COMMENT TO THE PUBLIC CONSULTATION ON THE REACH RESTRICTION PROPOSAL ON PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

Public version

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Substance:	Polytetrafluoroethylene (PTFE)

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LIST OF ABBREVIATIONS

AoA	Analysis of Alternatives
AODD	Air-Operated Double Diaphragm
CAGR	Compound Annual Growth Rate
CSR	Chemical Safety Report
EBIT	Earnings Before Interest and Taxes
ECHA	European Chemicals Agency
EEA	European Economic Area
EU	European Union
EUR	Euro
FDA	Food and Drug Administration
FGEW	Functional Group Equivalent Weight
FTE	Full-Time working Equivalent
FP	Fluoropolymer
LCI	Labour Cost Index
NPV	Net Present Value
PEEK	Polyetheretherketone
PFAS	Per- and polyfluoroalkyl substances
PLC	Polymer of Low Concern
PTFE	Polytetrafluoroethylene
PFPE	Perfluoropolyether
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RFG	Reactive Functional Groups
SEA	Socio-Economic Analysis
US	United States
USA	United States of America
USP	US Pharmacopeial Convention

1 INTRODUCTION

PSG Germany GmbH, also referred to under its brand name Almatec, is a subsidiary of PSG and located in Duisburg, Germany. For the production of their air-operated double-diaphragm (AODD) pumps, components containing polytetrafluoroethylene (PTFE) are required. These pumps are critical components in a multitude of industries and used for various applications. As the recent restriction proposal on PFAS may include the use of PTFE, PSG Germany GmbH aims for a derogation of the restriction for a period of minimum 12 years. To support this requested derogation period, an analysis of possible alternatives, a presentation of the socio-economic costs of a restriction and the chemical safety report for the handling and disposal of PTFE at PSG Germany GmbH's site will be presented in the following.

2 SCOPE AND AIMS

The objective of the present submission is to provide comments to the public consultation on the PFAS Annex XV REACH Report ("Restriction Proposal") launched by the European Chemicals Agency ("ECHA") on March 22, 2023.

Currently, there is no restriction in place for PTFE. However, the PFAS Annex XV REACH Report, jointly submitted by the national authorities of Germany, the Netherlands, Norway, Sweden, and Denmark, aims to limit the risks to the environment and human health from the manufacture and use of the whole PFAS group, including PTFE. The possible date of entry into force for the restriction is expected in 2025, with two restriction options:

- A full ban with no derogation and a transition period of 18 months;
- A full ban with the use of specific time-limited derogation (18 months transition period plus a 5-year or a 12-year derogation period).

It is PSG Germany GmbH's position that the intended PFAS restriction proposal is too extensive, considering the vast majority of PFASs and their differentiating properties. PTFE is used in the production of PSG Germany GmbH's highly specialised air-operated double-diaphragm pumps, the E-Series and the Futur series. Likewise, PTFE is used in replacement diaphragms and valves parts used in the AHD-Series, CXM-Series, Chemicor, and Biocor. Specifically, PTFE is used in housing parts, valve seats, valve balls, diaphragms, O-Rings, and face seals of the pumps. These parts are also the areas which come into contact with the media. Media includes Hydrocarbons (aromatic, halogenated, and chlorinated), fuels, solvents (e.g., Cyclohexan), alcohols (e.g., Benzene), and aqueous cell culture media. PSG Germany GmbH's pumps are used in a range of sectors, including the chemical sector, semiconductor sector, the food and beverage sector, biopharma sector, and electrical sector. Due to the wide variety of media and sectors which PSG Germany GmbH's pumps are used in, PTFE is an ideal material based on the combination of its chemical stability and thermal resistance.

The aim of this document is to:

i. From the Analysis of Alternatives (AoA) to demonstrate that there is no technically nor economically feasible alternative for PTFE in the application of PSG Germany GmbH's diaphragm pumps;

ii. From a Socio-Economic Analysis (SEA) to demonstrate the socio-economic benefits associated with the continued use of PTFE by PSG Germany GmbH's diaphragm pump market outweighs any impacts due to PTFEs use; and
iii. From a Chemical Safety Analysis (CSR) to demonstrate that PSG Germany GmbH's use of PTFE poses no significant harm to humans or the environment.

Based on this information, PSG Germany GmbH petitions the committee to consider adjustments to a blanketed PFAS ban, in order to reflect the substantial differences in PFAS substances. Specifically, to consider a derogation on alternative restriction approaches, e.g. separating polymeric PFAS from the restriction of non-polymeric PFAS

3 DESCRIPTION OF THE FUNCTIONS OF THE SUBSTANCE

Fluoropolymers, or FPs, while considered within the category of per- and poly-fluoroalkyl substances (PFAS), are a special family of polymeric PFAS within themselves. They are composed of polymers with fluorinated side chains, perfluoropolyethers (PFPEs), and polymers with backbones comprised of carbon and fluorine atoms.

FPs are bio-inert and cannot be degraded by microorganisms under aerobic or anaerobic conditions. Additionally, they demonstrate exceptional thermal stability, requiring high temperatures for their decomposition. Due to their safety and high performance, FPs are widely used in highly technical applications, such as in batteries, photovoltaics, and medical devices.

Within this family of FPs is Polytetrafluoroethylene (PTFE). PTFE is a white, hydrophobic solid, is chemically inert, and has high thermal stability and a low coefficient of friction (Puts *et al*., 2019). Table 1 lists PTFE's criteria as a Polymer of Low Concern (PLC). PLC criteria have been progressively developed due to chemical hazards assessment processes. These chemical hazard assessments have been used to evaluate a polymers bioavailability by determining its physical-chemical properties, elucidating a polymer's potential hazard. Due to PTFE's characteristics as a polymer, it is classified as a PLC. Therefore, PTFE is deemed to have insignificant environmental and human health impacts.

Table 1: Polymer of Low Concern Criteria for Polytetrafluoroethylene (adapted from Henry et al. 2018).

Structure	$-(CF_2-CF_2)-_n$
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to C)	Yes
Molecular weight	389 000 – 8 900 000[a,b]
(M_n > 1000 Da and oligomer content < 1%)	520 000 – 45 000 000[a,c]
Molecular weight distribution MW ÷ number average M_n (M_n and heterogeneity of MW distribution indicate if majority are >1000 or <1000 Da, which could penetrate the cell)	2.3[d]
Wt % oligomer (<5% for <1000 Da oligomers, <2% for <500 Da oligomers)	Negligible

Ionic character (cationic polymers associated with aquatic toxicity; polycationic with adverse human health effect)	Neutral
RFGs[e] (some highly reactive functional groups (RFG) associated with adverse human health and ecotoxicology effects, e.g., acrylates, isocyanates, anhydrides, aziridines)	<1 see section Reactive functional groups and RFG ratio to MW)
FGEW[e] (typical value) (the lower the FGEW, the more reactive the polymer and the higher the potential for health and environmental impact)	$>10^5$–10^7
Low molecular weight leachables (MW<1000 Da able to enter cell)	<1 ppm
Residual monomers (monomers have lower MW than polymers; typically more hazardous than polymers)	<1 ppm
Ratio of residual monomers to molecular weight (typical value) (more low MW monomer content per mole increases bioavailability and hazard potential)	$\sim 10^{-13}$ to 10^{-15}
Structural similarities to RFG of concern (increases potential risk of adverse effects)	None
Reference standard see also ISO 1133 (ISO 2011), ISO 12086 (ISO 2006)	ASTM D 4894 (ASTM 2015a), D 4895 (ASTM 2015b)
Physical-chemical properties	
Water solubility (per USP 2011) (water solubility <10mg/L showed generally low health concerns; 10mL/L to 10000 mg/L had potential health concern)	Practically insoluble or insoluble ($1x10^{-5}$ mg/L)
Octanol–water partition coefficient, K_{OW} (higher K_{OW} associated with lipophilicity and a high potential to bioaccumulate or bioconcentrate)	NA
Particle size (median mass aerodynamic diameter, MMAD, should be >5 µm)	100–500mm (powders)
Stability	
Hydrolysis (breaking into M_n < 1000 Da increases hazard potential)	Stable
Light ($h\nu$) (breaking into M_n < 1000 Da increases hazard potential)	Stable
Oxidation (breaking into M_n < 1000 Da increases hazard potential)	Stable

Biodegradation (aerobic and anaerobic) (breaking into M_n < 1000 Da increases hazard potential)	Stable
Thermal stability at normal foreseeable use maximum continuous temp (°C) (breaking into M_n <1000 Da increases hazard potential)	260
Meets PLC criteria[f] (Y/N)	Yes

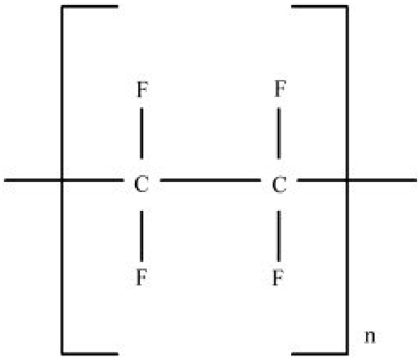
[a]Molecular weight is number average molecular weight.
[b]Berry and Peterson 1951; Doban et al. 1956.
[c]Suwa et al. 1973
[d]Chu et al. 1989
[e]For definition of reactive functional group; lists of low-, moderate-, and high-concern functional groups; and FGEW limits, see USEPA Polymer Exemption Guidance Manual (USEPA 1997b), BIO by Deloitte 2015 (p 191–192), and USEPA 2010. See Supplemental Data from Henry et al. 2018.
[f]See OECD 2009 and BIO by Deloitte 2015 for details on characteristics of a "polymer of low concern."

Table 2 lists PTFE's substance identity and Figure 1 display's PTFE's structural formula. In Table 3, PTFE's physiochemical properties are listed.

Table 2: Substance identity.

EC number	618-337-2
CAS number	9002-84-0
Chemical name	Polytetrafluoroethylene
Other names	PTFE, Teflon
Molecular formula	(C2F4)n

Figure 1: Structural formula of PTFE[1].



[1] Figure obtained from ScienceDirect. Poly(tetrafluoroethylene) webpage. Accessed from https://www.sciencedirect.com/topics/chemistry/poly-tetrafluoroethylene

Table 3: Physicochemical properties of the PTFE.

Property	Description of key information	Source
Physical state	Solid	Material data sheet in Appendix 1 and MatWeb[2]
Color	Natural	
pH	-	
Melting point	321 - 344 °C	
Density	2,16 g/cm³	
Vapor pressure	-	
Partition coefficient n-octanol/water (log value)	-	
Water solubility	0,000 – 0,010 %	

3.1 Key properties of PTFE

PTFE is part of a group of high-performance plastics with unique properties. As a distinctive Fluoropolymer, it exhibits performance properties unrivalled for temperature, chemical resistance, and non-stick properties. These unique material characteristics are due to PTFE structure, which consists of a carbon chain with attached fluorine atoms. PTFE is thermally resistant, flame retardant, physiologically safe, anti-adhesive, biocompatible, chemically resistant, and has anti-bacterial effects and a low coefficient of friction.

These properties aid in the function of PSG Germany GmbH's air-operated diaphragm (AODD) pumps, especially considering PTFE's virtually universal resistance to chemicals and its wide range of working environment temperatures. Due to this, PTFE offers uniform material properties across a wide variety of sectors and applications which utilise PSG Germany GmbH's pumps.

3.2 Functionality of PTFE in PSG Germany GmbH's pumps

PSG Germany GmbH's pumps are used in various industrial processes, in which the highest demands are placed on quality and material properties. Thermal resistance and media resistance, for example against acids, alkalis, alkali compounds or solvents and various other critical media, are requisite material properties of pumps from PSG Germany GmbH. These unique properties can only be guaranteed through the use of polyfluorinated plastics, according to the current state of developments regarding plastics.

PSG Germany GmbH has one of the largest production portfolios in the field of AODD pumps and designs, assembles, and conducts the final tests of the highly specialised air diaphragm pumps. This includes E-Series and Futur pumps, as well as replacement diaphragms and valves parts used in the AHD-Series, CXM-Series, Chemicor, and Biocor. These pumps, replacement diaphragms and valve parts require the use of Polytetrafluoroethylene (PTFE) due to the

[2] PEEK Technical Data Sheet. Accessed from https://www.matweb.com/search/datasheet_print.aspx?matguid=2164cacabcde4391a596640d553b2ebe

substance's chemical compatibility for aggressive chemicals, temperature range, and the desired mechanical properties for the pump housing, diaphragm, and valve material.

PSG Germany GmbH's pumps are used in battery production and recycling, semiconductor manufacturing, ceramic applications, pulp and paper applications, industrial wastewater treatment as well as in the chemical, paints and coatings, bio-pharma, food and beverage, and the photovoltaic industries. PTFE is used in the housing parts, valve seats, valve balls, diaphragms, O-Rings, and face seals of the pumps. These parts are also the areas which come into contact with the media. See Table 4 for the standard working environment of the pumps. E-Series pumps are used for all applications in normal environments and are in most cases freely accessible, whereas Futur pumps are exclusively used in a clean-room environment.

Table 4: Standard working environment of PSG Germany GmbH's pumps.

Pressure	0 – 7 bar
Environment Temperature	10 – 40 °C
Environmental Conditions	E-Series: Normally inside industrial processes in various conditions from very clean to dirty Futur: In cabinets and clean areas or clean room conditions
Temperature	0 – 100/ 120 °C (Hot-Application Futur Pump up 200 °C)
Media	Hydrocarbons (aromatic, halogenated, and chlorinated); fuels; solvents (e.g. Cyclohexan), alcohols (e.g. Benzene), and aqueous cell culture media

PSG Germany GmbH's main focus is on the chemistry and speciality chemistry sector, as well as on pure chemistry in the production of semiconductors, batteries and solar cells. Fundamental properties of PTFE in these sectors are its very high chemical and high thermal resistance, as well as its characteristics as a flame-retardant.

Furthermore, PTFE's physiologically safe, anti-adhesive, antibacterial and biocompatible properties, as well as its low coefficient of friction are necessary for the use of PSG Germany GmbH's PTFE pumps in food and beverage and bio-pharma processes. For the bio-pharma sector, for example, PSG Germany GmbH's PTFE pumps come into contact with aqueous cell culture media, aggressive cleaning solutions, or solvents. PTFE's properties guarantee a quality material in PSG Germany GmbH's pumps, while delivering lasting compatibility under a range of conditions. To certify that the pumps are physiologically safe and biocompatible for usage in the food and beverage sector, PSG Germany GmbH was certified by the Food and Drug Administration (FDA) for the United States and received the EC 1935/2004 certification for the European Union.

Furthermore, PSG Germany GmbH supports regulatory efforts to protect and safeguard the environment and humans, including the sensitive handling of hazardous substances and strict regulatory measures of individual PFAS substances with human toxicological properties in consumer products. Additionally, PTFE material that is used to manufacture PSG Germany GmbH's pumps and is then used by PSG Germany GmbH customers is applied in industrial processes under strict safety regulations.

3.3 Product applications and sectors of use

PSG Germany GmbH has one of the largest production portfolios in the field of highly specialised AODD pumps. The area of operation of these diaphragm pumps is diverse. While pumps are, to the best of PSG Germany GmbH's knowledge, not covered, as such, in the Annex VX Per- and polyfluoroalkyl substances (PFASs) restriction proposal, the different affected sub-sectors are listed below in Table 5. As a manufacturer of pumps made from plastic material, including PTFE, for highly specialised and demanding applications, PSG Germany GmbH's pump products are used in a wide variety of sectors. PSG Germany GmbH's customers require the company's highly specialised AODD pumps due to their unique properties, which PTFE enables.

Table 5: Sectors and sub-use sectors which use PSG Germany GmbH's PTFE air diaphragm pumps.

Sector: Manufacture (Annex E.2.1)	
Sub-Use	**Descripiton**
Sector as a whole	Diaphragm pumps are basic components in countless manufacturing processes. Due to this, this sector would apply to almost all applications in the various industries. <u>Necessary properties of PTFE:</u> • Very high chemical resistance • High thermal resistance • Flame retardant • Anti-adhesive • Low coefficient of friction
Sector: Food contact materials and packaging (Annex E.2.3.)	
Sub-Use	**Description**
Industrial food and feed production	Hygienic pumping processes in the food industry. Conveying of foods and end products in the food and feed industry. <u>Necessary properties of PTFE:</u> • Very high chemical resistance • High thermal resistance • Flame retardant • Anti-adhesive • Low coefficient of friction
Sector: Electronics and semiconductor (Annex E.2.11.)	
Sub-Use	**Description**
Electronics	Conveying of various critical media in the electrical/ semiconductors/ solar industry or in the
Semiconductors	

Battery and battery recycling Solar and photovoltaic	battery production and recycling industry like acids, caustics, and other extremely reactive liquids. Necessary properties of PTFE: • Very high chemical resistance • High thermal resistance • Flame retardant • Anti-adhesive • Low coefficient of friction
Sector: Energy sector (Annex E.2.12.)	
Sub-Use	**Description**
Sector as a whole	Various applications require diaphragm pumps. Necessary properties of PTFE: • Very high chemical resistance • High thermal resistance • Flame retardant
Hazardous waste disposal	Thermal recycling of liquid hazardous waste such as paints, varnishes, medicines, residues from chemical manufacturing processes, etc. Liquids of various compositions have to be pumped.
Sector: Chemical sector[3]	
Sub-Use	**Description**
General manufacturing and processing of critical chemicals	Various applications require diaphragm pumps. Necessary properties of PTFE: • Very high chemical resistance • High thermal resistance • Flame retardant • Anti-adhesive • Low coefficient of friction • Antibacterial effect
Acids	Various applications require diaphragm pumps.
Alkalis and caustic solutions	Various applications require diaphragm pumps.
Solvents	Various applications require diaphragm pumps.
Oxidising agents	Various applications require diaphragm pumps (likewise for Hydrogen peroxide or Hypochlorous acid).
Elemental chlorine	Pumping applications where elemental chlorine may outgas.
Chemical production for semiconductor and solar applications	Pumps are required for the production of high purity, aggressive liquids such as H2O2, H2SO4, NH3, HF, solvents, coatings, etc.
Production of activated carbon	Specially impregnated activated carbon for use in: Air & Gas Treatment, Flue Gas Treatment,

[3] Not included in Table 9 of the Annex XV Restriction Proposal.

	Personal Protective Equipment, Water Treatment. Pumping the impregnation liquids.
Production of personal protection clothing	Production of spherical absorbents that are used in different protective clothes of SARATOGA® for military, civil defense, fire brigades, police forces and international organizations worldwide. Pumping chemicals for production of spherical adsorbents.
Sector: Biopharmaceutical Sector[1]	
Pharmaceutical products	Various pumping processes of primary, secondary, and final products under the highest hygienic requirements Necessary properties of PTFE: • Physiologically safe • Anti-adhesive • Low coefficient of friction • Antibacterial effect • Biocompatibility

3.4 Tonnage Overview

PSG Germany GmbH supplies air-operated diaphragm pumps to various industries and applications in the European Union. For product applications and sectors of use, please see section 3.3. The distribution of tonnage of PTFE is supplied to the food, electronic, energy, manufacture, chemistry, and bio-pharma industries. The majority of PTFE is supplied to the chemical sector, accounting for 71.5 %, or 17 733 kg, of the distribution of PSG Germany GmbH's PTFE material. The supply to the electronic sector, at 12.3 %, or 3 040 kg, is the second largest distribution. However, if ECHA definitions are considered, both chemistry and bio-pharma would be allocated to the manufacturing sector, which would then lead to the largest distribution of PSG Germany GmbH's PTFE material, at 82.3 % or 20 416 kg.

Table 6: Tonnage (kg) and distribution of the use of PSG Germany GmbH PTFE material in the EU by industries.

	Food	**Electronic**	**Energy**	**Manufacture**	**Chemistry**	**Bio-Pharma**
Sum	452	3 040	904	1 528	17 733	1 155
%	1.8	12.3	3.6	6.2	71.5	4.7
Sum according to ECHA definitions[4]	452	3 040	904	20 416		
% according to ECHA definitions[1]	1.8	12.3	3.6	82.3		
Total tonnage in the EU in 2022				**24 812 kg**		

[4] The sectors Chemistry and Bio-Pharma are allocated to Manufacturing as a whole.

3.5 The value chain of AODD pumps

Almatec, as a fully owned subsidiary of PSG Dover, offers air-operated double-diaphragm (AODD) pumps to be used for multiple applications, such as the industrial production of food and feed, in the electronics and in the energy sector, as well in the manufacturing and processing of critical chemicals and for biopharmaceutical applications.

The company is certified according to DIN EN ISO 9001:2008 aiming to achieve the highest level of customer and supplier satisfaction through continuous improvement, further development and error prevention in all phases of value creation. To document the relevance of Almatec's environmental policy, the manufacturer was additionally certified according to DIN EN ISO 14001 in 2006. The E-series pumps comply with the requirements set by the US FDA for all materials used for food and beverage applications and all non-conductive variants in the pharmaceutical industry comply with USP Class VI requirements[5].

3.6 Key stakeholders involved in the supply chain

The vertical supply chain described in the following relates to the use of PTFE along the supply chain and PSG Dover's and Almatec's position in the supply chain of pumps used in various sectors. It covers suppliers (upstream supply chain) as well as customers (downstream supply chain) that are relevant to the scope of this derogation request.

PSG Dover is part of **Dover Corporation** and a global provider of pump solutions, enabling the safe and efficient transfer of critical and valuable fluids and materials. PSG is headquartered in Illinois, USA, running multiple brands across the globe. One of them is the submitter of this dossier, **PSG Germany GmbH** or also referred to under its brand name **Almatec**.

Headquartered in Duisburg, Germany, Almatec is specialised in the production of air-operated double diaphragm (AODD) pumps since 1984. In 1991, Almatec started the production of Futur pumps, which were particularly developed for the supply and circulation of chemicals in the semiconductor industry.

Generally, Almatec acts as an in-between supplier (processor) in a large supply chain. Thus, the design, assembly from pre-machined parts and conduction of final tests is done by the dossier submitter, whereas the manufacturing of parts is completely outsourced to external suppliers. Consequently, the PTFE used for the manufacture of housings parts, valve seats and other components is supplied by producers located in Germany to these external suppliers, as this is where the mechanical processing is taking place. All other raw materials required in the production of pumps mainly come from suppliers located inside the European Economic Area (EEA).

Concerning the downstream supply chain, Almatec serves diverse customers with a multitude of highly specialized and demanding applications. As pumps are basic components in various industries and used in almost every fluid manufacturing process or where fluids are auxiliary materials, intermediate products or by-products, Almatec is a relevant supplier for various

[5] Standard set by the US Pharmacopeial Convention (USP) on the biocompatibility of a material used in medical devices.

markets. Some of the most important markets are the following: battery production and recycling, chemical processing, ceramics, hygienic industries, paint and coatings, pulp and paper, semiconductors, as well as solar and water treatment. Around half of Almatec's customers are based in Germany, whereas all other customers are located in multiple other European countries.

3.7 Market and financial considerations

Given the versatility of double diaphragm pumps, their global market is expected to substantially grow over the next few years. This growth is further influenced by multiple factors, such as increases in industrialization, population, and urbanization. In Europe, the growing demand for double diaphragm pumps is mainly driven by an increasing number of wastewater treatment plants, given a large number of industries in that region (Fortune Business Insights, 2022). The European market for diaphragm pumps is expected to grow at a compound annual growth rate (CAGR) of 5 % during the next years and the most dominant market across Europe exists in Germany with an anticipated market value of EUR 433[6] million in 2027 (Research and Markets, 2022).

In general, the market for double diaphragm pumps can be divided into electrically operated and air operated, whereas the market share for air operated pumps is larger than the one for electrically operated ones (Fortune Business Insights, 2022).

PSG Germany GmbH currently holds a share of approximately [redacted] % in the AODD pumps market in the EEA. In 2022 the company accounted EUR [redacted] million of total sales, out of which [redacted] %, namely EUR [redacted] million, are dependent on the use of PTFE. In total, [redacted] people are employed under the brand Almatec at the site in Duisburg, out of which [redacted] employees are either directly or indirectly involved in PTFE-dependent business activities.

3.8 Efforts made to identify alternatives

PTFE, as previously mentioned in section 3.1 has unique properties which make it indispensable as a material used in PSG Germany GmbH's pumps. Due to this, PTFE can only be replaced in some applications to a very limited extent. This replacement would be combined with high financial costs. However, in the majority of cases, replacement of PTFE is not possible, due to the combination of its exceptional chemical resistance with thermal stability. These properties, which arise due to PTFE's molecular bonding and give it its chemical inertness, are essential in the applications in which PSG Germany GmbH's pumps are used. These chemical characteristics guarantee the cleanliness of the medium which is passed through PSG Germany GmbH's pumps. Without this unique combination, the dossier submitter cannot assure such quality.

PSG Germany GmbH has considered and rejected the use of Polyetheretherketone (PEEK) as an alternative (See Figure 2 for PEEK's structural formula and Table 7 for its physicochemical properties). PEEK has very high thermal resistance. However, its chemical resistance does not meet the same standard as PTFE. Specifically, it is susceptible to strong acids, as well as to some halogenated compounds and aliphatic hydrocarbons. Additionally, the availability of PEEK

[6] Note: Exchange rate of USD 1 to EUR 0.934491 as of 14, September 2023.

in larger quantities is limited and the price for PEEK material is almost three times higher than the one for PTFE material, thus PEEK was not deemed economically feasible as a replacement of PTFE in the European Union.

Polyethylene (PE) has also been considered as an alternative for PTFE (See Figure 3 for PE's structural formula and Table 8 for its physicochemical properties) and is already used in some of Almatec's pumps. PE has similar chemical resistance properties; however, it does not have the thermal stability to match PTFE. Additionally, white PE is not resistant against UV-Light, and thus, is not suitable for pumps which are located outdoors. Furthermore, PE does not have an equal chemical resistance for highly aggressive acids, hydrocarbons (aromatic, halogenated, and chlorinated), fuels, as well as some solvents (e.g. Cyclohexam) and alcohols (e.g. Benzene). Therefore, the use of PTFE in most applications cannot be substituted by PE, especially when chemical and thermal resistance are required.

Another alternative that was taken under consideration is the use of high alloy steels, such as Hastelloy. However, this option was quickly rejected, as it can be used in only a few of PSG Germany GmbH pumps' applications. Moreover, it is extremely cost-intensive and can solely be shaped to a limited extent.

As mentioned in section 3.2, PTFE is used in the housing parts, valve seats, valve balls, diaphragms, O-Rings, and face seals of PSG Germany GmbH's pumps, which is then in contact with an assortment of media, such as hydrocarbons (aromatic, halogenated, and chlorinated), fuels, solvents (e.g. Cyclohexan), alcohols (e.g. Benzene), and aqueous cell culture media. Due to the variety and severity of chemicals that come into contact with the pumps, it is necessary to have a combination of chemical resistance and thermal stability of the material used in PSG Germany GmbH's pumps. Therefore, thus far, no alternative on the market of polyfluorinated plastics can be used to replace PTFE in PSG Germany GmbH's pumps.

Due to PSG Germany GmbH's position in the market as a processor supplier, PSG Germany GmbH is financially and technically not in a feasible position to develop new materials. The company is dependent of large raw material producers and manufacturers of PTFE to supply equivalent alternatives to the market. Therefore, PSG Germany GmbH can only evaluate potential alternatives in existing materials. With the current options available, there are no PFAS-free alternatives to PTFE that have the same unique combination of chemical characteristics, especially PTFE's high chemical resistance under simultaneous thermal stress. Furthermore, any alternatives that may arise within a reasonable period of time would have to be vigorously tested to ensure the substance is biocompatible, physiologically safe, and does not negatively impact the environment. PSG Germany GmbH therefore requests a derogation period of minimum 12 years. This request is based on the consideration of lengthy internal and external research and development, obtaining production certifications and regulatory approval, consumer testing and approvals, upscaling production, adaptation to production facilities, and market introduction.

Figure 2: Structural formula of PEEK[7].

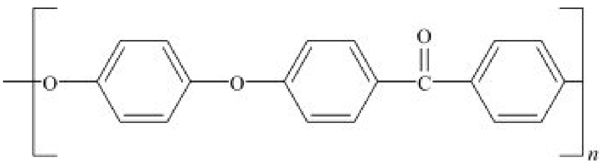
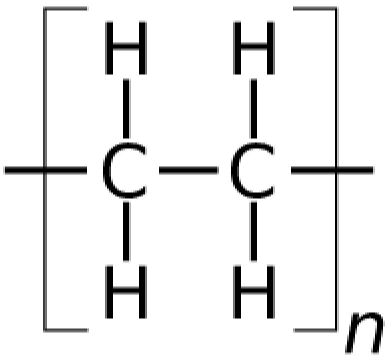


Table 7: Physicochemical properties of PEEK.

Property	Description of key information	Source
Physical state	Solid	
Color	Natural	
Melting point	340°C	
Density	1.34 g/cm^3	MatWeb Technical Data Sheet[8]
Surface resistivity	1.64e^{17} Ohm	
Water absorption (24 hrs)	0.19%	
Coefficient of Friction	0.27	

Figure 3: Structural formula of PE[9].



[7] Figure obtained from ScienceDirect. Polyetheretherketone webpage. Accessed from https://www.sciencedirect.com/topics/chemistry/polyetheretherketone

[8] PEEK Technical Data Sheet. Accessed from https://www.matweb.com/search/datasheet_print.aspx?matguid=2164cacabcde4391a596640d553b2ebe

[9] Figure obtained from Davidson, 2014. The monomer repeat structures of polyethylene and polypropylene, the two most commonly used synthetic polymer materials. Accessed from https://www.researchgate.net/figure/The-monomer-repeat-structures-of-polyethylene-and-polypropylene-the-two-most-commonly_fig1_295404630/download?_tp=eyJjb250ZXh0Ijp7ImZpcnN0UGFnZSI6Il9kaXJlY3QiLCJwYWdlIjoiX2RpcmVjdCJ9fQ

Table 8: Physicochemical properties of low density PE.

Property	Description of key information	Source
Physical state	Solid	MatWeb Technical Data Sheet[10]
Color	Natural	
Melting point	110°C	
Density	0.92 g/cm^3	
Surface resistivity (per square)	1.00e^{15} Ohm	
Water absorption (24 hrs)	0.01%	

4 SOCIO-ECONOMIC ANALYSIS

4.1 Emissions as a proxy for risk

As PSG Germany GmbH is not engaged in manufacturing processes with PTFE and only assembles pre-manufactured parts, no emissions can be attributed to PSG Germany GmbH during the manufacturing of pumps. According to the findings in chapter 5.1 and 5.2, emissions during the assembly and use of PSG Germany GmbH's products can therefore assumed to be negligible. Additionally, for the end-of-life of pumps, no exact estimates on potential emissions can be made (see section 5.3).

Consequently, as no complete data set or release rates were available, it was concluded that no estimate on PFAS emissions at PSG Germany GmbH is possible at this time. Therefore, no emission data were considered available for further assessment under this SEA.

4.2 Restriction scenario

This chapter describes the hypothetical scenario resulting from a PFAS restriction which serves as a basis for the following assessment. According to current expectations, a potential PFAS restriction is assumed to enter into force mid-2025, with an 18-months transition period. Depending on whether and which derogations for PFAS uses would be foreseen within the restriction text, there would be different socio-economic costs as well as health and environmental benefits for the EEA society.

If the proposed restriction is executed, the most likely action of PSG Germany GmbH regarding the PTFE business in the EEA would be the shutdown of those business processes in the EEA that depend on the use of PTFE, whilst all other business activities not depending on the use of the substance would be continued in the EEA. In this scenario, the producer surplus associated with the sale of AODD pumps and other components containing PTFE incurred within the EEA would be lost. Consequently, the dossier submitter assumes that 45 % of full-time working equivalents (FTEs) in the EEA, which equates to approximately [redacted] FTEs, could face dismissal.

[10] PE Technical Data Sheet. Accessed from https://matweb.com/search/DataSheet.aspx?MatGUID=671D3B28C79349B1A39FCAEA8B8A8E91&ckck=1

4.3 Impact Assessment

This chapter assesses the impacts of PSG Germany GmbH's most-likely restriction scenario in the EEA. The impact assessment assumes that the restriction enters into force mid-2025. However, for simplicity in the assessment, values were discounted to the beginning of 2025. Based on a transitional period of 18 months, the impact realization period commences in the beginning of 2027. The socio-economic impacts are then discounted to the base year of 2025 using a social discount rate of 3 %.

Based on the restriction scenario demonstrated in chapter 4.2, the following impacts were considered:

- Foregone profits
- Job dismissals
- Additional investment costs and additional annual operating costs

4.3.1 Producer surplus losses

To estimate producer surplus losses, SEAC's guidance on evaluating losses in producer surplus, was followed (ECHA, 2021). This approach focuses on the estimation of profit losses from premature retirement of productive capital assets as an indicator of producer surplus losses. To maintain a conservative approach, foregone profits were considered to accrue over a period of 2 years only. As a financial indicator for the profit, the approach proposes to use the substance-dependent EBIT of the dossier submitter for the assessment. However, as due to some internal policies, PSG Germany GmbH could not disclose its EBIT, this impact will only be assessed qualitatively and not be monetized for further assessment.

Taking into account that PSG Germany GmbH attained total sales of EUR 25 million in 2022 (see chapter 3.7) it can be assumed that the company's EBIT is also in the range of several million EUR. Since the PFAS-dependent EBIT makes up 30 % of PSG Germany GmbH's total EBIT, foregone profits of some million EUR are likely to be incurred in the EEA in case of a restriction scenario.

4.3.2 Societal costs of unemployment

Methodology

Following the methodology presented in a report commissioned by ECHA (Dubourg, 2016), the social costs related to the expected employment loss in the restriction scenario are valued considering multiple components, such as the value of lost output/wages during the period of unemployment, the cost of acquiring a new job or recruitment costs. The NPVs for the social costs of one job position made redundant in the perspective country in 2025 are calculated by using the figures from the paper from Dubourg, which have been updated with data on wages presented by Rogers and Marques (Rogers & Marques, 2021) and data on the duration of unemployment in 2021 as reported by Eurostat (Eurostat, 2022 a).

First, annual salaries (as of 2021) for the respective country were taken from the paper by Rogers & Marques. These salaries were then adjusted to 2027 values taking an average Labour Cost Index (LCI) of 2.425 % into account, which is based on LCI values registered between 2016 and 2021 and provided by Eurostat (Eurostat, 2022 b). Note that, although data estimations of Rogers & Marques on wages might be already available for 2022, for consistency issues data of 2021 have been used for the estimation of social costs.

Assumptions

As a result of the restriction, [redacted] FTEs from PSG Germany GmbH, overall, in the EEA are likely to be dismissed. Since all of these employees are based in Germany, the annual salaries for Germany were consulted. These values are discounted to the base year of 2025 by using a social discount rate of 3 %. Based on this, the cost of losing one job in Germany is valued at EUR 0.15 million in 2027.

Results

Consequently, the total social costs of unemployment due to the restriction at PSG Germany GmbH in the EEA are estimated at EUR [redacted] million. The NPV in 2025 for that amount is approximately EUR [redacted] million and the annualised value is EUR [redacted] million per year over a derogation timeline of 12 years.

4.3.3 Additional investment and operating costs

As, in a restriction scenario, PSG Germany GmbH would decide to shut down its PTFE-dependent business activities in the EEA, the company would incur additional one-off investment costs, such as decommissioning costs for its site in the EEA and potential fines from not fulfilling contractual obligations towards its clients. However, as it is highly uncertain to what extent these costs would occur, these were not further monetized but only qualitatively considered for the impact assessment.

4.3.4 Impacts on the supply chain

The dossier submitter expects devastating impacts on multiple actors in the field of AODD pumps. Namely, an enormous loss of sales for PTFE suppliers and jobs being cut - eventually, also leading to a complete shutdown of those businesses. These make up around 10 to 20 suppliers in the EEA. Furthermore, besides PSG Germany GmbH, around 20 to 40 other processors or manufacturers of pumps would be affected in the EEA. Lastly, PSG Germany GmbH estimates that around 500 to 800 customers in Germany, as well as approximately 500 to 1 000 customers in other European countries from diverse industries would be immensely impacted by a restriction. The most affected markets would be semiconductor manufacturing and the chemical industry. As the chemical industry is estimated to have a worth of EUR 600 billion in the EU and the impacts of a PFAS ban are estimated at 10 – 15 %, the damage would be around EUR 60 to 90 billion. Nevertheless, due to uncertainties related to the extent of this cost impact, these costs are not assessed quantitatively under the scope of this derogation and are only considered in a qualitative manner.

4.4 Combined Impact Assessment

The proposed restriction would disrupt the supply chain, potentially leading to shortages on the market. A restriction would seriously affect a multitude of markets and businesses. Substantial financial losses, job dismissals, and potential disruptions in critical industries would result from the proposed restriction.

Table 9 shows the total socio-economic impacts of a PFAS restriction for PSG Germany GmbH.

Table 9: Socio-economic impacts of a PFAS restriction for PSG Germany GmbH.

Cost Impact Category	**NPV 2025 (in EUR million)**	**Annualised value over ## years (in EUR million)**
Producer surplus losses	not included quantitatively in the monetised impact assessment	
Social cost of unemployment (25 job dismissals)	[redacted]	[redacted]
Additional investment and operating costs	not included quantitatively in the monetised impact assessment	
Impacts on the supply chain	not included quantitatively in the monetised impact assessment	
Total socio-economic costs for PSG Germany	[redacted]	[redacted]

Conclusively, the total socio-economic costs for PSG Germany GmbH due to a restriction of PFAS amount to EUR [redacted] million in 2025 or annual costs of EUR [redacted] million over the requested derogation period of minimum 12 years.

5 LIFECYCLE STAGES OF PTFE PUMPS

5.1 Design and assembly phase

PSG Germany GmbH is not a manufacturer of PTFE, and they assemble pumps from pre-manufactured parts. As such it is highlighted that PSG Germany GmbH only has a limited overview over the whole lifecycle of PTFE.

The lifecycle of PTFE begins with the production of the raw material in power form, by suppliers such as 3M, Dupont, Dyneon, among others. This material is then processed by PSG Germany GmbH's suppliers who press the powdered PTFE into blocks from which the parts are manufactured. All parts are produced according to the specifications of PSG Germany GmbH and delivered as finished parts.

Once the finished parts have been received, PSG Germany GmbH uses them to assemble the pumps. It is important to note that no mechanical processing of the parts is performed. Parts are delivered in their finished state, where no further processing is necessary. For this reason, during the manufacturing (assembly) of the pumps, there is only very limited exposure of workers expected to PTFE. Furthermore, there are no expected PFAS-containing air emissions, waste or wastewater emissions from the assembly of the pumps. Any faulty PTFE part would be sent back to the supplier.

5.2 Use phase

As mentioned in section 3.3, AODD pumps are used in very varied applications and sectors to pump critical solutions/media. In many cases the media that are processed using the pumps, are hazardous and/or have strong alkaline or basic pH values. Consequently, a highly resistant material is required.

The exceptional properties of PTFE make it the preferred material over others. Properties include a very high chemical resistance, high thermal resistance, low friction coefficient, antibacterial effect and anti-adhesive effect among others. As mentioned in a review article by Korzeniowski et al. (2023), fluoropolymers like PTFE have unique properties which include durability, mechanical strength, inertness, thermal stability, chemical resistance to acids, bases and solvents, among others. Henry, et al. (2018) also mentions that the "durability in harsh conditions makes PTFE a superior material of choice in aerospace, environmental controls, energy production and storage, and electronics, as well as in technical apparel."

Due to such properties, the use phase can extend up to 20 years with minimal wear and tear expected. However, during the use phase minimal emissions to the air or wastewater cannot be fully excluded but are considered almost negligible.

5.3 End of life phase

After the use phase of up to 20 years, the material is disposed of as hazardous waste – due to the hazardous conveying media used – and is usually thermally recycled and fed into the energy cycle via a combustion plant. In a worst-case scenario, based on the tonnage used for pump assembly in 2022, around ~25,000 kg of PTFE will end up incinerated.

5.3.1 Incineration

Disposal takes place thermally in all areas at the sub-use level. The media pumped is usually aggressive, toxic and contains hazardous chemicals that contaminate the material and make it necessary to completely incinerate the pump components.

Since in almost all cases the waste is hazardous waste, residual components are neutralized after use in special hazardous waste combustion plants. Here, in contrast to normal combustion plants, the incineration takes place at significantly higher temperatures, well above 1 000°C. In this combustion process, residual materials are incinerated and [-CF2-] and [-CF3-] compounds are broken down.

This is supported by Aleksandrov *et al.* (2019), who studied the transformation and generation of PFAS from the incineration of PTFE in a municipal waste treatment plant in Germany. Results indicated that, "no statistically significant evidence was found that the PFAS studied were created during the incineration of PTFE. Therefore, municipal incineration of PTFE using best available technologies (BAT) is not a significant source of the studied PFAS and should be considered an acceptable form of waste treatment".

However, as mentioned in the Annex B of the ECHA PFAS restriction proposal (2023), thermal degradation products from fluoropolymer (FP) degradation may contain CO_2, HF, trifluoroacetic acid and other perfluorinated gases, among others. Therefore, the formation of fluorinated by-products cannot be fully excluded and remains unclear. PSG Germany GmbH acknowledges and supports the need for further studies to prevent any emissions from the waste products generated by their activities.

5.3.2 Landfilling

No PFAS containing waste is expected to end up in landfills, as all waste is considered to be incinerated. Even though, no waste is expected to end up in landfills, such waste may end up in landfills as a result of miss-handling. However, it has been reported by Korzeniowski *et al*. (2023) that as fluoropolymers are "chemically, thermally and biologically stable", the transformation into dispersive non polymeric PFAS is not expected.

5.3.3 Recycling

No PFAS containing waste is expected to go into recycling processes. The media pumped is usually aggressive, toxic and contains hazardous chemicals that contaminate the material limiting the recyclability. In addition, due to the material properties and inertness of the material, it is not possible to transfer it to other uses after use.

5.4 CONCLUSION

Overall, emissions to the environment are assumed to be negligible during the assembly and use of the parts. During the end-of-life phase, as pumps are usually discarded as hazardous waste and incinerated, the emissions are assumed to be very low based on reported studies. Furthermore, it cannot be excluded that potential emissions may occur as a result of improper handling. Moreover, PSG Germany GmbH acknowledges the need for further studies to understand the fate of PFAS substances in the environment.

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7 APPENDICES

7.1 Appendix 1: Material data sheet for PTFE

PRODUKTINFORMATION – SPEZIFIKATIONSBLATT
PRODUCT INFORMATION – SPECIFICATIONSHEET

Produktmerkmale und Richtwerte / Characteristics and standard values

Mechanische Eigenschaften / Mechanical Properties			**PTFE – Natur PTFE – natural**	**PTFE – Leitf. PTFE – Cond.**
Farbnummer / Colour no.:			**FN 0000**	**FN 9320**
Dichte Density	DIN-EN-ISO 1183-1 (05/2004)	g/cm³	2,16	2,17
Reißfestigkeit Tensile strength (break)	DIN-EN-ISO 527-2 (07/1996)	N/mm²	> 30	> 20
Reißdehnung Elongation at break	DIN-EN-ISO 527-2 (07/1996)	N/mm²	> 50	> 50
Zug-E-Modul Tensile modulus	DIN-EN-ISO 527-2 (07/1996)	N/mm²	600	---
Kugeldruckhärte Ball indentation hardness	DIN-EN-ISO 2039 (--/----)	N/mm²	25 - 30	25 - 30
Shore-Härte Shore-hardness	DIN-EN-ISO 868 (10/2003)	D	55 - 58	55 - 58
Wasseraufnahme Water absorption	DIN-EN-ISO 62 (--/----)	%	< 0,1	< 0,1
Thermische Eigenschaften / Thermal Properties				
Wärmeleitfähigkeit Thermal conductivity	DIN 52612 (--/----)	W / m*K	0,22	---
Linearer Ausdehnungskoeffizient Coefficient of linear expansion DIN 53752 (--/----)	30 – 100 °C 30 – 200 °C 30 – 260 °C	K^{-1} K^{-1} K^{-1}	12×10^{-5} 14×10^{-5} 17×10^{-5}	--- --- 16×10^{-5}
Elektr. Eigenschaften / Electrical Properties				
Durchgangswiderstand Volume resistivity	IEC 60093 (12/1993)	Ω*cm	$> 10^{18}$	$\leq 10^{5}$
Oberflächenwiderstand Surface resistivity	IEC 60093 (12/1993)	Ω	$> 10^{17}$	$\leq 10^{5}$

Weitere Materialeinstellungen bzw. Zulassungen auf Anfrage! / Further composition or approvals on request!

Die vorstehenden Angaben stützen sich auf den heutigen Stand unserer Kenntnisse und stellen keine Zusicherung von Eigenschaften dar. Bestehende Gesetze und Bestimmungen sind vom Empfänger unseres Produktes in eigener Verantwortung zu beachten. Die Entscheidung über die Eignung eines Werkstoffes für einen konkreten Einsatzzweck obliegt dem jeweiligen Anwender. Änderungen der angegeben Daten sind vorbehalten.
The above data are based on the present knowledge and are given without guarantee. Existing laws and conditions are to be respected by the user of our products. The decision about the suitability of a material for a certain application must be made by the user. We reserve the right to alter the indicated data.

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