laboratory equipment cannot be manufactured without PTFE and this subsidiary will lose its total relevant revenue related to digestion and reactor technology. The contribution of *Berghof Fluoroplastic Technology* related to laboratory equipment and technology is described in section 0. *Berghof Products + Instruments* submitted their own contributions to the public consultation on 04.05.2023 (no. 4002 – 4007)!

Berghof Fluoroplastic Technology is also the main PTFE calibration standard supplier for the subsidiary *Gigahertz Optik*. The contribution of *Berghof Fluoroplastic Technology* related to optical applications and technology is described in section 2.6.7. *Gigahertz Optik* will submit their own contribution to the public consultation!

The existence of the total Berghof Group is highly endangered because of the entanglement of the PTFE products in the Berghof Group. Other subsidiaries cannot apply these high-quality products with fit-to-purpose properties anymore. The high-value products cannot be offered in the market anymore in a fair and competitive way.
It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubtful.

Conclusion
As soon as the restriction takes effect, it is expected that *Berghof Fluoroplastic Technology* will lose a large proportion of the total revenue which is related to European business. Customer demands cannot be met anymore and no competitive products can be offered. Relocating the production of *Berghof Fluoroplastic Technology* to outside Europe is the only alternative for the company to remain. This will result in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. It will be a challenge (or an impossible mission) to compensate the revenue of the European market outside of Europe.
This does not have an impact solely on *Berghof Fluoroplastic Technology* but on whole Berghof Group as well. *Berghof Fluoroplastic Technology* is a significant pilar for the Berghof Company. The existence of the total Berghof Group is highly endangered because of the entanglement of the PTFE products in the Berghof Group. It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubtful.

1.9. Transitional period

No transitional period requested. **An exemption of fluoropolymers in general and PTFE in particular is required**.

1.10. Request for exemption

Berghof Fluoroplastic Technology cannot comprehend the possible ban of fluoropolymers in general, PTFE in particular and more specifically: suspension PTFE. This fluoropolymer type is a polymer-of-low-concern and can be manufactured without using fluorinated production aids, like fluorosurfactants. It is already confirmed by various sPTFE manufacturers that PTFE applied at *Berghof Fluoroplastic Technology* is manufactured with no such production aids. *Berghof Fluoroplastic Technology* endeavor a supply chain, from raw material to shipped products, without PFAS-of-concern.
We are not against a restriction/limitation of hazardous, persistent and mobile PFAS-of-concern, and support a scientific approach differentiating high and low risk substances based on risk assessment. *Berghof Fluoroplastic Technology* supports the initiative to restrict the use of any hazardous PFAS classes which are scientifically proven to be associated with risks to human health and environment. It should be concluded that fluoropolymers should not be treated in a similar way as these other PFAS substances and should be taken completely out the ECHA restriction dossier.
In general, it can be stated, that PTFE will only be applied, when this is really required for the application, otherwise a less costly material will be chosen. PTFE is not used for conveniency, but for high-end products where a certain combination of properties is really necessary (essential use!). Furthermore, it is no discussion that the fluorine loop should be closed. This is manageable for PTFE applied in industrial applications or in high tech products. These products are traceable and/or recyclable. The application of PFAS in consumer goods should be minimized and only applied if really necessary.
The socio-economic impact of a possible restriction or a ban of PTFE on *Berghof Fluoroplastic Technology* is severe. Relocating the production of *Berghof Fluoroplastic Technology* to outside Europe is the only alternative for the company to survive. This will result in losses of i. jobs, ii. taxes and iii technical/production knowhow in Europe. The existence of the total Berghof Group in Europe is

highly endangered because of the entanglement of the PTFE products in the Berghof subsidiaries. It can be concluded that the impact of a possible fluoropolymer ban will be devastating to the Berghof Group and its further existence is extremely doubtful. The uncertainty among various stakeholders, which is already evident in the initial reluctance to invest after the publication of the restriction dossier, already suggests how dramatically and quickly the Berghof Group would be hit by a possible fluoropolymer ban.

General: **Fluoropolymers should be exempted from any regulatory action under the REACH restriction!!**

Specified: **Exemption for PTFE used in high tech products and products and production aids for industrial applications!!**

2. Specific information

2.1. Sectors and (sub-)uses

Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.

Sector	Annex	Sub-sector
Manufacture	E.2.1.	Sector as a whole
Food contact materials and packaging	E.2.3.	Industrial food and feed production
Food contact materials and packaging	E.2.3.	Plastic packaging
Metal plating and manufacture of metal products	E.2.4.	Manufacture of metal products not addressed elsewhere
Medical devices	E.2.9.	Diagnostic laboratory testing
Medical devices	E.2.9.	Membranes used for venting of medical devices
Medical devices	E.2.9.	Packaging of medical devices
Transport	E.2.10.	Use of PFASs in applications affecting the proper functioning related to the safety of vehicles, and affecting the safety of operators, passengers or goods, to the extent not addressed under other parts of this restriction (e.g. under lubricants, electronic equipment and TULAC)
Transport	E.2.10.	Mobile Air Conditioning (MAC)
Transport	E.2.10.	MAC- and refrigeration in military applications
Electronics and semiconductor	E.2.11.	Electronics
Electronics and semiconductor	E.2.11.	Semiconductors
Energy sector	E.2.12.	Sector as a whole
Lubricants	E.2.14.	Sector as a whole
Petroleum and mining	E.2.15.	Fluoropolymer applications

2.2. Emissions in the end-of-life phase

The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:

a. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.

b. If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.

Answer:
This information is already provided in section 1.3.

2.3. Emissions in the end-of-life phase

With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.

Answer:
This information is already provided in section 1.3.

2.4. Impacts on the recycling industry

To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:

a. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).

b. The measures that recyclers would need to take to achieve the proposed concentration limits.

c. The costs associated with these measures.

Answer:
This information is already provided in section 1.3.

2.5. Proposed derogations – Tonnage and emissions

Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.

Answer:
This information is already provided in section 1.3.

2.6. Missing uses – Analysis of alternatives and socio-economic analysis

Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report (page 5)). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:

2.6.1. PTFE for filtration and separation media used in high performance air and liquid applications

Industry: Automotive, Electronics and Electrical, Chemical Industry, Semiconductor industry, Food & Beverage

Application: Filtration and separation media used in high performance air and liquid applications, i.e.

- Pressure compensation elements (e.g. high voltage batteries)
- Porous elements with bursting function for passenger safety
- Sensor protection caps
- high performance membranes that repel water and oil
- Parts for crankcase pressure regulation
- Diaphragms

Background information:
Filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency for filters used in industrial settings functionalized by PFHxA related substances was noticed, acknowledged and deeply investigated by RAC and SEAC with the following restriction proposal:

Annex XV restriction proposal - undecafluorohexanoic acid (PFHxA), its salts and related substances
Document: Compiled RAC and SEAC opinion (and minority positions) – document final opinion (website: https://echa.europa.eu/documents/10162/97eb5263-90be-ede5-0dd9-7d8c50865c7e)

SEAC (page 56): 'Filtration and separation media: PFHxA related substances in filtration and separation media have a very broad range of applications across several market sectors. The products affected are e.g. medical devices; PPE; heating, ventilation and air conditioning (including high-purity applications for hospitals, laboratories etc.); air pollution controls; dust collectors; hydraulic systems; coalescers; gas turbines; fuel systems and many more.'

The necessity of filtration and separation media used in high performance air and liquid applications is well-known!
If PFHxA related substances in filtration and separation media have a very broad range of applications across several market sectors, the use of PTFE show definitely a much broader range of applications across assumably even more market sectors! Our PTFE products are skived sheets and porous forming parts and cannot be classified under 'textiles'.
So, it is quite peculiar that we have to address this in the category 'missing uses' because fluoropolymers and PTFE in particular play a significant role in these filtration and separation applications.

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- High-molecular weight and a high melting point
- Temperature range from -250 to +260°C
- Universal chemical resistance
- Anti-adhesive surface, extremely low coefficient of friction
- Hydrophobic properties
- Porous properties available by special treatment
- High UV resistance and resistance to weathering
- High purity
- High flame resistance according to UL94 V-0
- Good processability / forming / shaping
- High Flexlife
- Possibility to burst at a certain pressure
- Oleophobic properties

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology:	Details are provided in the 'confidential document' in section V
Related to the whole market:	Different OEM-Automotive companies (BMW, VW, Porsche, Audi, etc.)
Further downstream users:	Filtration and separation media are used in a variety of products. Thousands of small-, medium-, and large-sized companies will be affected regarding safety, reliability and efficiency.

Since porous PTFE in automotive sector has a large revenue share within Berghof Fluoroplastic Technology, we would like to emphasize the contribution of **ACEA - European Automobile Manufacturers' Association**, 'ACEA COMMENTS ON THE ANNEX XV DOSSIER OF THE UNIVERSAL PFAS RESTRICTION PROPOSAL' [ACEA 2023]. They gave an in-depth description and clear and thorough assessment of 'PTFE Membrane' in the automotive industry. They clearly state: **'Fluoropolymers should be completely taken out of scope'.**

References

[ACEA 2023] **ACEA - European Automobile Manufacturers' Association**, 'ACEA COMMENTS ON THE ANNEX XV DOSSIER OF THE UNIVERSAL PFAS RESTRICTION PROPOSAL', May 2023 (ACEA_2023_Comments on Universal PFAS Restriction Proposal.pdf)

d. *The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected*.

Alternative materials: PE or PP (polyethylene or polypropylene) , Polyimide (PI), polyetheretherketone (PEEK), elastomer

	PTFE	PE or PP	PI	PEEK	Elastomer
Molecular weight					
Processability / forming / shaping					
Temperature range					
Chemical resistance					
Anti-adhesive surface, friction					
Hydrophobic properties					
Porosity					
UV resistance and resistance to weathering					
High purity					
High flame resistance					
Physiologic properties					
Product portfolio options					
Development stage					
Flexlife					

Very important to mention the combination of specific properties which makes PTFE very hard to replace. Based on pricing, PE or PP is very advantageous, meaning that all applications where replacement is possible, it is already replaced by PE/PP. Since specific user requirements still demand a combination of certain properties (e.g. T-range, hydro- and oleophobic, chemical resistance and low friction) there is no alternative without making compromises.

e. *For cases in which alternatives are not yet available, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.*

No information can be provided; there is no interest from our side to investigate alternative materials for this application.

Status of R&D processes for finding suitable alternatives for filtration and separation media should be done by the equipment manufacturer (i.e. downstream-user). Data are provided in the mentioned public consultation submissions (section 2.6.1 - c).

f. *For cases in which substitution is technically and economically feasible but more time is required to substitute:*

i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);

A substitute will always be a compromise. Berghof Fluoroplastic Technology offers high quality, fit-for-purpose products.

ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);

iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);

Functionality cannot be assured (reliability, safety and efficiency). Inferior mechanical properties, no-stick properties, temperature application range with required chemical stability will result in decreased lifetime, leading to more often exchange (**CO_2 footprint ↑, material use ↑, maintenance costs↑**)

iv. *information on the benefits for alternative providers.*

g. *For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.*

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is significant in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.
The socio-economic impacts are described in detail in Section 1.8 and will be devastating for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

Please note that due to time constraints, this document may not include all detailed information about the 'missing uses – Analysis of alternatives and socio-economic analysis', but further submissions by *Berghof Fluoroplastic Technology* will provide this information during the course of the public consultation. This concerns the contributions to the missing uses described in section 2.6.2 – 2.6.7!

Further on in this document, following is presented in section 2.6.2 – 2.6.7:

- **Missing use (industry and application)**

a. **The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.**

b. **The key functionalities provided by PFAS for the relevant use.**

c. **The number of companies in the sector estimated to be affected by the restriction.**

g. **information on what the socio-economic impacts would be for companies, consumers, and other affected actors**

Contributions to question d – f per missing use will be submitted at a later stage.

2.6.2. PTFE for industrial process equipment

Industry: Chemical Industry, Semiconductor industry, Food & Beverage

Application: Industrial process equipment, i.e.

- Tanks and vessels; i.e. etching tanks, process tanks, storage tanks
- Pump components; i.e. pump housings, containment shells, pump impellers, can inserts for pumps, pump diaphragms/membranes
- Bellows
- Sealings and gaskets
- Bubbling systems
- Stirrers
- Heaters
- Clamps shells
- Hollow cylinders
- Guiding strips
- Filters for liquid processing (see section 2.6.1)

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- High thermal resistance
- Low permeation of chemicals
- Non-flammability acc. to UL94 V-0
- Anti-adhesive surface
- Outstanding chemical resistance
- Hydrophobic properties
- Ultra-High purity

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology:	Details are provided in the 'confidential document' in section V
Related to the whole market:	unknown

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is significant in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.
The socio-economic impacts are described in detail in Section 1.8 and will be devastating for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

2.6.3. PTFE for laboratory equipment, laboratory technology

Industry: Laboratory equipment / laboratory technology

Application: Reactor vessels used in:

- Digestion technology
- Reactor technology

The main customer for this product is Berghof Products and Instruments (https://www.berghof-instruments.com/)

Figure 8: Reactor vessels for digestion technology (left) and reactor technology (right).

One important feature is emphasized, i.e. the insitu, contact-free measurement in the reactors. This is only possible with use of PTFE reactor vessels due to the characteristics of PTFE (IR-gap). The PTFE material is 'transparent' and the heat radiation in a spectral range can be detected. This is not possible with any other material!
(https://www.berghof-instruments.com/en/downloads/ - Berghof Sensor Technology.pdf)

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- High-molecular weight and a high melting point
- Temperature range from -250 to +260°C
- Universal chemical resistance
- Anti-adhesive surface, extremely low coefficient of friction
- Hydrophobic properties
- Ultra-high purity
- High flame resistance according to UL94 V-0
- Good processability / forming / shaping
- Low permeation of chemicals
- Hydrophobic properties

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology:	Berghof Products and Instruments GmbH, amongst others
Related to the whole market:	several laboratory equipment suppliers
Further downstream users:	analytical laboratories, research institutes, companies working with profound analytical instrument

An in-depth assessment with further details is provided in the **public consultation submission by *Berghof Products and Instruments* (Eningen, Germany)** on 04.05.2023 (4002 – 4007)

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is significant in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.
The socio-economic impacts are described in detail in Section 1.8 and will be devastating for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

2.6.4. PTFE for sensor applications

Industry: Electronics and Electrical

Application: Sensor applications, i.e.

- Microwave level measuring sensor
- Pressure measuring sensor
- Point level sensor
- Capacitive and conductive level sensor
- Radiometric level, density and flow sensor

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- Anti-adhesive surface, extremely low coefficient of friction
- Temperature range from -250 to +260°C
- Universal chemical resistance
- Hydrophobic properties
- Excellent dielectric properties
- High UV resistance and resistance to weathering

A wide variation of sensor application need a material with excellent overall properties. Microwave, capacitive or conductive level sensor are highly dependent on the excellent **dielectric properties** of PTFE, and will not function as accurate and reliable with other materials.

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology: Details are provided in the 'confidential document' in section V

Related to the whole market: unknown (cities and municipalities to check levels of rivers/lakes to prevent floods, companies who measure levels in storage tanks, …)

Further downstream users: sensors for process and factory automation used in a variety of industries. Thousands of small-, medium-, and large-sized companies will be affected regarding safety, reliability and efficiency.

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is significant in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.

The socio-economic impacts are described in detail in Section 1.8 and will be devastating for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

2.6.5. PTFE for varnishing aids

Industry: Painting/varnishing technology (automotive, amongst others)

Application: PTFE electrode ring as varnishing aid

Short description:
atomizer for robot assembly with external electrodes and multi-trigger technology for water-based coatings. Allows paint-saving and sustainable processing of water-based paints and reduces material losses enormously, while still offering excellent cleanability, and therefore long and sustainable lifetime.

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- Universal chemical resistance
- Anti-adhesive surface, extremely low coefficient of friction
- Hydrophobic properties
- Ultra-high purity
- Good processability / forming / shaping

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology:	Details are provided in the 'confidential document' in section V
Related to the whole market:	none
Further downstream users:	varnish-equipment manufacturer, automotive companies

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is important in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.

The socio-economic impacts are described in detail in Section 1.8 and will be devastating for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

2.6.6. PTFE for transmission and communication

Industry: Transmission and communication

Application: Wifi Antenna parts

Short description:
These are broadband antenna technologies having a focus on commercial aviation and high-performance, high-end broadband antennas that make it possible to stay connected in flight.

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- Temperature range from -250 to +260°C
- Anti-adhesive surface, extremely low coefficient of friction
- Hydrophobic properties
- Ultra-high purity
- Excellent dielectric properties
- Good processability / forming / shaping

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology: Details are provided in the 'confidential document' in section V.

Related to the whole market: Maybe the following: Airbus, Boeing, Bombardier, Embraer, COMAC

An in-depth assessment with further details is provided in the public consultation submission by the above mentioned aircraft-manufacturers.

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is significant in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.

The socio-economic impacts are described in detail in Section 1.8 and will be devastating for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

2.6.7. PTFE for optical applications and photonics

Industry: Optical industry, light measurement technology

Application: Optical properties of PTFE applied in

- Reflection standards
- Interior of Ulbricht integrating spheres
- Diffuse reflectors
- Projection screens
- Display backdrops
- Reflectors for highly intensive radiation sources

Short description:
Integrating spheres are very versatile optical elements designed to achieve homogeneous distribution of optical radiation through multiple Lambertian reflections at the sphere's inner surface.

Figure 9: left: integrating sphere by Gigahertz Optik (www.gigahertz-optik.com]; right: optical PTFE parts by Berghof Fluoroplastic Technology (https://www.berghof-fluoroplastics.com/)

a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

Following data is provided in the 'confidential document' in Section V

Annual tonnage of this PTFE-product:	2022: XX tons		
Emissions during production:	none		
Scrap rate of the production:	2022: XX tons →	reuse/recycling:	XX tons
		upcycling:	XX tons
		incineration:	XX tons

The annual tonnage is an indicative number and can vary year by year. These numbers can be related to the total manufacturing numbers presented in section 1.3. Reuse/recycling/upcycling/incineration can be calculated proportional to the presented data.

b. The key functionalities provided by PFAS for the relevant use.

PTFE:

- Temperature range from -250 to +260°C
- Excellent Lambertian reflectivity over a wide range of wavelength
- Anti-adhesive surface
- Hydrophobic properties
- Ultra-high purity
- Good processability / forming / shaping

c. The number of companies in the sector estimated to be affected by the restriction.

Related to Berghof Fluoroplastic Technology:	Gigahertz Optik GmbH (Türkenfeld, Germany); amongst others
Related to the whole market:	unknown
Further downstream users:	Many supermarkets that operate bottle deposit machines

An in-depth assessment with further details will be provided in the **public consultation submission by Gigahertz Optik (Türkenfeld, Germany)**

g. For cases in which substitution is not technically or economically feasible, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.

The revenue loss an European business share are presented in the 'confidential document' in Section V.
The impact on downstream users, companies and consumers is significant in case no alternative materials (with similar or better properties regarding safety, health and technical) can be found.

The socio-economic impacts are described in detail in Section 1.8 and will be severe for the Berghof Group in general and *Berghof Fluoroplastic Technology* in particular.

2.7. Potential derogations marked for reconsideration – Analysis of alternatives and socio-economic analysis

Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

Answer:
No comments.

2.8. Other identified uses – Analysis of alternatives and socio-economic analysis

Table 8 in the Annex XV restriction report (starts on page 80) provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.
For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.
More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

Answer:
No comments.

2.9. Degradation potential of specific PFAS sub-groups

A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.

Answer:
PTFE has no degradation potential. This is elaborated in detail in section 1.3 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)).

2.10. Analytical methods

Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

Answer:
Analytics for PFAS determination if provided in section 1.3 and 1.5 in the attached public consultation reports (non-confidential (Section IV) as well as confidential (Section V)).