



SEA of restricting the use of PFAS in filters

Final Report

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Executive summary

This Socio-Economic Analysis (SEA) has been prepared in response to a potential REACH restriction on the manufacture and use of per- and polyfluoroalkyl substances (PFAS) within the EU. It covers specific products made with PFAS that are used within “**filters**”. Whilst this SEA has been commissioned by Gore impacts are assessed from a societal perspective and includes both Gore products and similar products placed on the EU market by other companies.

The products covered within this SEA include PFAS-containing filters that serve industries, such as cement production, an industry that underpins most construction works, which requires durable filters to contain harmful particulates that are produced during manufacture. These filters can operate in harsh environments where they can be exposed to high temperatures, dust, and hazardous chemical and material gases and particulates. For example, GORE® Mercury and SO₂ Control Modules are used to separate Mercury from predominantly aggressive and corrosive gas streams and convert SO₂ into a dilute sulphuric acid. Gore’s products are used across many industries, including, but not limited to, chemical manufacturing, semiconductors, electrical equipment, metallurgy, and petroleum refining.

Gore only uses three types of PFAS for the products covered within this SEA, all of which are defined as polymers of low concern (PLC). Around 50% of similar products on the EU market does not contain PFAS, but these are inferior in performance and therefore not used for the same end-use applications. This is because some of these filters containing PFAS are used to protect against the emission of harmful, aggressive, or hazardous air particles.

Gore continually follows external developments of new materials while also pursuing an R&D program to develop novel materials that meet the market’s needs. However, no materials have been identified that can replace PFAS in all of Gore’s products. As it is chemically resistant and inert and can withstand the operating temperatures required while remaining non-stick (water and oil repellent). In addition, if it is expanded and laminated to a backing material it can still function as a highly efficient surface filter, which can be cleaned in use. No other known material can provide these unique set of necessary properties. However, the industry continues to look for alternative materials for cost saving opportunities but has yet to find any suitable alternative materials that have the same chemical/physical properties as PTFE.

The socio-economic analysis clearly shows that restricting (and not granting a derogation for) the use of PFAS in products similar to those in **Table 2.1** will have large and wide-reaching impacts on the EU. The adverse impacts induced by a potential restriction includes significant economic costs throughout the value chain, impacts on employment (lost jobs) as well as adverse impacts on human health and the environment. Restricting the use of PFAS in products covered within

this SEA may, in fact, result in net costs (rather than benefits) to the environmental and human health. For example, non-PFAS filters are less effective than their PFAS-containing counterparts in containing aggressive or hazardous air particles during industrial manufacture and waste management. This loss in product effectiveness, and potential product failure, would significantly increase the risk of particulate leaks and, subsequently, the risk of workers being exposed to such pollutants. Additionally, lower performing (non-PTFE membrane) filters would allow more fine dust to pass during manufacture or waste disposal processes and be released into the environment, as well as more dioxin, heavy metals and other toxic or carcinogenic pollutants to be emitted from certain industrial processes, eventually ending up in ambient air and surface water.

It has only been possible to (partially) quantify a few of the identified impacts, due to data limitations. This also extends to the calculations of emission and emission reductions, which was detailed in Section 2.5.3. A key aspect to highlight is that a conservative approach has been chosen throughout analysis, in the sense that the monetised costs of a potential restriction have been underestimated and quantified emission reductions are believed to be overestimated. Emissions are overestimated, as the analysis uses conservative emission data from the dossier submitters (National Institute for Public Health and the Environment (RIVM) et al., 2021), even though Gore reported significantly lower emissions for all stages of the product lifecycle. The costs, on the other hand, are underestimated, as key costs elements could not be quantified.

It is not possible to determine the nature of impacts associated with a reduction in emissions and exposure to the PFAS used to manufacture products covered within this SEA. It is therefore not possible to monetise potential benefits so as to directly compare these to the costs. Instead, a cost-effectiveness analysis has been carried out.

The minimum annuity costs, including lost profits and impacts on employment, of restriction the use of PFAS in products covered within this SEA is estimated at €1.2 billion per year. The analysis shows that despite taking a highly conservative approach, the cost per kg PFAS emission reduced is high – in the range of €4.2 – €6 million per kg PFAS emissions reduced. The substances involved are not mobile in the environment, are demonstrated to be non-toxic and extremely stable, and are also identified as PLCs. This, combined with the conservative approach taken throughout the analysis, indicates that the costs of restricting the use of PFAS within the products covered by this assessment will likely outweigh any benefits.

Considering the lack of suitable alternatives to PFAS, combined with the significant economic and social costs as well as the adverse impacts to human health and the environment of using inferior alternatives, it is believed that a derogation is justified for the products covered within this SEA.

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Abbreviations & Acronyms

AoA	Assessment of Alternatives
C	Carbon
CAGR	Compound annual growth rate
CARACAL	Competent Authorities for REACH and CLP
CLH	Harmonised Classification and Labelling
DS	Dossier submitters
EAV	Equivalent annual values
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environment Agency
EiF	Entry into Force
ELV	End-of-life vehicle
EoL	End of Life
EPC	European Patent Convention
ETFE	Ethylene tetrafluoroethylene
EU	European Union
F	Fluorine
FEP	Fluorinated ethylene propylene
GHG	Greenhouse Gases
H	Hydrogen
HF	Hydrogen fluoride
KIT	Karlsruhe Institute of Technology
OECD	The Organisation for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
PBT	Persistent Bioaccumulative Toxic
PFA	Perfluoroalkoxy alkane
PFAS	Per- and polyfluoroalkyl substances
PFPE	Perfluoropolyether
PLC	Polymers of Low Concern
PPM	Parts per million
PTFE	Polytetrafluoroethylene
PUE	Power usage effectiveness
PV	Present Value
PVDF	Polyvinylidene fluoride
PVF	Polyvinyl fluoride
R&D	Research and Development
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restrictions of Chemicals
RIVM	National Institute for Public Health and the Environment



RMOA	Risk Management Option Analysis
SEA	Socio-Economic Assessment
SEAC	Committee for Socio-economic Analysis
SHL	Shredder heavy fraction
SLF	Shredder light faction
TFE	Tetrafluoroethylene
TiO ₂	Titanium dioxide
TULAC	Textiles, Upholstery, Leather, Apparel and Carpets
USD	US Dollar
UV	Ultraviolet
V ₂ O ₅	Vanadium(V) oxide
vPvB	Very Persistent and very Bioaccumulative
WEEE	Waste Electrical and Electronic Equipment
WO ₃	Tungsten trioxide
WUE	Water usage effectiveness
WWTP	Wastewater Treatment Plant

1.Introduction

1.1 Background

In July 2021 Member State Competent Authorities for Germany, the Netherlands, Norway, Sweden, and Denmark registered their intention to submit a REACH restriction proposal, which aims to limit the risks to the environment and human health from the manufacture and use of per- and polyfluoroalkyl substances (PFAS) (ECHA, 2020a). The aim of the restriction proposal is to ban the entire group of PFAS substances to avoid regrettable substitution where one PFAS is replaced by another similar PFAS of potentially similar concern (RIVM, n.d.). Recent communication from the dossier submitter (DS) indicates that the restriction dossier will be submitted to the European Chemicals Agency (ECHA) on the 13th of January 2023. **Figure 1.1** below provides an indicative timeline for the REACH restriction for PFAS (adapted from timeline presented by ECHA at a webinar in October 2020).



Figure 1.1: Indicative timeline for the REACH restriction proposal for PFAS

There are at least 6,000 currently known PFASs (RIVM, n.d.), and the substances are in widespread use in a large number of industries (e.g., automotive, medical, chemical and oil & gas) and have numerous applications (e.g., textiles, electronics, pharmaceuticals, wire and cable insulation, gaskets and hoses, and medical devices). Due to the broad scope of the restriction, there may therefore be potentially long-ranging impacts on manufacturers, importers, and users of PFAS and PFAS-containing products. The DS initially envisaged derogations for 'essential uses' of PFAS, however, the definition and criteria for what makes a use 'essential' have yet to be finalised. Recent communication from the European Commission indicates that the EU definition of 'essential use' will not be ready in time, hence, will not be included in the restriction proposal (Chemical Watch, 2022).

1.2 Objective and scope

The aims of this socio-economic assessment (SEA) were to provide information on (i) specific applications of PFAS, (ii) the availability of suitable alternatives, and (iii) the impacts of banning the use of PFAS in these applications, which can be utilised by the DS when finalising the restriction proposal as well as in the assessments later carried out by RAC and SEAC.

This assessment focusses on impacts of restricting PFAS for specific products used within “**filters**”. The assessment is limited to the European Union (EU) over a twenty-year period (2022 – 2041). This SEA does not cover all potential applications of PFAS within filters. The assessment includes Gore products and similar products placed on the EU market by other companies. Types of filters and their uses included in the scope of the analysis are detailed in Section 2.2.

1.3 Approach

This SEA builds upon the ‘use assessment’ note submitted to the DS during February and March 2022, which was based solely on readily available information at the time. The assessment presented in this report is a continuation of the analysis presented in the previous report, but with more focus on the impacts of a possible restriction. Additional data gathering was carried out in relation to the SEAs, both as a validation exercise as well as providing more details than what was provided in the use assessment. The information set out in this SEA thus supersedes the information provided in the use assessment, should the two reports conflict.

The socio-economic analysis (SEA) has been carried out in accordance with ECHA’s SEA Guidance for restrictions (ECHA, 2008) and the Better Regulation Toolbox (European Commission, 2021a). An overview of the approach taken is shown in **Figure 1.2**.

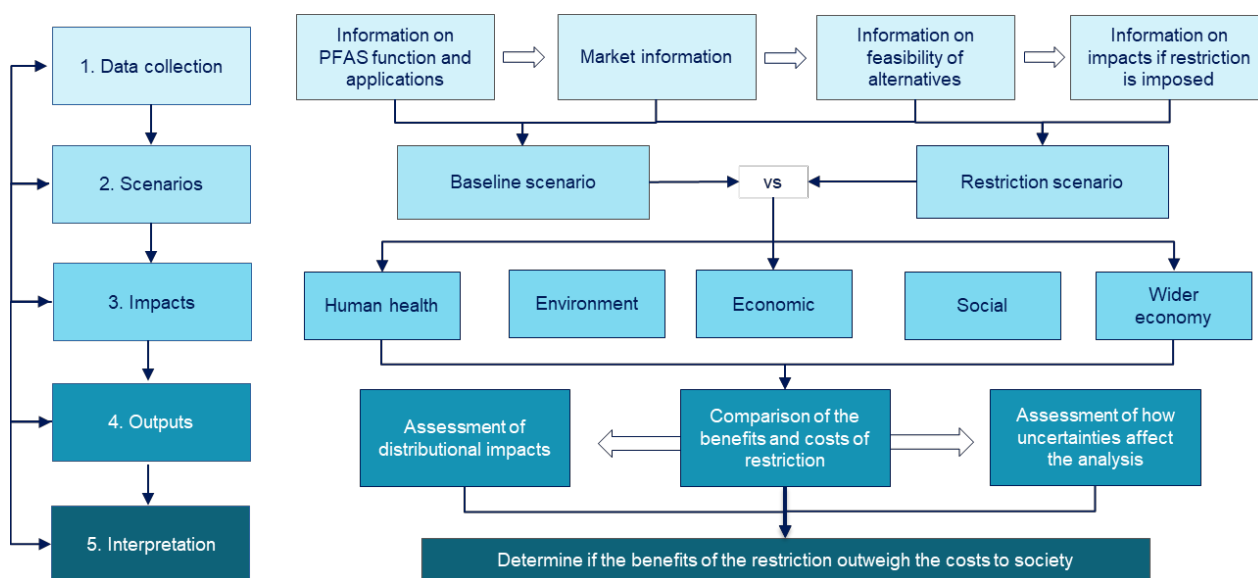


Figure 1.2: SEA approach

The SEA seeks to assess the impacts, i.e., costs and benefits, of a potential restriction relative to the baseline scenario, which is the current situation in the absence of a restriction. The assessment is focussed on

affected Gore products, but where possible the data has been extrapolated by eftec to the entire EU market. As per ECHA's Guidance, the analysis has been carried out from society's perspective rather than the perspective of the filters sector.

The price year used in the analysis is 2022, meaning that all numbers have been adjusted for inflation using GDP deflators (ECB, 2022; World Bank, 2022). Monetary impacts are expressed as present values (PVs) and as annuities using a 4% discount rate. PVs represent the discounted value of a stream of future costs and/or benefits and are the most common method used to compare costs and benefits over time (ECHA, 2008). Annuity values represent the annualised cost/benefit, or the equalised yearly value of an impact over its discounted lifetime and is particularly helpful for understanding impacts that are commonly measured on a yearly basis or comparing impacts that occur over different lifetimes (ECHA, 2008).

Further details on the approach are also provided in the relevant sections where the results are presented.

Figure 1.3 provides an overview of the data sources used for this study. The main source of information is Gore's responses to a bespoke questionnaire developed for this SEA where quantitative and monetary data as an annual average over the period 2016 - 2021. This covered a variety of topics such as impacts on Gore, its customers and society if PFAS could no longer be used in specific products used within filtration products in the European Union (EU). Data was also collected by eftec from publicly available sources via desk-based research, including information on the wider filters market in the EU. The study also required some assumptions and professional judgements to be made where data was not available, but these were kept to a minimum. The report highlights where such assumptions had to be made and uncertainties induced by these.

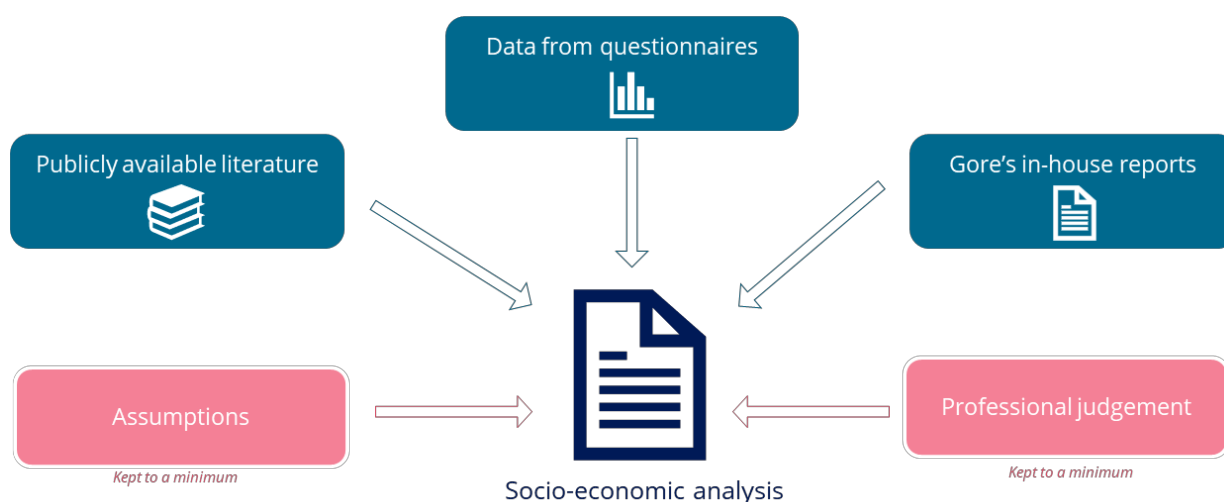


Figure 1.3: Data sources used in this socio-economic analysis (SEA)

1.4 Structure of the report

The remainder of the report is structured as follows:

- Chapter 2: Baseline scenario
- Chapter 3: Availability of suitable alternatives

- Chapter 4: Restriction scenario
- Chapter 5: Comparison of costs and benefits
- Chapter 6: Conclusions and recommendations

2. Baseline scenario

2.1 Introduction

The baseline scenario (also called the business-as-usual scenario) refers to the situation where PFAS is not restricted for the types of affected products listed in **Table 2.1**. This would be the case if the potential PFAS restriction is not adopted or if these products receive a time-unlimited derogation (with no conditions imposed on their continued use).

The baseline was derived in a stepwise manner where Gore's use of PFAS serves as a starting point. Section 2.2 presents the Gore products used within filters that could be affected by a potential REACH restriction and their downstream uses. These products and similar products manufactured by other companies are the only type of products covered within this SEA. Gore sales and supply chain linked to the affected products is covered in Section 2.3. Section 2.4 sets out the type and volumes of PFAS used by Gore and their technical functions within Gore products. It also provides an overview of the PFAS material flow in terms of manufacture, service life and disposal of the products.

Section 2.5 provides a broader perspective on the use of PFAS in the EU, covering manufacture of PFAS as well as production, use and end-of-life of products. This provides some context for the EU baseline for the products covered within this SEA, which is derived in Section 2.5. This is done by using data from Gore combined with the broader data from Section 2.5 as well as using professional judgement and assumptions. Risk indicators, including the hazard profile of the PFAS in question is also covered within this section.

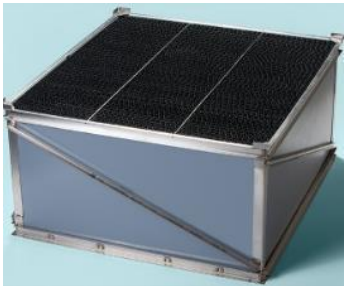
2.2 Products and end-uses

2.2.1 Gore products affected by a possible restriction

The use category 'filters' relates to a variety of products Gore manufactures that are used at different stages of the filtration process. A full list of products that may be affected within the scope of a possible future REACH restriction of PFAS and their descriptions are set out in **Table 2.1**.

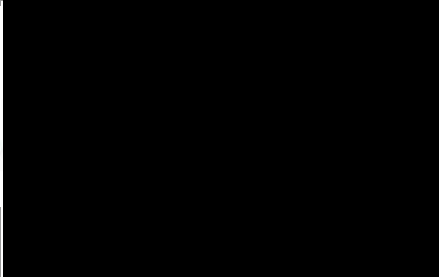
Table 2.1: Gore's filtration products and descriptions

Product	Illustrations	Description
GORE® Catalytic Filter Bags		Filter bags that are used in baghouses to convert predominantly toxic or hazardous components such as gaseous dioxins and furans or nitrous oxides from predominantly aggressive and corrosive gas streams into harmless substances (i.e., to levels below regulatory limits). The filter's surface captures fine particles and releases these particles to be collected in the bottom of the baghouse hopper. Then, the filter lets the gaseous pollutants pass through into the catalytic felt where the catalyst reacts with the dioxin, furan or nitrous oxides (NOx) molecules to convert them into insignificant amounts of carbon dioxide (CO ₂), water (H ₂ O), nitrogen (N ₂) and

Product	Illustrations	Description	
		hydrogen chloride (HCl) (Gore, 2021a). The catalytic conversion takes place at temperatures above 200 degrees Celsius. These filters are typically applied in waste incineration, chemical processes, metallurgical processes, and cement manufacturing to help them meet regulatory requirements for limiting their air emissions.	
GORE® Mercury and SO ₂ Control Modules		These modules are used to separate Mercury from predominantly aggressive and corrosive gas streams and convert SO ₂ into a dilute sulphuric acid. The modules consist of a metal frame which houses a PTFE based composite that contains adsorptive and catalytically active components. Typically used in waste incineration, coal fired power generation, metallurgical processes and cement manufacturing to help them meet regulatory requirements for limiting their air emissions.	
GORE® Industrial Dry Filtration Products		These filter products are used to separate particulate from predominantly aggressive and corrosive gas streams. The dust often consists of toxic, fine (sub-micron, sometimes nanoparticles), non-agglomerative, abrasive and/or sticky particulate such as heavy metals or dioxin containing fly ash. In operation, the filters are cleaned by a high-pressure pulse jet blast, or a reversed air flow, often combined with mechanical vibration. Typically used in waste incineration, chemical processes, metallurgical processes, and cement manufacturing at temperatures above 200 degrees Celsius to help to help them meet regulatory requirements for limiting their air emissions.	
GORE® Turbine Filters		A high efficiency particulate air (HEPA) proprietary thin, three-layer filter used in gas turbines, offshore oil platforms, or industrial sites with heavily contaminated air. The durable and watertight technology ensures longevity by maintaining clean engine performance, minimising downtime, and reducing maintenance costs over the filter's lifetime. The filter only lets pure air through by pre-screening larger contaminants, capturing small contaminants, and blocking water droplets. Furthermore, the filter prevents ingestion of both dry and soluble contaminants helping to eliminate processor fouling over a long lifetime. Hence, the filters are suitable for operators who run intermediate and base load engines, experience fouling-induced losses in compressor efficiency and power output and seek protection from corrosion due to salt ingestion.	
GORE® Liquid Filtration Products		MicroE membranes	Incorporated into filters that clean process chemicals to produce semiconductor chips and LED/OLED displays for the Microelectronics market.

Product	Illustrations	Description	
			
		Ozonation Module	Used to produce ozonated water for silicon wafer production and LED/OLED display production.
		Gore Filter Tube Assemblies (GFTA)	Used in pulp and paper production and chlor-alkali plants to purify brine.
		Filter socks	
GORE® Cooling Filters		These filters are used in direct air cooling (DAC) systems whereby the filter enables the end user to take full advantage of the natural thermal efficiencies of ambient air while simultaneously lowering the system costs. DAC is a highly efficient cooling method – when combined with high efficiency filters, DAC offers high protection from salt, dust, water, and other contaminants resulting in the most reliable and cost-effective protection for sensitive electronics.	
GORE® CLEANSTREAM® Filters		A high efficiency filter (99.5% efficient at 0.3 microns) for use by consumers that traps wet or dry dirt and/or debris on the surface. It therefore does not require being removed or changed when used for water leaks, wet cellars, plumbing emergencies, and spills. The filter is easily cleaned by tapping or rinsing.	
Heat Exchanger Laminate		A two-layer laminate (one membrane and one backer) used in an indirect cooling system. The laminate allows water to run through channels but not across channels and it has a	

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Product	Illustrations	Description
		low-level resistance for heat transfer between surfaces. This  is deployed at data centres to maintain operating temperatures while increasing PUE (power usage effectiveness) and WUE (Water Usage Effectiveness) compared to other cooling solutions. Gore laminate maximizes evaporative cooling while ensuring the air and liquid sides of the heat exchanger remain separate.
Rastex® / Gore industrial fibre		A sewing thread engineered specifically for the demands of filtration applications – it withstands exposure to chemicals, high temperatures, abrasives, and moist environments. The fibre can also be processed as a “staple fibre” used to create non-woven filter media.

Source: Gore (2021b, 2022a)

Notes:

1. Filter socks image taken from (McFarlen Engineering Ltd., 2022)
2. Heat exchanger laminate image is taken from 
3. Remaining images are taken from Gore's website (Gore, 2022b)

2.2.2 End-uses and affected industries

There are nine products/product categories that have been deemed relevant under the category of ‘filters’, which can be grouped according to two broader use categories. The first use category includes the products that act as filters for pollution and emissions control from harmful, aggressive or hazardous air particles and waste. The second category includes filters that are used in cooling or cleaning devices.

Figure 2.1 offers a non-exhaustive overview of the downstream uses and industries that may be affected by a potential restriction. The inner circle (teal) represents the products containing PFAS that are set out in **Table 2.1** and similar products manufactured by Gore's competitors. The second circle (dark pink) shows some of the downstream uses that rely on these PFAS-containing products. Lastly, the outer circle (lighter pink) lists some of industries utilising the downstream products and thus would be affected by a potential restriction.

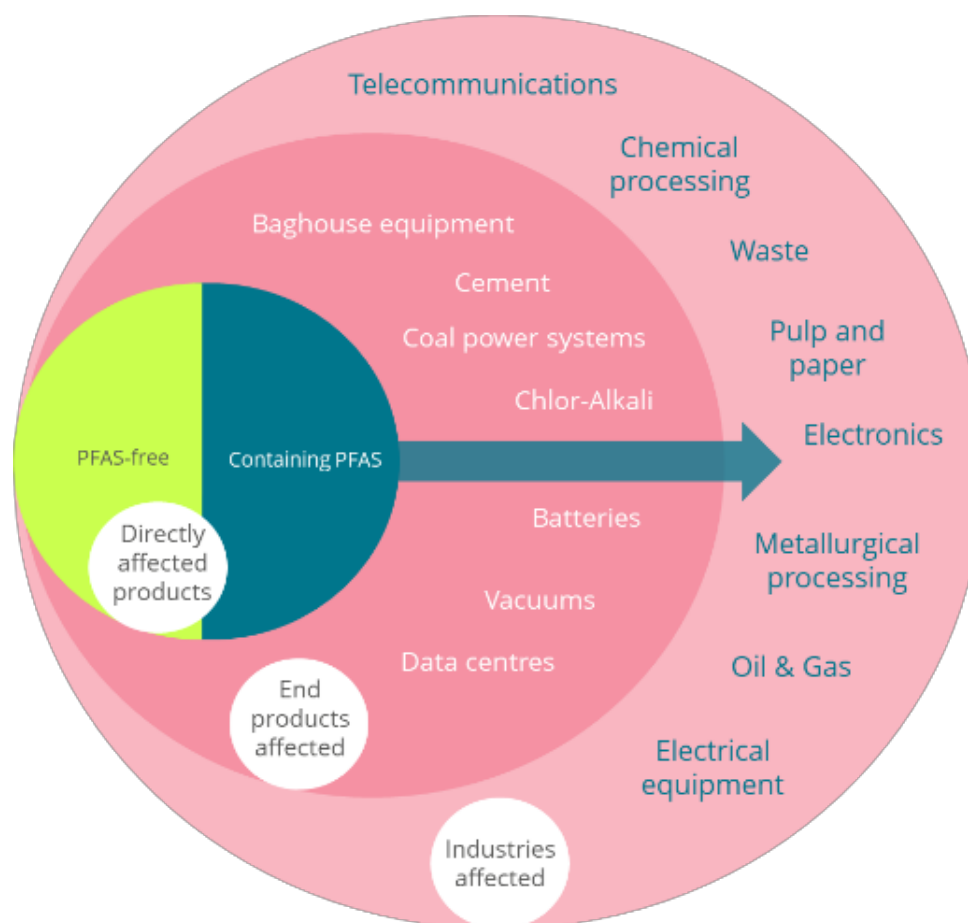


Figure 2.1: Products containing PFAS and affected end-uses and industries

Notes: Directly affected products refers to products listed in [Table 2.1](#) and similar products by other manufacturers.

Gore believes that 50% of all filter products for industrial applications that are manufactured by other companies contain PFAS. This is because some of these filters containing PFAS are used to protect against the emission of harmful, aggressive, or hazardous air particles. Other non-PFAS materials may not be able to effectively support these uses, posing a potential risk to the health and safety of workers and end-users that may result from lower filter performance.

Most of the downstream industries affected are involved in the manufacture and processing of a large variety of products that emit harmful air particles during production, and therefore are utilised in many further downstream products and end uses.

Filter bags containing PFAS used in **cement production** and the **generation of power** separate particulate from gas streams and convert gaseous pollutants (Dioxin, NO_x) into harmless substances. They lower elongation, meaning less damage is caused from heavy dust loads in filter bags as well as stopping the filters degrading in chemically aggressive, high temperature or moist environments. They can destroy up to 99% of total dioxins and furans. As a result, they help generate environmental and health benefits for society by reducing exposure to hazardous pollutants. Cement production is needed for the construction of roads, homes, and wider infrastructure – all important for the functioning of the modern economy. The generation of power is vital for the functioning of society, whether powering our homes, factories, offices or providing electricity to the technology we use for work.

Filters containing PFAS are also used by sewage sludge, municipal solid waste, and hazardous waste incineration sites that dispose of unwanted and hazardous waste to effectively manage the variety of pollutants that are associated with this waste via thermal destruction. The PTFE membrane on the surface of these filters collects the particulate and releases it when the filters are cleaned. Without the membrane, the filter would not perform as effectively. Proper waste disposal ensures that human contact with the waste is minimised.

Filters containing PFAS separate Mercury from incineration flue gas, which helps minimise overall emissions. Mercury and SO₂ control modules help reduce damaging emissions associated with the **extraction of coal**, garnering environmental benefits for society. For example, coal continues to remain an important industry, accounting for around 20% of EU electricity production and providing jobs to around 230,000 people (Gore, 2021b). Although not part of the EU's long-term plan for energy production, the EU still relies on coal production to power the economy, and without it there would be large socio-economic impacts.

During **metallurgical processes**, filtration products separate particulates from gas streams and reduce their emissions. Many of these particulates are toxic and can lead to adverse effects on health and environmental benefits if not extracted. Metallurgy involves the crushing, grinding and creation of various metals and alloys derived from earth metals. These metals/alloys are used in a huge variety of products and sectors, such as vehicles, electronics, construction, and household appliances, amongst many others.

Cooling filters, used for temperature control of electronic enclosures containing **batteries** and **telecommunications equipment**, enable direct air cooling by providing protection from salt, dust, water, and other contaminants. Electronic equipment has seen large increases in power density and heat dissipation requirements over the years as functionality has increased, which has led to the potential for overheating unless efficient cooling systems are in place. Cooling filters containing PFAS keeps the device at a suitable temperature, which ensures that functionality is maintained as well as keeping the device safe over the long terms. Batteries play an important role in the modern economy, being used in a vast array of electronic devices. Data and telecommunication products are also important for the functioning of modern society. Networking, communicating and almost every job relies on this system and without it there would be considerable economic impacts and large disruption to the economy.

Filters are built into cleanable and long-lasting cartridges form filters used in **wet-dry vacuums**. Wet-dry vacuums assist in the clean-up of wet items and/or spillages. This boosts productivity as it avoids the need to carry out this process manually as well as ensuring that items can be cleaned and re-used rather than simply thrown away and replaced.

Laminate products containing PFAS are utilised in and deployed at **Data centres** to maintain temperatures at the right levels required by the electronic equipment, while resulting in PUE (Power Usage Effectiveness) and WUE (Water Usage Effectiveness) savings. Data centres are buildings/places dedicated to hosting computer systems and associated components. These systems could be backing up/supporting computer systems for entire businesses, office blocks, retails centres etc. As it is widely understood, computers and their associated datacentres are vital for almost every element of the modern economy.

Turbine filters help ensure power generation equipment, such as gas turbines, continue to function

efficiently by preventing 99.5% of suspended particles from entering the turbines. These gas turbines are used mainly during **oil and gas exploration and processing, and electricity generation**. Furthermore, they offer economic benefits by helping minimise downtime of power generation, reducing maintenance costs over the lifetime of the equipment.

Liquid filtration products containing PFAS are incorporated into filters, which are used during the production of semiconductor chips. **Semiconductors** are a crucial component in virtually all electronic devices such as **computers, smart phones, TVs, and cars**, and they provide environmental benefits e.g., semiconductors provide environmental benefits by enabling critical technologies in electric vehicles.

Liquid filtration products are also used during the production of **chlorine and sodium hydroxide**. Both chemicals provide important benefits to society, for example sodium hydroxide is used in the manufacture of a variety of medicines and pharmaceutical products, while chlorine is used as a disinfectant e.g., in drinking water.

Gore's fibre materials provide temperature and harsh chemical resistance that enable production of a variety of processing components, like filters, that reduce environmental and human safety risk. Examples are **Industrial process chemicals, mining, paper production, acid reclamation, and fertilizer production**.

2.3 Gore sales and direct supply chain

2.3.1 Gore sales of products affected by a potential restriction

Gore's annual sales revenue (average 2016-2021) globally from the products set out in **Table 2.1** is around ██████████ per year, of which direct sales to EU customers totals €██████████ per year. The profit margins within and outside the EU are █████ and █████, respectively. The resulting global profit is estimated at █████ million/year, of which █████ per year is associated with direct EU sales. **Table 2.2** presents breakdown of the sales and profits associated with Gore's products for filters.

Table 2.2: Gore revenue and profits for filters containing PFAS, annual average 2016-2021

Gore product	Gore sales revenue (€ million/year)		Gross profit margin (% of sales revenue)		Gross profit (€ million/year)	
	Within the EU	Outside the EU	Within the EU	Outside the EU	Within the EU	Outside the EU
GORE® Catalytic Filterbags						
GORE® Mercury and SO ₂ Control Modules						
GORE® Industrial Dry Filtration Products						
GORE® TURBINE FILTERS						
GORE® Liquid Filtration Products						
GORE® COOLING FILTERS						
GORE® CLEANSTREAM®						
Heat Exchanger Laminate						
Rastex® / Gore industrial fibre						
Total						
Total global						

Source: Gore (2021b, 2022a)

Notes: Values are given in 2022 prices and rounded to the nearest € million, or to the nearest significant decimal if below a million. Totals may therefore not sum up.

Table 2.2 shows that the majority of Gore sales occurs outside the EU. These products, albeit not placed directly on the EU market, may still be impacted by a potential restriction. For example, if a Gore customer is a distributor located outside the EU who imports PFAS-containing products to the EU market, a potential restriction would prohibit the distributors sales in the EU. Gore's products sold outside the EU may also enter the EU market as components in complex products (e.g. cooling and filtration systems) that are imported to the EU. If Gore's customers cannot sell their products in the EU, they will stop purchasing Gore products for the EU market and Gore would lose the associated sales revenue. Sales of products that enters the EU market through customers (rather than Gore directly selling to the EU market) are henceforth called 'indirect sales'.

Taking into account both direct and indirect sales, the total revenue linked to Gore products set out in **Table 2.1** containing PFAS that ultimately enters the EU market is around [REDACTED], of which around [REDACTED] is associated with indirect sales. Gore's sales revenue (direct and indirect) per product that would be affected by a potential restriction is set out in **Table 2.3**.

Table 2.3: Gore total sales, direct and indirect, affected by a potential restriction

Gore product	EU sales (€ million/year)	Sales outside the EU (€ million/year)	Share of Gore's sales outside the EU entering the EU market (%)	Total Gore revenue affected by a potential restriction (€ million/year)
			Indirect sales	Direct & Indirect EU sales
GORE® Catalytic Filterbags				
GORE® Mercury and SO ₂ Control Modules				
GORE® Industrial Dry Filtration Products				
GORE® TURBINE FILTERS				
GORE® Liquid Filtration Products				
GORE® COOLING FILTERS				
GORE® CLEANSTREAM®				
Heat Exchanger Laminate				
Rastex® / Gore industrial fibre				
Total				

Source: Gore (2021b, 2022a)

Notes: Values are given in 2022 prices and rounded to the nearest € million, or to the nearest significant decimal if below a million. Totals may therefore not sum up.

2.3.2 Gore direct supply chain

Gore processes polytetrafluoroethylene (PTFE) resin into its finished filtration products that serve important uses in:

- Filtering chemical, metallurgical, cement and power generation waste gases,
- Removing submicron water salt and dust particulates in oil and gas turbines, gas pipelines and chemical refining,
- Filtering liquids in hot operating temperatures and aggressively acidic or base environments,
- Providing filter cooling in telecommunication and data infrastructure, digital signage, battery products and electrical grid infrastructure, while generating savings on PUE and WUE,
- Extending cleaning efficiency and lifetime of wet-dry vacuum cleaners

■ people are associated with the production and sales of Gore's filtration products, ■ of whom are located within the EU. **Figure 2.2** provides a graphical representation of Gore's supply chain.

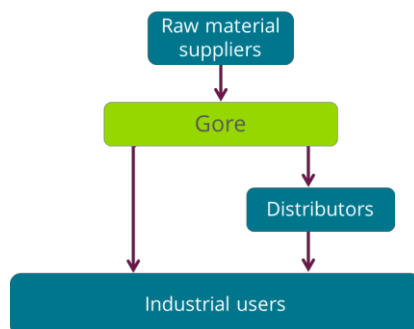


Figure 2.2: Gore's supply chain for filtration products

Gore purchases polytetrafluoroethylene (PTFE) resin from several global manufacturers, but the SEA focusses on "key raw material suppliers" in the EU, as these are believed to be at greater risk of incurring significant costs if Gore were to cease production of PFAS-containing filtration products. Key raw material suppliers are defined as suppliers for which Gore's purchases of raw materials (for the products set out in **Table 2.1**) accounts for at least one third of their sales revenue. While no key raw material suppliers were identified specifically for the products in **Table 2.1**, in aggregate, a broad restriction of PFAS would lead to significant disruptions across the wider supply industry of fluoropolymers. This is further detailed in Section 2.5.2.

Gore sells its filtration products to customers within and outside of the EU. provides a breakdown of direct downstream users per product. Due to potential customer overlap across different products, it is not possible to provide an exact figure for the total number of unique customers. Gore has between [REDACTED] and [REDACTED] customers within the EU which employ between [REDACTED] and [REDACTED] people.

Table 2.4: Gore customers (average 2016-2021) associated with filters

Product	Number of customers		Number of employees	
	Within the EU	Outside the EU	Within the EU	Outside the EU
GORE® Catalytic Filterbags	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® Mercury and SO ₂ Control Modules	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® Industrial Dry Filtration Products	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® TURBINE FILTERS	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® Liquid Filtration Products	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® COOLING FILTERS	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® CLEANSTREAM®	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Heat Exchanger Laminate	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Rastex® / Gore industrial fibre	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Minimum number of customers/employees (no overlap, but underestimated)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Maximum number of customers/employees (potential overlap)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Source: Gore (2021b, 2022a)

Notes:

1. The minimum number of customers corresponds to the highest number of customers associated with one product (GORE® Industrial Dry Filtration Products). The maximum number of customers is the total across all products (which does not take into account potential overlaps in the customer base).
2. The minimum number of employees corresponds to the maximum number of employees associated with one product alone (GORE® TURBINE FILTERS). The maximum number of employees is the total across all products (which does not take into account potential overlaps in the customer base).

Gore's products have a wide reach across several downstream user industries (detailed in section 2.5.2). As such, the number of downstream user companies and employees affected by a potential restriction increases significantly further down the supply chain.

2.4 Gore's use of PFAS

2.4.1 Technical functions of PFAS

The PFAS used in Gore's filtration products are polytetrafluoroethylene (PTFE), perfluoroalkoxy alkane (PFA), and polyvinylidene fluoride (PVDF). Due to their unique properties, the use of these PFAS enable extremely high filtration efficiency, very low resistance to flow, and extremely long filter life. More specific PFAS functions in filters are as follows:

- **Low adhesion forces** - the force required to detach a liquid droplet from a surface it is in contact with; Low adhesion force means that little force is required for liquid droplets to detach from the filters.
- **Mechanical strength** - filters are not readily broken, even in harsh environments.
- **Dimensional stability** - filters that do not change shape throughout their lifespan.
- **Chemical stability** - filters are not readily broken, even in harsh environments.
- **High porosity** - porous materials have more space (pore volume) that can contain fluid; therefore, filters with high porosity can contain more fluid than filters with a lower porosity.
- **Temperature resistance** - can be used throughout a large range of temperatures.
- **High airflow rates** - air readily passes through the PTFE membrane.
- **Waterproofness** - hydrophobicity (and oleophobicity) stops water (and oil-based substances) passing through the filters.

Table 2.5 details more specific high-level functions and a detailed description of the function of PFAS in Gore filtration products.

Proprietary and confidential

Table 2.5: Gore filtration products, high-level function, and detailed description

Gore product(s)	High-level function	Detailed description
Heat Exchanger Laminate	- Waterproofness - Heat transfer	Heat Exchanger Laminate requires water protection with low level of resistance for heat transfer between surfaces.
GORE® Cooling Filters	- Waterproofness - Low airflow resistance - High porosity - Temperature resistance - Chemical stability - Mechanical strength	The PTFE membrane functions as a high efficiency filter. It collects the particulate and releases it when the filters are cleaned. Without the membrane, the filter would not reach the same level of performance (of removing submicron-sized dust, water, and salt particles – without restricting airflow). In many filters, when the temperature or the chemical environment require it, PTFE is also used as backing material. In high temperature filters, fibreglass fabrics are used as backing material. The glass fibres are coated with PTFE to minimise abrasion.
GORE® Turbine Filters,		
GORE® CLEANSTREAM®,		
GORE® Catalytic Filter Bags		
GORE® Industrial Dry Filtration Products		
GORE® Mercury and SO ₂ Control Modules	- High porosity - Chemical stability - Hydrophobicity	In the modules, PTFE is holding the adsorptive and catalytic components. PVDF is used as reinforcement in the composite. Also, the long-life, stackable modules virtually eliminate elemental and oxidised mercury from flue gas streams and reduce SO ₂ concentrations.
GORE® Liquid Filtration Products	- Chemical stability - Temperature resistance	Fluoropolymers provide the chemical resistance to very aggressive acids and bases, high operating temperatures, and cleanliness. For example, filters are used at 150°C during sulfuric acid filtration. Cleanliness is defined as parts per trillion (ppt) of metal ions (i.e., very low levels), and <5 particles / mL at 20 nm.
Rastex® / Gore industrial fibre	- Chemical stability - Temperature resistance - Mechanical strength	PTFE fibre is used to create components in harsh chemical applications. The product offers temperature and chemical resistance in a high strength weaving/sewing fibre or non-woven (carded) filter media, insulating material.

Source: Gore (2021b; 2022a)

2.4.2 Types and volumes of PFAS used

The 9 Gore products affected and assessed within this assessment (see **Table 2.1**) are manufactured both within and outside the EU, where [REDACTED] tonnes fluoropolymers are used in EU manufacture per year (average 2016-2021). The types and volumes of PFAS used for each product manufactured by Gore inside and outside the EU are detailed in **Table 2.6**.

All [REDACTED] fluoropolymers referenced in this SEA meet the criteria for Polymers of Low Concern (PLCs), under the definition provided by the OECD Expert Group on Polymers: PLCs are polymers “deemed to have insignificant environmental and human health impacts” (OECD, 2009).

Proprietary and confidential

Table 2.6: Type and volume of PFAS used in Gore products manufactured in EU and non-EU countries

Gore product	Type of PFAS	CAS number	EU annual volume used (tonnes/year)	Non-EU annual volume used (tonnes/year)	Is this PFAS a PLC?
GORE® Catalytic Filterbags					
GORE® Mercury and SO ₂ Control Modules					
GORE® Industrial Dry Filtration Products					
GORE® TURBINE FILTERS					
GORE® Liquid Filtration Products					
GORE® COOLING FILTERS					
GORE® CLEANSTREAM®					
Heat Exchanger Laminate					
Rastex® / Gore industrial fibre					
Total share PLC			100%	100%	-

Source: Gore (2021b, 2022a)

Notes: Volumes have been rounded to the nearest tonne or to the first significant decimal if below a tonne. Total may therefore not sum up.

As explained in Section 2.3.1, Gore products containing PFAS (set out in **Table 2.1**) are manufactured in the EU and also enter the EU market via direct sales by Gore to EU customers and Gore's customers outside the EU places the products on the EU market (e.g. as a component of a complex product). Some of the products Gore manufactures outside the EU containing PFAS will therefore eventually enter the EU market and may be affected by a potential restriction. The share of PFAS comprising the products after the manufacturing stage is presented at a product level in

Table 2.8. This, together with the share of the products ending up on the EU market, via direct or indirect sales (shown in **Table 2.2**), was used to calculate the total PFAS volume ending up on the EU market via imports.

Table 2.7 splits the volume used or placed on the EU market into three categories:

1. PFAS used in EU production that does not comprise the final product includes the amount of PFAS recovered for reuse during manufacturing and the amount ending up in production waste. It also includes volume contained in products manufactured in the EU but exported outside the EU. **Table**

2.9 presents a more detailed breakdown of the PFAS material flow during production.

2. PFAS contained in products placed on the EU market, via:

- i. *Direct sales* include Gore products that are manufactured inside and outside the EU that are placed on the EU market. This has been estimated based on Gore's share of the total EU market - detailed in Section 2.3.1.
- ii. *Indirect sales* refer to PFAS entering the market via imports by Gore's customers (e.g., as a component in a complex products).

Table 2.7 shows that the total estimated volume PFAS affected by a potential restriction associated with their product portfolio for filters, amounts to around [REDACTED] tonnes per year. Around [REDACTED] tonnes/year are contained in products sold by Gore directly to EU customers, whilst [REDACTED] tonnes/year enters the market via import of complex products (manufactured by other companies) that have a Gore product as a component.

Table 2.7: Total volume PFAS manufactured in the EU and placed on the EU market by Gore

Gore product	PFAS used in EU production that does not comprise the final product (tonnes/year)	PFAS comprising the final products placed on the EU market (tonnes/year)		Total volume PFAS affected by a potential restriction (tonnes/year)
		Direct Gore sales	Customer's import of complex products (indirect sales)	
GORE® Catalytic Filterbags	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® Mercury and SO ₂ Control Modules	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® Industrial Dry Filtration Products	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® TURBINE FILTERS	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® Liquid Filtration Products	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® COOLING FILTERS	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
GORE® CLEANSTREAM®	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Heat Exchanger Laminate	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Rastex® / Gore industrial fibre	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
All products	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Source: Gore (2021b, 2022a)

Notes: Volumes have been rounded to the nearest tonne, or to the nearest significant decimal when below a tonne. Total may therefore not sum up.

2.4.3 PFAS material flow

The lifecycle of PFAS can be divided into four stages, namely PFAS production, product manufacturing, product use and waste management, as detailed in **Figure 2.3**. This provides a framework for understanding the movement of PFAS throughout the economy and where there are potential for releases to the environment. This SEA primarily focusses on product manufacturing, but high-level information is also provided on product service life and disposal. For the uses in this assessment, Gore purchases fluoropolymer resins from suppliers, therefore PFAS production is not covered.

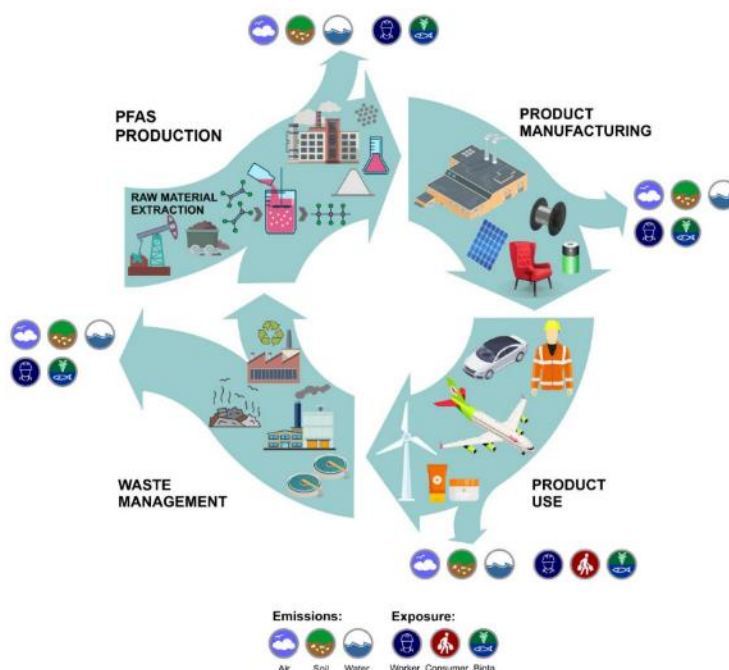


Figure 2.3: PFAS lifecycle (European Commission, 2020)

Manufacture of products containing PFAS

Gore processes PTFE resin into filter products. Based on information provided by Gore, the amount of PFAS released into the environment as air emissions from Gore's production of filter products manufactured inside the EU are negligible due to existing emission control technologies in place. Further, there are no water emissions as no water is used in the processing of PTFE resin into final products by Gore for this use.

Specifications are established for PTFE resin that Gore purchases related to the maximum amount of residual non-polymeric PFAS (including fluorinated polymerization aid) which is less than 1 ppm. These residual levels are further reduced through additional processing within Gore facilities. The vast majority of these polymerization aids are destroyed by the heat used in our processes and thermal oxidizers are used to treat air emission from the fluoropolymer processing operations.

Table 2.8 shows the PFAS material flow through the manufacturing process. For the sake of completeness this does also cover product manufacturing outside of the EU. The majority of PFAS, approximately 98%, used in production of filter products manufactured in the EU is the material that comprises the products

themselves. Approximately 1% of the PFAS used in the product manufacturing process ends up as production waste. The PFAS that ends up as production waste is non-hazardous and is predominantly disposed of through incineration, with a smaller proportion of waste disposed of via landfill. PTFE is decomposed during incineration and emissions generated, such as resulting hydrogen fluoride (HF), are controlled by the flue gas cleaning systems (emissions control technologies).

Table 2.8: PFAS material flow through manufacturing process

Gore product	Volumes used in production in the EU (tonnes/year)	Volumes used in production outside the EU (tonnes/year)	Material flow: Manufacture within the EU		
			Comprising the product	Recovered for re-use within the production process	Production waste
GORE® Catalytic Filterbags					
GORE® Mercury and SO ₂ Control Modules					
GORE® Industrial Dry Filtration Products					
GORE® TURBINE FILTERS					
GORE® Liquid Filtration Products					
GORE® COOLING FILTERS					
GORE® CLEANSTREAM®					
Heat Exchanger Laminate					
Rastex® / Gore industrial fibre					
All products - Inside the EU					

Source: Gore (2021b, 2022a)

Notes:

1. The average proportions of PFAS at each of the manufacturing stages across all products is estimated according to EU volumes of PFAS.
2. Volumes are rounded to the nearest tonne. Totals may therefore not sum up

Product service life

Gore does not have quantitative data on emissions of PFAS from service life of its filter products because they are used within a range of end-uses by different end-users. However, Gore believes that emissions during their service life are negligible. According to Gore, neither the release of relevant quantities of non-polymeric residuals nor the release of degradation products of the used fluoropolymers during service life is to be expected for the following reasons:

- The concentration of short-chain residual fluorinated polymerization aids in the intermediate PTFE articles leaving Gore plants have been tested and are typically below the limit of quantification of the test method used which is 3 ng/g (3ppb).

Fluoropolymers are specifically used in filter applications because they do not react or degrade, even when

exposed to aggressive chemicals or elevated temperatures. The specified service temperature for these products is up to 260°C. This is less than the processing temperatures used to manufacture the products.

Disposal of end products

No specific information on end-of-life (EoL) of the end-products is available to Gore, however, it is believed that the majority of the products are incinerated at EoL. This understanding is based on Gore's knowledge of end-uses as well as information from a study prepared for Plastics Europe on fluoropolymer products, which states that around 15% of products and articles containing fluoropolymers were landfilled at EoL and 80% were incinerated (ChemService, 2021)¹. End products containing the GORE® Mercury and SO₂ Control Modules are believed to be disposed via landfill on dedicated sites due to the contamination caused by the use.

To understand the effect of the incineration of waste containing PFAS, Gore evaluated scientific resources worldwide and commissioned the Institute of Technical Chemistry at the Karlsruhe Institute of Technology (KIT), Germany, to conduct a study on the incineration of PTFE in its pilot size municipal incineration plant at temperatures typical of a municipal waste incinerator. Based on Gore's current scientific understanding, incineration is an acceptable way to dispose of fluoropolymers and does not show significant generation of a range of PFAS that would be relevant to environmental concerns. For PTFE this was confirmed by a paper published in the July 2019 issue of Chemosphere, a peer reviewed scientific journal (Aleksandrov et al., 2019). This paper is based on the above-mentioned KIT study, which found that municipal incineration of PTFE shows no significant generation of the studied PFAS. It is likely that other PFAS show similar characteristics in the combustion process, and incineration of waste is therefore believed to be a small contributor to the overall emissions.

Gore further notes that landfilling of high-weight fluoropolymer products is not expected to contribute to emissions associated with landfill leachate, since high-weight fluoropolymers are not water soluble, not biodegradable and do not degrade in the environment. In addition, these substances are not precursors and are stable substances that do not degrade across a wide range of conditions, suggesting that they would not break down into any other PFAS when in a landfill. The stability of high-weight fluoropolymers is further highlighted in the varied applications for which they are used, including the use in outdoor environments, in high and low temperatures, and with exposure to many harsh chemicals.

Further information on the degradation potential can be found in Charles River Lab studies (still underway, with partial results of which have been shared with the authorities).

2.5 EU baseline

2.5.1 Introduction

This section seeks to set out the EU baseline (i.e., the situation in the absence of the proposed REACH restriction), whereby the assessment goes beyond Gore and includes information on all affected actors in the EU who make similar products to those presented in **Table 2.1**. The baseline derived for this SEA consists of three main components: (i) Projections for the EU market value of the products affected (products similar to those in **Table 2.1**), (ii) Projected EU use volumes associated with these products, and

¹ The source does not specify the EoL treatment for the remaining 5% of PFAS-containing waste.

(iii) indicators of risks.

There is limited publicly available data on the EU market for the affected products covered by this SEA, which is why Gore's best estimate for the EU market size has been used. This market size should be considered indicative ('best guess'), as Gore does not have accurate information on production and sales for other companies.

The location of manufacturing facilities (EU vs. non-EU) and the type and volume of PFAS used by other companies than Gore are also not known. The volume of PFAS used within the EU has therefore been extrapolated using market share assumptions and must be used with caution. It is possible that the dossier submitters (DS) will have received information on other companies affected (i.e., other than Gore) and may therefore be in a better position to understand if these extrapolated estimates are a reasonable reflection of the overall size of the EU markets affected.

Indicators of risks of using PFAS is partly based on publicly available information and partly based on information from Gore. The substance hazard profile has been assessed using information found on ECHA's website and literature provided by Gore, whilst consideration of emissions is based on information from Gore and the DS. Risks cannot be derived for the substance involved, but some broad conclusions can be made by synthesising the available information on hazards and emissions.

All information has been provided in good faith and uncertainties and caveats are further highlighted within the assessment.

2.5.2 Market information²

EU market for affected products

It is challenging to derive an accurate EU market size estimate for the type of products similar to the ones listed in **Table 2.1** as Gore does not have access to other companies' sales data. Gore has instead provided an indicative ('best guess') estimate for the EU market size for these types of products based on publicly available information and/or internal estimates, which is presented in **Table 2.9**. The EU market size, and the derived sales of other companies supplying similar products on the EU market, are thus associated with a high level of uncertainty.

Gore believes that around [REDACTED] of products similar to those listed in **Table 2.1** that are placed on the EU market by other companies also contain PFAS.

Table 2.9: Impacted sales and EU market, annual average 2016-2021

Sales of products similar to those in Table	Gore's direct sales in the EU (€ million/year)	Other companies' sales of similar products (€ million/year)	Impacted EU market (€ million/year)	EU's share of global market (%)
Products containing PFAS	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

² Any discussion of markets, shares, or market sizes or shares in this document is preliminary, based on publicly available information and/or internal estimates, and subject to change. Markets identified are not necessarily only relevant markets (product or geographic) for antitrust purposes, and shares may be incomplete and not reflect all competitive sales or all competitors.

Notes:

1. The sales revenue only includes direct sales of products similar to those in Table .
2. Values are given in 2022 prices and rounded to the nearest € million, so sums may not add up.

No indirect sales³ (beyond those estimated for Gore) have been included in the estimates in Table 2.9 as this would require detailed knowledge (that Gore does not have) of the location of the manufacturing sites of Gore's competitors and their customers as well as information on products sold outside the EU that eventually end up on the EU market. As explained in Section 2.3.1, around [REDACTED] million (~[REDACTED]) of Gore's sales revenue associated with filter products is from indirect sales (products placed on the EU market by Gore customers). This means that the EU sales revenue (from products similar to those listed in Table 2.1) that would be affected by a potential REACH restriction could be significantly higher than what is presented in Table 2.9.

PRODCOM product categories

Only a small set of products (listed in Table 2.1 and similar products made by Gore's competitors) is included in this assessment. To provide some broader context, data was also collected from the statistics on the production of manufactured goods within the EU (PRODCOM, 2020).⁴ The selected PRODCOM codes include the products within this assessment, but also comprise a larger set of products, as can be observed from the sales data presented in Table 2.10. The extent to which these wider product categories relies on PFAS is not known, but it is not unlikely that the use of PFAS goes beyond the products covered by this assessment. Note this list is non-exhaustive and PRODCOM codes may not include all Gore's products.

Table 2.10: EU Sales statistics for relevant PRODCOM categories

Broader product group	PRODCOM code	Average market size 2015-2019 € million	Gore product(s) within the broader product group
Machinery and apparatus for filtering or purifying gases by catalytic process (excluding intake air filters for internal combustion engines, machinery and apparatus for filtering or purifying air)	28251440	2,452	GORE® Catalytic Filter Bags
			GORE® Mercury and SO ₂ Control Modules
Machinery and apparatus for filtering and purifying gases (other than air and excluding those which operate using a catalytic process, and isotope separators)	28251430	800	GORE® Industrial Dry Filtration Products
Machinery and apparatus for filtering or purifying air (excluding intake filters for internal combustion engines)	28251410	2,476	GORE® Cooling Filters
			GORE® Turbine Filters
Machinery and apparatus for filtering or purifying water	28291230	2,924	GORE® CLEANSTREAM®
			[REDACTED]

³ Indirect sales are when a product/component containing PFAS is manufactured and sold outside the EU but enters the EU market via import of a complex product. See Section 2.3.1 for a more detailed explanation.

⁴ Eurostat (2015-2019). PRODCOM Annual Data 2015-2019 (PRODCOM).

Broader product group	PRODCOM code	Average market size 2015-2019 € million	Gore product(s) within the broader product group
Parts for filtering and purifying machinery and apparatus, for liquids or gases (excluding for centrifuges and centrifugal dryers)	28298250	3135	MicroE Media Ozone Modules
Machinery and apparatus for solid-liquid separation/purification excluding for water and beverages, centrifuges and centrifugal dryers, oil/petrol filters for internal combustion engines	28291270	2,614	GFTA/Socks
Total	All	14,402	All

Notes:

1. Data taken Eurostat (2015-2019). PRODCOM Annual Data 2015-2019 (PRODCOM).
2. Values are given in 2022 prices.

EU supply chain and end-use industries

Gore and manufacturers of similar products to those in **Table 2.1** purchase large volumes of PTFE from raw material suppliers both within and outside the EU. **Table 2.11** presents the total quantity sold and total value across relevant industries in the EU fluoropolymers market. Though Gore's and similar products outlined in **Table 2.1** are only a portion of the fluoropolymer market, the table demonstrates the size of potential buyers that Gore's suppliers are reliant upon for their sales. The fluoropolymers market is expected to grow by a compound annual growth rate (CAGR) of 6.5% from 2020 to 2027 (Fluoropolymer Product Group of PlasticsEurope, 2022). Note that the list is non-exhaustive, i.e., not all affected industries are covered in the table.

Table 2.11: EU market for fluoropolymers

Sector	Total quantity sold (tonnes)		Total value (€ million)	
	2020	2015	2020	2015
Chemical and Power	11,000	16,500	213	253
Electronics	3,500	3,500	75	58
Total	14,500	20,000	288	311
Total fluoropolymer market	39,500	52,000	799	881

Source: (Fluoropolymer Product Group of PlasticsEurope, 2022)

Notes: Monetary value is given in 2022 prices.

Emissions control in harsh and aggressive environments is an essential function across many industries (e.g., chemical manufacturing, refining of petroleum products, metallurgy, etc.) and is interlinked with many downstream industries. Filters containing PFAS are used in the most demanding applications such as hazardous waste incinerators, to prevent toxic pollutants from being released to the environment. Products containing PFAS have a common benefit of reducing risk of emissions, which protect health and safety for people and the environment. Gore calculates that if a plant spends 5% of its revenue on pollution control equipment, the respective pollution control products' value is approximately £100 million per year in the EU market.

Filters containing PFAS also provide necessary cooling and cleaning for advanced electrical products to avoid overheating. Gore believes that nearly all the advanced semiconductor chip sets and memory devices imported into the EU use filters containing PFAS. Semiconductors and memory devices are essential devices for the function of many end-uses across many industries.

Any disruption to the filters industry will flow from initial production through all end use applications of the material, amplifying the effect. A potential restriction on PFAS without a derogation for the type of products set out in **Table 2.1**, could pose significant disruptions to businesses and employment, both within and outside of the EU.

Table 2.12 presents key economic indicators (turnover and employment) for some of the downstream industries that would be affected by a ban on products containing PFAS in the filters industry. Note that the list is non-exhaustive, i.e., not all affected industries are covered in the table.

Table 2.12: Economic overview of downstream user industries in the EU that use filters containing PFAS

Industry	Turnover (€/billion)	Employment (million)	Year of publication	Source
Chemical manufacturing	642	1.2	2019	(Eurostat, 2022a)
Semiconductors	1	unknown	2020	(PRODCOM, 2020)
Electrical equipment	334	1.5	2020	(Eurostat, 2022a)
Manufacture of basic metals	349	0.9	2019	(Eurostat, 2022a)
Manufacture of coke and refined petroleum products	315	0.2	2020	(Eurostat, 2022a)
Total	1,641	4		

Notes: Monetary values are given in 2022 prices and rounded to the nearest € billion.

2.5.3 PFAS use and product life cycle

PFAS use volumes

The products listed in **Table 2.1**, and similar products manufactured by other companies, are highly specialised, and Gore believes that around half of the similar products on the EU market will also contain PFAS. To derive indicative EU estimates for PFAS use volumes, it is therefore assumed that 50% of the similar products placed on the EU market (not manufactured by Gore) is also manufactured using PFAS. However, since the 98% of the PFAS used in the production process comprises the product (see Section), the most critical component when estimating total volumes ending up on the EU market will therefore be the EU sales of PFAS-containing products (i.e., those products containing PFAS that are placed onto the EU market).

In Section 2.4.2 it was shown that Gore places around [REDACTED] tonnes PFAS per year on the EU market through direct EU sales. This volume is extrapolated to the EU using Gore's market share, which implicitly assumes that the amount of PFAS contained in Gore products is, on average, representative for similar products on

the market⁵. This is considered a reasonable assumption in the absence of other available information.

Extrapolating indirect sales is more complicated, as this would require information on the market size for all the end-user markets in the EU, as well as the share of these markets Gore products serve. Considering the wide range of uses for the products set out in **Table 2.1**, it is not feasible to assemble this information nor come up with reasonable assumptions that can be used to extrapolate the PFAS use volumes placed on the EU market through indirect sales. Similarly, it is not possible to extrapolate potential PFAS production waste in the EU, as the location of other companies' manufacturing sites are unknown.

For transparency, two estimates for the amount of PFAS used (volumes) have been derived. "PFAS use volume contained in products" comprise the volumes contained in products similar to those in **Table 2.1**. The second estimate also contains the additional volume used in production but not placed on the EU market and Gore's indirect sales, but these have not been extrapolated (i.e., only volumes from direct sales are extrapolated). The EU use volumes presented in **Table 2.13** may therefore underestimate the total PFAS volume placed on the EU market.

Table 2.13: Extrapolation of volumes of PFAS placed on the EU market, annual average 2016-2021

	Gore's total sales and total affected PFAS volumes	Other companies' direct sales in the EU and PFAS volumes	Total EU market
Revenue from sales of products containing PFAS (€ million/year)			227
PFAS use volume contained in products (tonnes/year)			867
PFAS use volume contained in products plus Gore's additional volumes associated with manufacture and indirect sales (tonnes/year)			935

Notes:

1. The figures in this table are extrapolated for the EU and are therefore associated with a high degree of uncertainty.
2. The volumes have been rounded to the nearest tonne, so sums may not add up.
3. Values are given in 2022 prices and rounded to the nearest € million.

PFAS material flow and product lifecycle

As detailed in Section 2.4.3, there are several stages in the lifecycle of PFAS and PFAS containing products. This begins with the production of PFAS to the manufacture of PFAS-containing products, the use or service life of PFAS-containing products and the end of life of PFAS-containing products. It should be noted that Gore do not produce fluoropolymers for the uses in this SEA itself, but rather manufacture fluoropolymer-containing products (in REACH terms they are a "downstream user" of PFAS). The analysis is therefore focussed on the product lifecycle, from manufacture of products containing PFAS to their end-of-life. However, as Gore is a producer of small volumes of fluoropolymers used in products not covered by this SEA, Gore has first-hand knowledge of fluoropolymer manufacturing and technical methods available to control emissions.

Section 2.4.3 presented information from Gore related to the PFAS material they use during their

⁵ This implicitly assumes that other companies manufacturing similar products do not have significantly higher PFAS waste volumes during the product production process. This is considered a reasonable assumption since PTFE is a relatively expensive raw material (See Chapter 3).

manufacturing process and information on the service life and end-of-life of their products. In order to map out the PFAS material flow associated with products similar to those presented in [Table 2.1](#), complementary information from “investigation report summaries” published by the DS in 2021 (National Institute for Public Health and the Environment (RIVM) et al., 2021) has been utilised. It should be highlighted that this information relates to broader product groups and are therefore not fully representative for the products covered in this SEA. Further, the emissions stated in the *investigation report summaries* are much higher than the emissions reported by Gore. **In the opinion of Gore, the emissions from product manufacture estimated by the DS are significantly overestimated** which might be based on the fact that the **BAT for emission reduction during manufacturing was not taken into account by the DS**. Gore also believes the emissions from service life and end-of-life of PFAS-containing products are overestimated by the DS. This is because, as explained in Section 2.4.3, **the fluoropolymers used does not react, degrade, or erode**, even when exposed to aggressive chemicals or relevant chemical process temperatures, which suggests that emissions during service life are negligible. Furthermore, based on Gore’s current scientific understanding, **incineration, which is the most common EoL treatment, does not show significant generation of a range of PFAS that would be relevant to environmental concerns**. Nonetheless, the data will be used in the following as a basis for conducting the socioeconomic analysis. A summary of information from all the “investigation report summaries” published by the DS is presented in [Appendix 1: PFAS volumes and emissions across multiple sectors](#).

[Figure 2.4](#) presents an overview of the PFAS material flow through the various lifecycle stages for the products included in [Table 2.1](#) and similar products on the EU market. It also shows the share of PFAS (as a percentage) that is carried over from one stage of the life cycle to the next, and the share of PFAS (as a percentage) that is released to the environment and the share that ends up in waste at each of the lifecycle stages. **All emission factors presented in and detailed in [Figure 2.4](#) the proceeding section are based on information from the DS and do not reflect Gore’s data on emissions.** The EU use volumes derived in the previous section (PFAS use volumes) was extrapolated from information provided by Gore⁶. The share of PFAS ending up as production waste (<1.5%) and the share being reused (<0.2%) are also based on data provided by Gore and assumed similar for other companies manufacturing similar products. The share of PFAS volume being sent for incineration (80%), landfill (15%) and other waste treatment (5%) is based on information from a study prepared for Plastics Europe on fluoropolymer products (ChemService, 2021). The shares are based information from Gore and the DS, and the corresponding volumes have been derived using these shares as well as the EU use volumes from the previous section (PFAS use volumes). and the estimates are associated with a high level of uncertainty. The approach and assumptions used to derive the estimates are further detailed below [Figure 2.4](#).

[Figure 2.4](#) shows that of the 867 tonnes PFAS that is estimated to be placed on the EU market via direct sales (of products similar to those in [Table 2.1](#)), almost all remain in the product until end of life. The majority of PFAS in waste streams (relevant for this SEA) is believed to be incinerated, for which emissions are likely negligible (Aleksandrov et al., 2019). The “investigation report summaries” indicates that overall emissions from PTFE in waste streams is <0.02%.

⁶ Note that PFAS contained in production waste and PFAS entering the EU market through indirect sales are only included for Gore, i.e., these have not been extrapolated to the EU – see further explanation in the previous section.

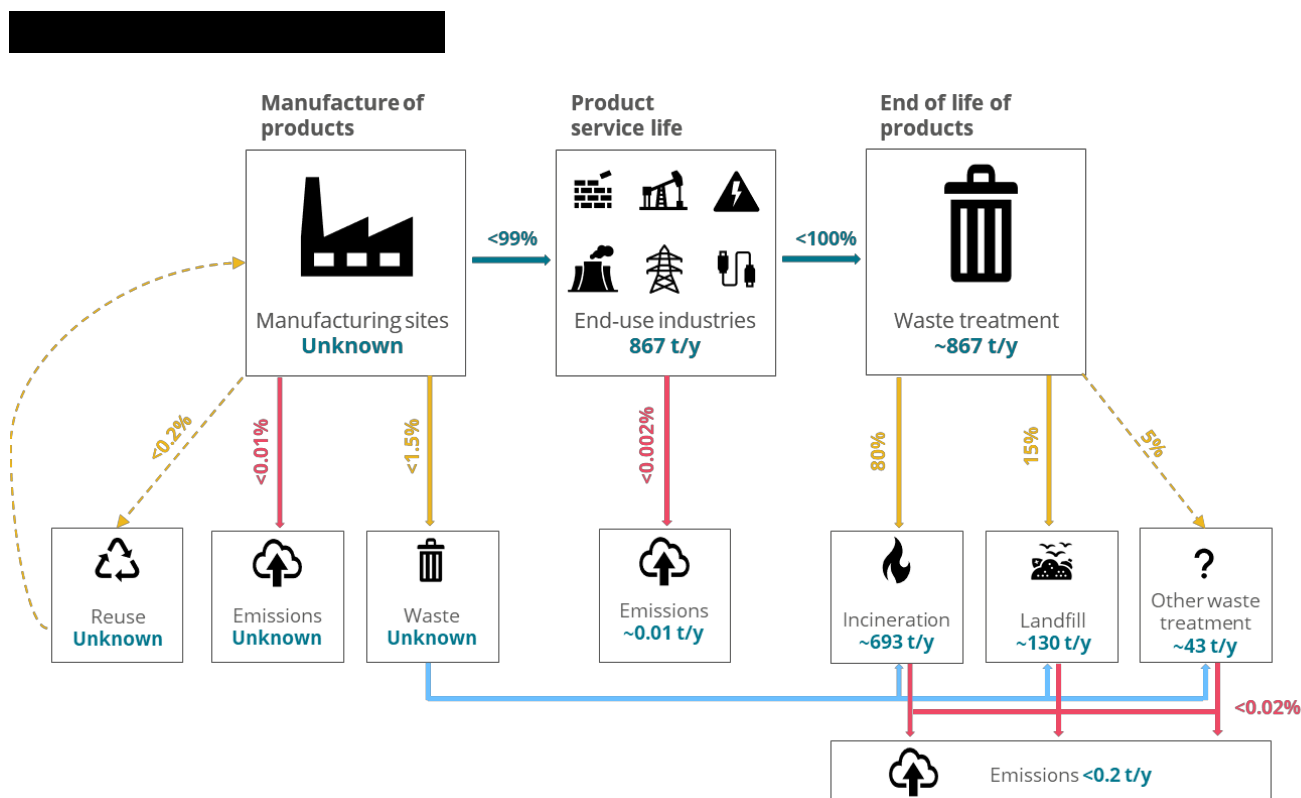


Figure 2.4: PFAS material flow for the EU market for products covered within the SEA

Notes:

1. The emission factors have been estimated based on the high scenario of non-polymeric PFAS emissions from fluoropolymers used in articles, taken from the petroleum and mining sector report of the "investigation report summaries" published by the DS. The emission factors were adapted to each lifecycle stage by subtracting the share of the PFAS volume being reused and/or the share ending up in waste (as reported by Gore).
2. The volume of PFAS in end-use industries in the EU has been extrapolated based on the direct sale of PFAS-containing products placed on the EU market, and therefore excludes the volume of PFAS used in manufacturing and the volume of PFAS placed on the EU market via indirect sales.
3. The share of PFAS contained in products that ends up in waste at the products' EoL is in the figure rounded to 100%. The actual share is, based on information from the DS, is $100\% - 0.002\% = 99.998\%$.

Manufacture of products containing PFAS

Gore manufactures these products both within and outside of the EU, however, information is not available on the location of the production sites of other companies manufacturing similar products, which means that there is no basis for deriving volumes used for the manufacture of filter products that does not end up in products placed on the EU market. The indicative share of PFAS used in the manufacture of such products that is released into the environment and the share that ends up in production waste and the share that is recovered for reuse are available, albeit the resulting EU volumes are unknown.

- Gore reported that there are negligible (~0%) PFAS emissions from the manufacturing of their products due to the use of emission control technologies in manufacturing sites located in the EU. Gore believe that similar / equally efficient emission control technologies are used by other companies which may have production sites located in the EU. Emissions from product manufacture are thus likely negligible (i.e., ~0%). See Section 2.4.3 for further details.
- The "investigation report summaries" published by the DS in 2021 (National Institute for Public Health and the Environment (RIVM) et al., 2021) (summarised in Appendix 1), provide estimates for

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PFAS volumes and emissions in the and petroleum and mining sectors⁷. This report covers a significantly broader range of products than the filter products included in this SEA and involve a wider array of manufacturing processes. The emission factor derived based on the DS data is therefore unlikely to be fully applicable to the products covered in this SEA. Despite these uncertainties, the report was considered more representative than the other “investigation report summaries”, as it specifically estimates emissions from fluoropolymer products.

The DS estimated that the upper bound for emissions of non-polymeric PFAS from fluoropolymer products is less than 0.01% w/w of the fluoropolymers/PFAS contained in the products during manufacturing. Even though **these emissions are significantly higher than the emissions reported by Gore**, they are – following a conservative approach – used as basis for this SEA.

The share of PFAS used to manufacture the products covered by this SEA in the EU that ends up in production waste, is reported by Gore to be less than █% (see Section 0). The “investigation report summaries” published by the DS do not go into the same level of detail with regards to the production waste, so the Gore estimate is used as the best available indicator for PFAS ending up in production waste at an EU level.

Some (<0.2%) of the PFAS used during manufacturing of filters in the EU is recovered for reuse. This was reported by Gore (see Section 2.4.3) and is assumed, in the absence of further information, to be representative of the share of PFAS recovered for reuse in other filter manufacturing sites in the EU. The “investigation report summaries” published by the DS do not provide any information on the share of PFAS recovered for reuse.

Lastly, share of PFAS that comprises the products after the manufacturing process is (<99%) based on the assumption that <1.5% of PFAS ends up in production waste, <0.2% of PFAS is recovered for reuse and a negligible amount (<0.01%) of PFAS is emitted during production.

Service life of products containing PFAS

The information provided on emissions from service life of the products differ between Gore and the DS:

- Gore reported (see Section 2.4.3) that it is unlikely that there will be releases of relevant quantities of non-polymeric residuals nor releases of degradation products of the used fluoropolymers during product service life. It is further believed that similar PFAS-containing products on the EU market would also exhibit this feature. As detailed in Section 2.4.1, PFAS are extremely strong and require a significant amount of energy to break, characteristics that are essential for products used in harsh environments. These characteristics also demonstrate that PFAS emissions are unlikely to be generated during the service life of products designed to operate in such harsh environments.
- Based on the “investigation report summaries” for the petroleum and mining sectors it was estimated that less than 0.002% of PFAS comprising products used in these industries are emitted during the products’ service life. This emission factor is based on the non-polymeric PFAS emissions from outdoor use of a wider set of articles and is therefore unlikely to be fully applicable to the products covered in this SEA.

⁷ The dossier submitters published investigation reports on a range of sectors. The sector reports used to extrapolate the share of emissions were considered to be most relevant to the end-use industries of the filters included in this SEA.

To keep the analysis conservative, the share of PFAS emitted throughout the service life of products similar to those set out in **Table 2.1** is assumed to be 0.002% (i.e., aligned with information provided by the DS).

Product end of life

Since the amount of PFAS in the products that then ends up as waste at the products' end of life is assumed to be close to 100%⁸, the volume of PFAS from the products similar to those in **Table 2.1** that ends up in waste streams is estimated at just below ~867 tonnes per year. It is believed that 80% of PFAS-containing end-products are incinerated (~693 tonnes per year), 15% are landfilled (~130 tonnes per year) whilst the waste treatment for the remaining 5% (~43 tonnes per year) is not specified in the reference study (Chemservice, 2021).

Based on Gore's current scientific understanding, incineration of fluoropolymers will not generate significant emissions and landfilling of PTFE products is not expected to contribute to emissions associated with landfill leachate, since PTFE is not water soluble, not biodegradable and does not degrade in the environment. See further details in Section 2.4.3.

In the *"investigation report summaries"* for waste it is also noted that incineration of PFAS-containing products at the end-of-life make a negligible contribution to overall emissions from waste streams. The DS further estimate that, in a high emissions scenario, the emissions of non-polymeric PFAS from fluoropolymer products in waste streams is less than 0.02%⁹ of the fluoropolymers entering the waste stream per year. Using this emission factor, the upper bound volume of PFAS being emitted in the EU at the EoL for the products covered by this SEA is estimated to amount to 0.2 tonnes per year.

Total emissions throughout the lifecycle

As explained above, Gore believes that the emission factors derived based on the DS' data are not representative and their use leads to significantly overestimated emissions at all life-cycle stages. Despite this, the DS' data will be used to calculate emissions for this SEA, to ensure that a conservative approach is taken.

Two emission scenarios have been defined:

- **Reasonable worst-case emissions:** This is derived using the DS' emission factors for service life and EoL but excludes potential emissions from manufacture of products. According to Gore, who has first-hand knowledge of the manufacturing process and emission from the specific group of products contained in this SEA, the emissions from manufacture of these types of products are negligible, and the overestimation of emissions from service life and EoL will by far outweigh the omission of emissions from manufacture. It is therefore believed that the reasonable worst-case emissions will be higher than actual emissions from all lifecycle stages for products covered within this SEA.
- **Worst-case sensitivity emissions:** To construct a worst-case sensitivity scenario, the DS' emission factors have been used at all life cycle stages, whilst also assuming that all manufacture of products similar to those set out **Table 2.1** will be manufactured in the EU. It should be noted that this is not

⁸ Exact number is <99.998%.

⁹ Based on 0.06 tonnes fluoropolymer emissions and 5,411 tonnes fluoropolymers entering the waste stream.

considered a realistic scenario but has been included as a conservative sensitivity that can inform the decision-making process.

Table 2.14 presents the two emission estimates alongside the best estimate for EU PFAS contained in products. Based on the argumentation presented above, the volumes and emissions presented in **Table 2.14** will be conservatively assumed as emissions of PFAS into the environment throughout the lifecycle of products similar to those set out in **Table 2.1**.

Table 2.14: Estimates of EU emissions, average 2016-2021

Estimate	Description	Volumes in tonnes/year
PFAS contained in products in the EU	PFAS volumes contained in product similar to those in Table 2.1 (excluding manufacture and indirect sales).	867
Reasonable worst-case emissions in the EU	Based on high estimate of emissions from service life and EoL, excluding emissions from manufacture and indirect sales.	0.2
Sensitivity of emissions in the EU	High emissions from all sources (this includes emissions from manufacture of products containing PFAS assuming all manufacture occurs in the EU).	0.2

Notes:

1. Reasonable worst-case emissions are derived using the higher emission factor associated with service life and EoL from the Investigation summaries published by the DS.
2. Worst-case sensitivity emission estimates also use the emissions factors from the DS, but further assumes that all products placed on the EU market will be manufactured in the EU
3. Volumes have been rounded to the nearest tonne or to the first significant decimal if below a tonne. The reasonable worst-case (0.16 t/y) and the worst-case sensitivity (0.22 t/y) are not identical but appear so due to rounding.

2.5.4 Indicators of risks under the baseline

The DS have communicated that the key risk indicator for PFAS is the substances' persistency. Another concern is that some of the substances are also highly mobile and can accumulate in biota. They note that *"the consequences of this persistence include that the presence of these substances in the environment is practically irreversible and pose an unacceptable risk to the environment and humans. All uses of PFAS (professional and industrial uses, consumer uses of mixtures and articles) result in emissions into the environment and contribute to the overall concentrations of PFAS in the environment"* (RIVM, n.d.). Toxicity has also been confirmed for some PFAS, which adds to the overall concern for this group of substances.

Hazard profile

Gore uses three types of PFAS for the manufacture of the filter products listed in **Table 2.1**, namely PTFE, PFA and PVDF.

Similar to other PFAS, PTFE, PFA and PVDF are persistent, but data demonstrate that they do not meet the criteria for being mobile, bioaccumulate or toxic (Henry et al., 2018; Korzeniowski et al., 2022). PTFE, PFA and PVDF do not have any harmonised hazard classifications (CLH) and fall under the OECD definition of Polymer of Low Concern (PLC), which the OECD Expert Group on Polymers *"deemed to have insignificant environmental and human health impacts"* (OECD, 2009). During the 5th meeting of the Competent Authorities Sub-Group (CASG) on Polymers (17 November 2021) industry and the Commission discussed as to how PLC should be defined in the EU. A complete set of definition criteria was not agreed, however,

it was discussed that if certain fluoropolymers do not breakdown into degradants of concern, this could indicate that the fluoropolymer was a PLCs (European Commission, 2021b). Examples of characteristics discussed include molecular weight, stability, and leachability (European Commission, 2021b). Moreover, Henry et al. (2018) found that PTFE and PFA are PLC based on widely accepted criteria¹⁰ one of which is that PTFE and PFA do not breakdown into degradants of concern.

PVDF is not specifically mentioned in Henry et al. (2018), but Gore informed that this polymer has similar properties that would classify it as a PLC using these criteria. A more recent study by Korzeniowski et al. (2022), building on the research conducted by Henry et al. (2018) found that 14 additional fluoropolymers¹¹ (including polyvinylidene fluoride (PVDF) and ethylene-chlorotrifluoroethylene (ECTFE)) are also PLCs – having passed the same 13 criteria (tests) outlined in the original 2018 study.

Table 2.15: PLC criteria from study by Henry et al. (2018)

Assessment criteria	Fluoropolymers			
	PTFE	ETFE	FEP	PFA
CAS Number	CAS 9002-84-0	CAS 25038-71-5 68258-85-5	CAS 25067-11-2	CAS 26655-00-5 31784-04-0
Polymer composition (must have C, H, Si, S, F, Cl, Br, or I covalently bound to C)	Yes	Yes	Yes	Yes
Molecular weight	389 000– 8 900 000	-	-	-
(Mn > 1000 Da and oligomer content < 1%)	520 000– 45 000 000	530 000–1 200 000 ¹²	241 000– 575 000 ¹²	200 000– 450 000 ¹²
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	1.4-2.7	1.55-2.09	1.7
Wt % oligomer (<5% for <1000 Da oligomers, <2% for <500 Da oligomers)	Negligible	Negligible	Negligible	Negligible
Ionic character (cationic polymers associated with aquatic toxicity; polycationic with adverse human health effect)	Neutral	Neutral	Neutral	Neutral
RFGs ¹³ (some highly reactive functional groups 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)	<1 (see section Reactive functional groups and RFG ratio to MW)	<1 (see section Reactive functional groups and RFG)	<1 (see section Reactive functional groups and

¹⁰ These criteria represent the combined experience and knowledge of global regulatory authorities on factors demonstrated to be predictive of health and environmental hazards of polymers.

¹¹ The full list of polymers is as follows: polyvinylidene fluoride (PVDF) homopolymer; PVDF copolymer; ethylene-chlorotrifluoroethylene (ECTFE) copolymer; ECTFE terpolymer; polychlorotrifluoroethylene (PCTFE); fluoroethylene-vinyl ether copolymer (FEVE); terpolymer of ethylene, tetrafluoroethylene, and hexafluoropropylene (EFEP); terpolymer of chlorotrifluoroethylene, tetrafluoroethene, and perfluoroalkyl-vinyl-ether (CPT); and terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride (THV), tetrafluoroethylene-propylene co-polymer (FEP); hexafluoropropylene-vinylidene fluoride co- and terpolymers (FKM); and a tetrafluoroethylene-perfluoromethyl vinyl ether perfluoroelastomer (FFKM).

¹² Molecular weight is weight average molecular weight.

¹³ For definition of reactive functional group; lists of low-, moderate-, and high-concern functional groups; and FGEW limits, see US EPA Polymer Exemption Guidance Manual (USEPA, 1997), (De Toni, A., Saidi, s., Santos, L. R., And Mudga, 2015, p 191–192), and (USEPA, 2010).

Assessment criteria	Fluoropolymers			
	PTFE	ETFE	FEP	PFA
			ratio to MW)	RFG ratio to MW)
FGEW ¹³ (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	>10 ⁵ -10 ⁶	>10 ⁵	>10 ⁵
Low molecular weight leachables (MW < 1000 Da able to enter cell)	<1 ppm	No active leachables by USP class VI ¹⁴ (121 °C)	No active leachables by USP class VI ¹⁴ (121 °C)	No active leachables by USP class VI ¹⁴ (121 °C)
Residual monomers (monomers have lower MW than polymers; typically more hazardous than polymers)	<1 ppm	<50 ppb	<50 ppb	<50 ppb
Ratio of residual monomers to molecular weight (typical value) (more low MW monomer content per mole increases bioavailability and hazard potential)	~10 ⁻¹³ to 10 ⁻¹⁵	~10 ⁻¹³ to 10 ⁻¹⁴	~10 ⁻¹³	~10 ⁻¹³
Structural similarities to RFG of concern (increases potential risk of adverse effects)	None	None	None	None
Reference standard see also ISO 1133 (ISO 2011), ISO 12086 (ISO 2006)	ASTM D 4894 (ASTM, 2015a) D 4895 (ASTM, 2016a)	ASTM D 2116 (ASTM, 2016b)	ASTM D 3159 (ASTM, 2015b)	ASTM D 3307 (ASTM, 2016c)
Physical-chemical properties				
Water solubility (per USP 2011) (water solubility <10mg/L showed generally low health concerns; 10mg/L to 10000 mg/L had potential health concern)	Practically insoluble or insoluble (1 * 10 ⁻⁵ mg/L)	Practically insoluble or insoluble	Practically insoluble or insoluble	Practically insoluble or insoluble
Octanol-water partition coefficient, K _{ow} (higher K _{ow} associated with lipophilicity and a high potential to bioaccumulate or bioconcentrate)	N/A	N/A	N/A	N/A
Particle size (median mass aerodynamic diameter, MMAD, should be >5µm)	100-500 µm (powders)	50-250 µm (powders)	150-250 µm (powders)	50-250 µm (powders)
	-	2-4 mm (pellets)	2-4 mm (pellets)	2-4 mm (pellets)
Stability				
Hydrolysis (breaking into M _n < 1000 Da increases hazard potential)	Stable	Stable	Stable	Stable
Light (hv) (breaking into M _n < 1000 Da increases hazard potential)	Stable	Stable	Stable	Stable

¹⁴ In the USP<88> testing for "class VI," 2 g of the plastic (e.g., FEP, ETFE, or PFA) were extracted at 121 °C in: 1) 0.9% sodium chloride solution, 2) sesame oil, NF, 3) alcohol saline, and 4) polyethylene glycol. The acute systemic toxicity and intracutaneous reactivity tests were conducted with those extracts. The intramuscular implantation was conducted with the plastic. Passing these 3 tests indicates that any leachables were not released in concentrations capable of causing these adverse effects but does not result in a quantitative concentration of leachables (US Pharmacopeia, 2018).



Assessment criteria	Fluoropolymers			
	PTFE	ETFE	FEP	PFA
Oxidation (breaking into $M_n < 1000$ Da increases hazard potential)	Stable	Stable	Stable	Stable
Biodegradation (aerobic and anaerobic) (breaking into $M_n < 1000$ Da increases hazard potential)	Stable	Stable	Stable	Stable
Thermal stability at normal foreseeable use maximum continuous temp (°C) (breaking into $M_n < 1000$ Da increases hazard potential)	260	150	200	260
Meets PLC criteria (Y/N)	Yes	Yes	Yes	Yes

Source: Henry et al. (2018) based on OECD (2009) and De Toni et al. (2015).

Risks

PFAS is, as mentioned, a large group of substances (>6,000) which is being proposed for a REACH restriction due to their persistence. All PFAS used by Gore in the products covered by this SEA, which includes PTFE, PFA and PVDF, have no harmonised classifications (CLH). In addition, the data demonstrates that they do not meet the criteria for being mobile, bioaccumulate, or toxic and have been categorised as PLC (Henry et al., 2018; Korzeniowski et al., 2022; OECD, 2009). Although information on the type of PFAS used by other companies is not available, according to Gore it is likely that most of these PFAS are fluoropolymers, such as PTFE, and likely to meet the criteria for a PLC.

It is therefore considered unlikely that the products covered in this SEA will lead to adverse impacts on the environment or human health.

2.5.5 EU baseline summary and projections

The EU baseline comprise projections for EU market size, PFAS use volumes and reasonable worst-case emissions volumes, using the recent (2016 - 2021) estimates presented in Section 2.5.3. As explained in Section 1.3, the analytical period for this assessment is 2022 – 2041. This means that the EU market size, PFAS use, and emission volumes must be projected over this period, in order to form a dynamic baseline that can be used for the assessment of impacts. Market projections for the specific products covered in this SEA is not available, but it is assumed that the market growth broadly follows the overall trends observed for the EU market for PRODCOM categories set out in Section 2.5.2 (Broader product categories). A compound annual growth rate (CAGR) of 3.1% based on historical EU PRODCOM sales data for this market is applied until 2031. Long-term growth is inherently difficult to predict, so a conservative approach has been taken, assuming a 0% growth rate from 2032 and onwards. The projections have been estimated in the absence of a possible REACH restriction whereby use of PFAS in filter products are not restricted during the assessment period.

As outlined in **Table 2.16**, in the absence of a possible REACH restriction, the annual average EU market value for filter products containing PFAS is projected at around €280 million per year between 2022 and 2041. The volume of PFAS contained in these products that are directly placed on the EU market is estimated at ~1,068 tonnes per year and corresponding emissions estimated at <0.2 tonnes per year.

Table 2.16: Extrapolated projection of sales, volumes for the EU market (2022-2041)

Estimate	Total (2022-2041)	Average annual (2022-2041)
Revenue from sales of products containing PFAS (PV - € million)	5,591	280
PFAS contained in products (tonnes)	21,364	1,068
Reasonable worst-case emissions (tonnes)	4	0.2

Notes:

1. Market size values are presented in undiscounted 2022 prices and are rounded to the nearest € million.
2. PFAS use volumes have been rounded to the nearest tonne and emission volumes to the first significant digit.
3. PFAS contained in products does not include indirect sales.

3. Availability of suitable alternatives

3.1 Introduction

Information on the suitability of possible alternatives is essential when assessing possible restrictions under REACH. The assessment of alternatives within this SEA is primarily based on information from Gore.

This chapter covers the following topics related to possible alternatives (either being tested or already on the market):

- R&D (Section 3.2)
- Technical feasibility (Section 3.3)
- Availability (Section 3.4)
- Cost and timeline for transitioning (Section 3.5)
- Hazard comparison (Section 3.6)

In order for an alternative substance (or process) to be viewed as a suitable substitute, it needs to be able to provide similar technical functions as the restricted substance, be economically feasible to implement, be available in sufficient quantity to replace the restricted substance, and not have a worse hazard profile (i.e., increase risks).

3.2 R&D undertaken by Gore to date

Gore continually follows external developments of new materials while also pursuing an R&D program to develop novel materials that meet these market needs. However, no materials that can replace the need for fluoropolymers have been identified to date.

R&D completed to date concludes that for GORE® Catalytic Filterbags, GORE® Mercury and SO₂ Control Modules and GORE® Industrial Dry Filtration Products that PTFE is not replaceable. As it is chemically resistant and inert and can withstand the operating temperatures required while remaining water and oil repellent. In addition, if it is expanded and laminated to a backing material it can still function as a highly efficient surface filter, which can be cleaned in use. No other known material can provide these unique set of necessary properties.

However, Gore has made efforts to minimise the use of PFAS in filters. As an example, the weight of the most sold PTFE felt filters was reduced from 24.5 oz (ounces per square yard) to 22.0 oz (830 g/m² to 746 g/m²; or 10%). Another example is the maximisation of using a by-product from PTFE membrane manufacturing to produce PTFE fibres. This reduces the amount of new PTFE required and increases the recycling rate of material which would otherwise end up as waste.

For Gore® Turbine Filters, Cooling Filters, GORE CLEANSTREAM and Heat Exchanger Laminate Gore is in the early stages of exploring an alternative material [REDACTED]. This is an investment to understand how the laminated material performs for the specific application. No further R&D efforts have been taken to find alternatives as in most of the products, fluoropolymers are not replaceable given the needs of high filtration performance, chemical resistance, temperature resistance and durability with

intrinsic water and salt protection.

3.3 Technical feasibility

Gore operates within markets that require the performance characteristics provided by fluoropolymers. As a result, Gore has been able to develop products to meet customer's performance specifications that could not be met by using other materials. Fluoropolymers are generally more expensive than other polymers, so customers have an economic incentive to use other materials, when it is possible to meet their performance requirements.

PTFE's chemical / physical properties (due to the chemistry of carbon-fluorine (C-F) bonds) are unique, and it is Gore's understanding that it is not possible to replace the use of PTFE in any of their filtration products without a negative impact on the performance on the end-products. **Table 3.1** details the function of the Gore product (that contains a Gore filter) and whether Gore are aware of any feasible (non-PFAS) alternatives to the Gore filter that provide the same level of performance.

Table 3.1: Gore Filter products, their technical function and if there are feasible alternatives

Gore products	Technical function of Gore product	Is there a technically feasible alternative to PFAS in the Gore product?
GORE® Catalytic Filterbags	Simultaneous removal of particulate and catalytic conversion of gaseous toxins.	No - not with similar performance. Non-PFAS materials would lead to higher emissions of toxic air pollutants.
GORE® Mercury and SO ₂ Control Modules	Removal of Mercury and SO ₂ from Flue Gases.	No - not with similar performance. Non-PFAS materials would not be usable in water saturated atmosphere, hence require energy consumption to heat the flue gas.
GORE® Industrial Dry Filtration Products	Removal of Particulate from gases.	No - not with similar performance. Non-PFAS materials would lead to higher emissions of toxic air pollutants.
GORE® TURBINE FILTERS	High Filtration Efficiency, removing submicron dust, water, and salt particulates, allowing also for high airflow.	No - not with similar performance. Non-PFAS materials would have lower efficiency, which will cause fouling of the turbine blades, resulting in lower energy output, higher fuel consumption and higher emission of greenhouse gases.
GORE® Liquid Filtration Products	Removal of particulate from liquid streams in semiconductor plants.	No - not with similar performance. Non-PFAS materials would have lower efficiency, which will cause contamination and potential failure of the manufacturing equipment.
GORE® COOLING FILTERS	High Filtration Efficiency, removing submicron dust, water, and salt particulates, allowing also for high airflow.	No - not with similar performance. Non-PFAS materials would have lower efficiency, which will cause fouling and premature failure of the electronic equipment.
GORE® CLEANSTREAM®	High Filtration Efficiency, removing submicron dust, water, and salt particulates, allowing also for high airflow.	No - not with similar performance. Non-PFAS materials would have lower efficiency, which will higher emission of fine particulate into the environment. Additionally, non-PFAS Filters would be less cleanable / washable, resulting in the need for frequent replacement, increasing levels of waste.

Gore products	Technical function of Gore product	Is there a technically feasible alternative to PFAS in the Gore product?
Heat Exchanger Laminate	Water protection with low level of resistance for heat transfer between surfaces.	No - not with similar performance. Non-PFAS materials would have lower efficiency and higher resistance, which would cause fouling and premature failure of electronic equipment in the data center.
Rastex® / Gore industrial fibre	Temperature and chemical resistance in a high strength weaving/sewing fibre or non-woven (carded) filter media, insulating material.	No - not with similar performance. Non-PFAS materials would have lower temperature and chemical resistance leading to premature failure of equipment.

Source: Gore (2021b; 2022a)

There are potential alternatives to some of Gore's filters' constituents (e.g. Rastex® Thread and Staple fibres) but these either contain asbestos or are of poorer quality materials which leads to a higher power consumption and have a shorter lifespan. Alternatives to Rastex® Thread and Staple fibres increase the risk of loss of containments that are collected in the baghouse. These baghouse pollutants¹⁵ can include dioxins, heavy metals, and other toxic or carcinogenic substances. The PTFE membrane filter has the capability to collect >99.9% of these pollutants, while non-PTFE membrane filters typically show an efficiency of ~50%-<99% depending on the particle size¹⁶ and the filter class (E10 - U17). Gore membrane filters usually fall into class H12 or H13 (i.e., >99.5%-99.95% efficiency) (EMW Flitertechnik, n.d.). This is one of the reasons filters used in harsh environments almost exclusively use PFAS materials to help maximise capture and control of potential air emissions.

Where there are no like-for-like alternatives to the use of PFAS, there are other technologies / products available that do not contain PFAS. For example, GORE® Cooling Filters could be replaced with heat exchangers as opposed to a lower performance (non-PFAS) filter and Gore's Catalytic Filter Bags can be replaced with solid catalyst pellets or 'honeycombs'. The catalyst material generally consists of the carrier material (e.g., titanium dioxide - TiO₂) with added active substances (vanadium(V) oxide - V₂O₅ and tungsten trioxide - WO₃). There are a number of disadvantages, including higher capital cost to implement and increased consumption of energy (usually natural gas, light oil or high-pressure steam) required to support the reheating of flue-gases so that it reaches the catalyst reaction temperature (European Commission, 2019). Similarly, Heat Exchangers¹⁷ also require increased power consumption (on average 5x greater than GORE® Cooling Filter for similar cooling capacity), which results in higher operating costs and increased emissions/carbon footprint. Furthermore, Heat Exchangers are usually heavier and larger, so require additional space when implemented.

While solid catalysts have an equivalent performance (with respect to the catalytic performance of Gore's filters), they need a separate housing, cause pressure loss (which increases energy consumption), have a shorter lifespan, generate more waste, and consume more (physical) space, and thus are not equivalent in 'total' performance. In addition, these solid catalysts are not suitable for collecting toxic or sub-micron dust.

¹⁵ A baghouse is an air pollution control device and dust collector that removes particulates or gas released from industrial processes (Britannica, 2000).

¹⁶ This is the Most Penetrating Particle Size (MPPS)

¹⁷ Heat exchangers work by utilising a closed box with an internal loop fan that circulates hot air inside the cabinet to the thermal exchange area, and an external loop fan that circulates outside air to the thermal exchange area.

Other alternatives, such as adsorbents, can be used but these need to be injected into the flue gas continuously and disposed of after use. A further challenge with using adsorbents as an alternative, is that the waste produced is hazardous because it collects the toxins rather than destroying them – Section 3.6 includes further information on the hazards of these alternative processes.

Lower performing filters (e.g. polyester) are already used in less demanding applications, (e.g. to collect coarse, non-hazardous dust from air streams). These non-PFAS alternative filters (to Gore's Filters) typically have shorter lifespans and thereby generate more waste. Using alternative filters is also expected to increase the energy used, and due to higher resistance to gas flow, will be more challenging to clean. For other products (e.g. GORE® CLEANSTREAM and Heat Exchanger Laminate) there are no alternative technologies / products that offers the same level of performance without a trade-off in the range of suitable operating conditions or durability available on the market. More specific barriers to substitution in relation to some of Gore's filtration products are **Table 3.2**.

Table 3.2: Barriers for substitution for Gore filtration products

Gore filter products	Barriers for substitution
GORE® Catalytic Filter Bags	Catalytic Filters can be replaced by regular filters and adsorption systems, or filters and solid catalysts. These techniques are more expensive for the user, particularly in operating expenses (OPEX). If the user is providing a public service (e.g., waste incinerators or power plants) the cost will be borne by the public.
GORE® Mercury and SO ₂ Control Modules	These modules can be replaced by reagent-based adsorption systems, which require more space, higher energy consumption (due to pressure loss), and generate more waste as they require consumption of additives.
GORE® Industrial Dry Filtration Filter Bags	Environmental regulations (such as the EU's IED (Industrial Emissions Directive) (European Commission, 2010) and human health considerations do not support PTFE membrane filters being replaced by lower performing alternatives because this would result in an increased volume of pollutants being released into the environment.
Gore® Turbine Filters	All known offerings in the European Region that have High Airflow E12 EPA Filtration Efficiency solutions contain at least one PFAS substance in their portfolios. The final products utilize either short-chain, side chain fluorinated polymers or PTFE for water tightness protection. Thus, there are no known non-PFAS High Airflow E12 alternatives on the market.
GORE® Liquid Filtration Products	Semiconductor fabricators would need to change the chemicals, processes recipes and equipment design to enable non-PFAS membranes to work because the semiconductor industry uses 150°C concentrated sulfuric acid, high temperature sulfuric acid and hydrogen peroxide, as well as various other strong acids and bases. When combined with the contamination control requirements of the advanced nodes (parts per quadrillion (x10 ⁻¹⁵) levels of metals, particles >10 nm, etc.) it requires PTFE and PFA components. High Density Polyethylene (HDPE) or polypropylene (PP) are not chemically compatible, which would result in the leaching out of products that would lead to defects on the wafers (best case, a really low yield, worst case, they cannot even make a single chip).
GORE® Cooling Filters	Heat Exchangers are in general more expensive and consume additional electricity compared to direct air cooling that is made possible by GORE® Cooling Filters. Lower performing filters would allow for water, salt, and dust particulates to enter the cabinets of the heat exchanger and cause temperature outages, creating loss of services and additional investments of resources / material for the service provider.



Gore filter products	Barriers for substitution
Heat Exchanger Laminate	No available alternative for the specific solutions, other heating, ventilating and air conditioning (HVAC) solutions are available on the market. However, these will have a high environmental impact on the carbon footprint due to higher PUE and WUE.
Rastex® / Gore industrial fibre	Gore's fibre materials provide temperature and harsh chemical resistance that enable production of a variety of processing components, like filters, that reduce environmental and human safety risk. An alternative material with the same chemical resistance, able to maintain material integrity under the same environmental conditions does not exist.

Source: Gore (2021b; 2022a)

As there are no alternatives that have the same performance as PTFE-based filters, any transition to non-PFAS alternatives by 2025 would require the customer to find a different solution that in most cases would decrease their performance, resulting in lower efficiency and (by default) additional emissions and/or reduced savings on the carbon footprint area. Less effective filters would also allow more fine dust to pass through; this means that more dioxins, heavy metals and other toxic or carcinogenic pollutants would be emitted and eventually end up in ambient air, surface waters and in the food chain. In addition, potential replacements would be expected to not meet the performance requirements of environmental regulation and potentially lead to concern with regard to ambient air quality.

3.4 Availability

The role of assessing 'availability' in an assessment of alternatives (AoA), is to make sure that there is sufficient quantity of the alternative substance (or, substances) that will be used to replace the hazardous substance in question.

However, there are currently no available alternative substances (including drop-in substances that mimic the role of PFAS, and substances that have different functions to PFAS) or alternative processes to the Gore products that are able to reproduce the same level of performance for the entire product portfolio. Therefore, it is not possible to assess the availability of a potential alternative substance (or substances).

3.5 Cost and timeline for transitioning to alternatives

Currently, there is no alternative material in development that might deliver comparable performance and durability, enabling the applications that Gore's filter products support. Any alternatives to Gore's products on the market currently cannot reproduce the performance of Gore's products.

Gore estimate that it will only be technically feasible to substitute PFAS materials in [REDACTED] of their Filter portfolio to (non-PFAS) alternative materials after [REDACTED] years after the Entry into Force (EiF).

Overall, Gore estimate that substitution of the entire filter portfolio will take [REDACTED] years¹⁸ and cost at least [REDACTED] million. However, if at any point during the substitution process a step ends with failure (e.g. a potential alternative substance does not pass a specific standard/certification), then the entire process will

¹⁸ Gore noted that if the transition period was shorter, they would not be able to substitute PFAS (with non-PFAS alternatives) in all of their Filter products. For example, if the transition period was 10 years, Gore estimate that they would only be able to substitute PFAS in 10% of their Filters.

need to be restarted, thus increasing the time required and costs.

This is based on the assumption that an alternative material is identified. The time needed to identify a material could not be taken into account as such a material is not apparent yet. This notwithstanding, **Table 3.3** details the steps, time and costs estimated for Gore to substitute PFAS with alternative materials.

Table 3.3: Substitution steps, activities required, timing and costs in the EU

Steps for substitution	What activities does this step entail?	Time required for step	Expected one-off cost for this step
Planning - this involves initiating the substitution or reformulation project internally.	Research on potential alternative materials.	1 year	Approximately 1 million
Development - this involves an iterative stage of R&D, (re)formulation and lab testing	Product Development from Technology Readiness Level 1 to 9, testing in lab, and pilot scale.	1 year	Approximately 1 million
Qualification and/or Validation - this may be required, and could involve testing and validation with customers and/or external testers	Validation by end users, OEM and EPC to be applicable.	1 year	Approximately 1 million
Certification - this may be required, and could involve review and testing by standard setters and/or regulators	Certification by test institutes to national and international standards. Other certifications and/or standards that need to be met by filters are EN 1822, ZH 1/487, VDI 3926.	1 year	Approximately 1 million
Production - this would involve implementing the manufacturing plan for the alternative, including a possible pilot phase, regulatory approval, and modifications to the production line.	Set up production, manufacturing capabilities, supply chains.	1 year	Over 1 million

Source: Gore (2021b; 2022a)

3.6 Hazard comparison

As there are no alternative substances (including drop-in substances that mimic the role of PFAS, and substances that have different functions to PFAS) or alternative processes to the Gore products that contain PTFE, PFA and PVDF, it is not possible to compare the hazard profile of a potential alternative substance (or substances) to the respective PFAS.

Alternative processes/techniques to Gore's Filters products (e.g., catalyst pellets) are not viewed as viable alternatives, as they cannot reproduce the same level of performance / have technical shortcomings (outlined in Section 3.3). Moreover, some processes require the use of more hazardous materials. For example, catalysts typically contain heavy metal oxides (which are toxic), so the handling, storing, and disposal of these substances creates hazards. The same is true for adsorbents, (another alternative process/technique), but as adsorbents are consumed in the gas cleaning process (thus, are single use –



compared to catalysts, which are not consumed) the quantity of hazardous materials required is several orders of magnitude higher.

4. Restriction scenario

4.1 Introduction

This chapter assesses impacts of a potential REACH restriction on the use of PFAS in filters included in **Table 2.1** and similar products placed on the EU market by other companies. As the exact scope of any possible restriction is unknown, this assessment assumes that all filter products containing PFAS are restricted within the scope of a possible REACH restriction following entry in force (EiF) + 12 months. For the purpose of this assessment and its quantitative analysis, this is assumed to occur in 2025.

The chapter covers:

- A description of the restriction scenario assessed and how we assume affected actors along the supply chain will react to this restriction (Section 4.2)
- The economic impacts of the restriction (Section 4.3)
- The environmental and human health impacts (Section 4.4); and
- The social and wider economic impacts (Section 4.5).

Information on behavioural responses to a possible restriction on PFAS was gathered from Gore and publicly available sources, combined with professional judgements. All relevant impacts are assessed where possible at an EU level (i.e., covering the whole market). Any monetary estimates that have been discounted are accompanied with the following bracket: (PV - present value). A 4% discount rate has been used, as recommended by the European Commission (EC, 2017), and values are shown in 2022 prices.

4.2 Behavioural responses

4.2.1 Introduction

When faced with a REACH restriction without any derogations, affected actors typically have a few options of actions they can consider, henceforth called “behavioural responses”. These can broadly be divided into:

- **Option 1:** Transition to an alternative (substance, material or technique/process, and in some cases a change of ‘service’ may be possible), before the Entry into Force (EiF) of the restriction;
- **Option 2:** Temporarily cease production of the affected products in the EU, until an alternative is implemented;
- **Option 3:** Permanently cease production of the affected products in the EU (with or without increasing production outside the EU).
- **Option 4:** Cease all operations in the EU (with or without relocation outside the EU).

For the purpose of this analysis, it is assumed that companies using PFAS in the manufacturing of products similar to Gore will be in a similar situation, and the most likely behavioural options will be the same.

The behavioural responses for the following actors are considered:

- *Manufacturers and importers of the filter products made with PFAS.* These comprise of Gore and manufacturers of similar products to those set out in **Table 2.1**.
- *Upstream raw material suppliers* include all suppliers of PFAS intended for the use in products similar to those set out in **Table 2.1**.
- *Downstream users* include all companies using products similar to those set out in **Table 2.1**.

4.2.2 Gore and manufacturers (importers) of similar products made with PFAS

As detailed in Chapter 3, changing the substance/material or the production process to avoid using PFAS is not currently technically feasible, due to the high performance needed for the products covered in the SEA. Gore also explained that alternatives will not be available in the foreseeable future (at least ■ years). Without a derogation, the only options therefore involve ceasing the production and import of such products in the EU. Whether all operations will have to cease depends on each company's reliance on PFAS in their product portfolio, and whether other products affected by a potential restriction would be granted a derogation.

4.2.3 Upstream raw material suppliers

Manufacturers and suppliers of fluoropolymers will be heavily affected by a restriction of PFAS, since they manufacture and sell the PFAS that are subject to a potential REACH restriction, and production of these will have to cease (unless derogated). If derogations are granted for some uses, manufacture of PFAS may still continue in the EU, but at a reduced capacity (i.e., supply PFAS for derogated uses only). In a best-case scenario, PFAS suppliers also manufacture non-PFAS substances that can be used to produce similar, albeit 'inferior', products. This would allow some of the profits losses to be recovered, but not start until after the demand for alternative substances increases (i.e., after alternatives have been identified, tested, and implemented by downstream users), which may take a significant amount of time. If a REACH restriction removes a large share of their EU business, it is likely that at least some raw material suppliers will cease all operations in the EU.

4.2.4 Industrial downstream users

The industrial downstream users are companies within industries in need of pollution and emissions control from harmful, aggressive air particles and waste, as well as industries where filters are used as cooling or cleaning devices. These include critical industries carrying out activities such as generation of power, cement production, extraction of coal, metallurgical processes and manufacture of semiconductors, described in Section 2.2 and Section 2.5.2. It is not realistic that all these end-user industries will collapse, but the industrial downstream users as well as some end-use industries may temporarily need to cease production until they are able to find alternative solutions. Since no alternatives with equal performance are available (and unlikely to become available within the foreseeable future), they will have to redesign their production process and/or products to alternatives with lower performance, which will take some time. Some industries (e.g. waste incinerators) may face challenges staying within regulatory emission limits in their operating permits. Besides the environmental impact of these excess emissions (see Section 4.4), fines and penalties might apply, and plants might lose their permit to operate until they were able to find and apply an alternative.

4.3 Economic impacts

4.3.1 Introduction

Restricting the use of PFAS in products similar to those set out in **Table 2.1** will induce significant economic impacts for upstream suppliers, product manufacturers (Gore and other companies), downstream industrial users as well as the actors in end-use industries. There is limited information available to estimate impacts throughout the value chain, so the quantitative analysis focusses on impacts on products manufacturers. Other economic impacts are assessed mostly qualitatively, with a few numerical examples to illustrate potential order of magnitude of non-quantified effects.

The quantitative analysis is estimated based on the behavioural assumptions set out in Section 4.2. All impacts are presented as total present value, average annual present value and equivalent annual values (EAV), using a discount rate of 4%, an analytical period of 20 years, and 2022 as the monetary base year.

4.3.2 Economic impacts on Gore and manufacturers (importers) of similar products made with PFAS

Lost Profits

As explained in Section 4.2, the manufacturers of products similar to those set out in **Table 2.1** have limited choices if faced with a restriction. As explained in Chapter 3.5, no suitable alternatives exist on the market, and it is not anticipated that alternatives will be found within the next 17 years. The uncertain outcome (i.e., an alternative may not be found) and time needed, means that substitution is likely not a feasible option for most manufacturers. Without a derogation, the most likely options therefore involve ceasing the production of such products in the EU, which will lead to large financial losses for society.

The largest cost at this level in the value chain (Gore and manufacturers (importers) of products similar to those set out in **Table 2.1**) is believed to be lost profit. SEAC has recently published guidance that streamlines the approach to estimating lost profits, which is linked to premature retirements of assets (SEAC, 2021). Assets may be intangible (e.g., R&D and patents) or tangible/physical (e.g., production equipment or a production plant). If a company, production plant or a production line has to shut down (e.g., due to a regulation) the associated assets will no longer generate value. The main assumption behind this methodology is that *"in the short run there is a fixed availability of tangible and intangible assets and in the long run incumbent or rival firms can augment assets by making investments"* (SEAC, 2021). The guidance provides a default time period over which profits lost should be estimated, which is dependent on whether suitable alternatives are generally available (SAGA) or not (no-SAGA). For SAGA cases, 2 years of profits is used to approximate producer surplus losses, whilst a 4-year period is recommended for no-SAGA cases. If a longer time period is to be used (5 years is suggested in the guidance), this must be *"justified by robust supporting evidence"* (SEAC, 2021).

Assets may, for example, be redeployed by companies manufacturing lower performing alternatives. Parts of the profits lost may therefore be redistributed to suppliers of these 'next best' alternative products. Limiting the profits lost to a short time period (4 years), thus accounts for this type of distributional impacts. It should, however, be noted that it is deemed unlikely that new assets (after the end of life of the 'old' assets) can be redeployed in equally beneficial or income-generating uses. Hence, it is believed that parts of the losses will remain way beyond the 4-year default period. Albeit likely significant, it is not achievable

to quantify the losses associated with deploying resources in less beneficial ('next-best' options) applications, so a conservative approach with a 4-year period has been used.

As explained in detail in Chapter 3, there are no suitable alternative available for the products covered within this SEA, which means that this is a no-SAGA case. Using the default value of 4 years, the resulting **lost profits amounts to €327 million (PV) over the period 2022-2041, which annualised over the 20-year analytical period is €24 million per year.**

Substitution costs

Section 3.5 details the necessary steps as well as the minimum time and cost Gore needs to transition to alternatives for the products set out in **Table 2.1**. The necessary steps include planning, development, qualification/validation, certification, and production. It is important to recognise that it is currently unknown what alternative could be used.

It is reasonable to assume that companies that manufacture similar products will have to go through a similar process, so these costs have been extrapolated to the EU market. This implicitly assumes that substitution costs will eventually be passed through to the price of the products, i.e., the substitution costs will be borne by actors on the EU market. It should be noted that the substitution costs are not likely to be equally distributed across all EU actors. Some companies may choose to exit the market, i.e., permanently cease their production and thus not incur substitution costs. Other companies may be willing to undertake large investments over an extended period of time, in order to capture current and/or new markets. These companies would thereby incur higher substitution costs, but less profits lost (there may even be some gains for these companies in the long term). As explain above, these distributional effects have been accounted for in the estimation of lost profits (i.e., net profit lost is estimated), which means that substitution costs can be added to the estimated profits lost. It has been assumed that the substitution process will start one year prior to entry into force (2024). The resulting **substitution costs is estimated at €84 million (PV) over the period 2022-2041, which annualised over the 20-year analytical period is €6 million per year.**

4.3.3 Upstream raw material suppliers

Suppliers of PFAS will be severely impacted by a potential restriction on PFAS, as the substances themselves are the products being restricted. The only options for these suppliers will be to permanently cease manufacture and sales of PFAS in the EU associated with all restricted uses. Even though some derogations may be granted, there a high risk of permanent closure of companies which rely on the sales of PFAS to an EU customer base. As a minimum the suppliers will lose their sales and corresponding profits associated with supply to all restricted uses of PFAS. Some companies may be in a position to start or increase production of substances that can be used as (inferior) alternatives, but the sales of such substances will only be possible after alternatives have been identified, tested, and implemented.

The volume fluoropolymers placed on the EU market in products covered by this SEA was estimated at an annual average of 1,068 tonnes. The total volume of fluoropolymers sold in the EU for relevant industries uses (See **Table 2.11**) comprised 39,500 tonnes in 2020, with a corresponding sales value of €799 million (Fluoropolymer Product Group of PlasticsEurope, 2022), which means that the volumes used for this type of filters in the EU comprise a relatively small share. The profit loss for these fluoropolymer suppliers, associated with filter products, is therefore expected to be small compared to costs further down the value

chain, albeit high for the individual companies. These costs have therefore not been estimated or included in the total cost estimates.

4.3.4 Industrial downstream users

One of the key benefits of using PFAS in filters is that it provides reliability and durability in harsh environments. As mentioned in Section 4.2, it is not realistic to assume that downstream users will (or can) wait a long period of time until equivalent performing filters are on the market. If PFAS can no longer be used, downstream users will therefore need to modify their processes and products to adapt to lower performance such as reduced ability protect against the emission of harmful, aggressive, or hazardous air particles. Furthermore, they will need to acquire product and regulatory approval to use different products or have reduced air emissions control until non-PFAS products have been found. This will induce costs of R&D, investments, testing, and regulatory approvals, to mention a few, resulting in significant costs for these downstream users. Due to data limitations, it has not been possible to estimate these substitution and compliance related costs.

If downstream users are not able to redesign and change their production or emissions control processes to fit the lower performing filters by the end of the transition period, there is a risk of temporary production halt for products relying on PFAS-containing filters. The EU industrial base, including but not limited to metallurgical processing, chemical processing and electronics would then be faced with significant disruptions, for which the duration of which is difficult to predict.

It is also uncertain if manufacturers of lower performing non-PFAS filters will be able to increase their product supply to meet the 'new' demand coming from downstream users switching from products containing PFAS after the end of the transition period. Any delay in the supply of non-PFAS filters could result in a temporary shortage in such products being available and therefore increase the risks of production halts and disruptions in downstream user industries.

Predicting the length and the extent of production halts, as well associated impacts on sales within downstream user industries is challenging, and available information does not allow for a full quantification of such impacts. Looking at only a few relevant sectors¹⁹ can give an indication of the minimum order of magnitude of profits loss due to production halts in downstream user sectors. As shown in **Table 2.12**, the turnover in these industries was close to €1,641 billion in 2019 and the total employment was around 4 million people during the same year. To keep the example conservative, it can be assumed that only 1% of sales in this industry is affected and that the profit margins are [REDACTED] than of Gore and similar manufacturers. Again, using the no-SAGA approach (SEAC, 2021) as there are no suitable alternatives on the market, the resulting **loss to downstream users is estimated at nearly €15 billion (PV) over the period 2022-2041, which annualised over the 20-year analytical period is €1.1 billion per year.**

In addition to substitution costs and lost profits, there will be economic impacts associated with using lower performing filters. A stakeholder consultation carried out for a recent report published by PlasticsEurope, "Socio-economic Analysis of the European Fluoropolymer Industry", found that fluoropolymer products (e.g., coatings, linings and components) used in the chemical and power industry have twice the lifetime of

¹⁹ Relevant sectors include chemical manufacturing, semiconductors, electrical equipment, metallurgy, and petroleum refining. See Section 2.5.2 for breakdown of figures.

other materials, potentially yielding savings in the order of €100 million annually (Fluoropolymer Product Group of PlasticsEurope, 2017). Amongst other benefits, they support savings in maintenance through increased component lifetime (Fluoropolymer Product Group of PlasticsEurope, 2017). This is, of course, not only related to the products covered within this SEA, but it shows that performance loss may induce significant costs for the downstream users.

4.3.5 Total economic impacts

The economic impacts of restricting the use of PFAS in products similar to those in [Table 2.1](#), are expected to be high for all affected actors, albeit not fully quantifiable. The total costs set out [Table 4.1](#) in should therefore be viewed as the minimum economic costs resulting from not granting a derogation for these products. The most significant omissions are believed to be at the downstream user level, where only a few relevant industries²⁰ have been assessed, the assumed share of sales affected is conservative (1%) and no costs of compliance (R&D, investments, testing, regulatory approval etc.) have been included. Limiting lost profits to 4 years for all levels of the value chain is also considered conservative. Lastly, cost of lower product performance, exemplified by PlasticsEurope, has been excluded, as the share attributable to the products within this SEA could not be inferred from the underlying report.

Table 4.1: Summary of quantified economic impacts in the EU

	Minimum costs 2022-2041 (PV - € million)	Minimum costs annuity (€ million/year)
Lost profits for Gore and manufacturers of similar products	■	■
Lost profits for suppliers	likely low	likely low
Lost profits for industrial downstream users	14,885	1,095
Substitution costs for Gore and manufacturers of similar	84	6
Substitution costs for downstream users	significant	significant
Cost of lower product performance, e.g., reduced product lifetime	significant	significant
Total	■	■

Notes:

1. Profits lost are only assumed to occur over 4 years in compliance with SEAC (2021).
2. Substitution costs have not been quantified for suppliers and downstream users.
3. Values are given in 2022 prices and rounded to the nearest € million. Totals may therefore not sum up.
4. Present value (PV) has been calculated using a 4% discount rate.

4.4 Impacts on human health and the environment

4.4.1 Introduction

Certain individual PFAS substances (e.g., PFOA, PFOS and PFHxS) are listed as Substances of Very High Concern (SVHC), due to vPvB and/or PBT properties, and their use has therefore been restricted in the EU. Not all PFAS, however, are substances of concern or very high concern. For example, as shown in Section

²⁰ Chemical manufacturing, Semiconductors, Electrical equipment, Manufacture of basic metals and Manufacture of coke and refined petroleum products.

2.5.4, PTFE and additional fluoropolymers have been established to meet the OECD criteria for a Polymer of Low concern (PLC) and are thus not expected to impact human health or the environment (Henry et al., 2018; OECD, 2009). Gore only uses PLCs in their manufacture of filter products both within and outside the EU. The exact composition of PFAS used by companies manufacturing similar products to Gore's is not known, but it is considered likely that the composition will be similar in order to achieve the similar product functions. The approach used to assess potential benefits of reducing exposure to PBTs and vPvBs (ECHA, 2016) may therefore not be appropriate to use for PFAS as a group, or more specifically the type of PFAS covered within this SEA.

4.4.2 Risk reduction indicators

Reductions in the use and emissions of PFAS from not derogating the uses within this SEA are set out in **Table 4.2**, and these estimates are integral in assessments carried out by the DS as well as by RAC and SEAC. However, caution must be taken when interpreting what these emission reductions mean in terms of actual impacts on human health and the environment. PTFE, PFA, PVDF and other fluoropolymers are not mobile in the environment, are demonstrated to be non-toxic, and are extremely stable. Because individual PFAS can have very different properties, the risks associated with potential emissions should consider both the amount and specific type of PFAS.

Table 4.2: Reduction in PFAS contained in products and emissions in the EU

Estimate	Total volumes over 2022-2041 (tonnes)	Annual volumes (tonnes/year)
Reduction in PFAS contained in products	21,364	1,068
Reduction in emission (worst-case sensitivity)	6	0.3
Reduction in emission (reasonable worst-case)	4	0.2

Notes:

1. Reasonable worst-case emissions are derived using the higher emission factor associated with service life and EoL from the Investigation summaries published by the DS
2. Worst-case sensitivity emission estimates also use the emissions factors from the DS, but further assumes that all products placed on the EU market will be manufactured in the EU
3. Volumes have been rounded to the nearest tonne or the first non-zero decimal

4.4.3 Other impacts on the environment and human health

Other impacts on the environment and human health may include the potential for higher risk of exposure of workers to hazardous substances, higher safety risks and increases in emissions arising from technical regression. For example, increase in emission arising from less effective pollution abatement technology and an increase in energy consumption in order to adapt to the non-PFAS alternatives. This could put at risk Europe's ability to meet its climate and energy goals (Fluoropolymer Product Group of PlasticsEurope, 2017).

Human health impacts

Increased risk of worker exposure to harmful air particles

A potential REACH restriction on PFAS-containing filters could increase the health and safety risks of workers in downstream industries, such as chemical manufacturing and petroleum refining industries. Non-PFAS filters are less effective than their PFAS-containing counterparts in containing aggressive or

hazardous air particles during industrial manufacture and waste management. This loss in product effectiveness, and potential product failure, would significantly increase the risk of particulate leaks and, subsequently, the risk of workers being exposed to such pollutants. Durable and reliable filters are therefore a fundamental enabling technology for safe production.

The human health risks of coming into contact with harsh chemicals and particulates during industrial processing span the range from minor irritation to death. Exposure to hazardous airborne pollutants have been connected to chronic illness, respiratory problems, cancer, liver diseases and many other conditions that threaten health. Industries processing harsh chemicals and materials have extensive regulation associated with reducing the health risk posed by accidental contact or inhalation of harmful air particles.

For example, PFAS-containing air filters and control modules remove mercury from flue gases (gases entering the atmosphere via a flue). Mercury can produce harmful effects on the nervous, digestive, and immune systems, the lungs and kidneys and can cause neurological and behavioural disorders, with often fatal consequences to those exposed (World Health Organisation (WHO), 2017).

In 2017, work-related injuries and illnesses cost €476 billion in the EU (EHS Today, 2017). Increased risk of exposure to harmful air particles at the workplace could increase these costs over time, which would negatively impact the EU economy.

Health and safety during waste incineration

PFAS-containing filters are used to filter out harmful gases created during waste incineration to the levels required by the Waste Incineration Directive (European Commission, 2000). For example, these filters are used to convert nitrous oxide (NO_x) to less harmful forms, protecting residents near waste incineration facilities. NO_x gases can cause severe health impacts, including breathing problems, headaches, chronically reduced lung function, eye irritation, loss of appetite and corroded teeth.

Environmental impacts

Increased risk of harmful air particles into the environment

PFAS-containing filters reduce the risk of environmental hazards. These products are used by downstream industrial users, such as the harsh chemicals and petroleum industry, to contain aggressive or hazardous air particles during industrial manufacture and or waste disposal. A possible REACH restriction would increase the use of less durable filters to contain harmful air particles, which would increase the risk of these air particles being released to the environment through leakage, lower capture efficiency and/or product failure. This could increase risk of threat to all environmental receptors, including air, water, and soil. For example, lower performing (non-PTFE Membrane) filters would allow more fine dust to pass and be released into the environment, as well as more dioxin, heavy metals and other toxic or carcinogenic pollutants to be emitted from certain industrial processes, and eventually end up in ambient air and surface water.

Using lower-performing non-PFAS filters during waste incineration reduces the safety of such processing and increases the risk of harmful gas leaks. A NO_x leak would have highly damaging impact on the surrounding habitats via acid rain or contaminating water.

Increased need for landfill of waste

PFAS-containing filters are used by a substantial majority of waste incinerators in the EU to contain

aggressive or hazardous air emissions. A possible REACH restriction would limit access to this critical technology, impacting the incinerators' ability to continue to operate within the limits of their operational permits. If household and commercial waste generators have less access to waste incinerators to manage these waste streams, the only alternative would be (if not restricted) to landfill or export these wastes.

Increased greenhouse gas emissions

Greenhouse gas emissions from product manufacturing could increase for those manufacturers that transition from PFAS-containing filters to less durable products since the rate at which these products need to be replaced will increase, which will consequently increase the number of products being manufactured. This could increase the greenhouse gas emissions from raw material extraction and product manufacturing itself. Additionally, membrane filters containing PFAS are easier to clean than their non-PFAS counterparts, saving energy against increased pressurized air generation (pressurized air is used to clean the filters).

The greenhouse gases emitted by downstream industrial users could also increase due to a reduction in production process efficiencies. Alternative non-PFAS products cannot match the durability of the Gore products which may force industrial downstream users to cease some production operations that require durable filters, which would reduce overall plant efficiencies. Gore® Turbine Filters provide a higher efficiency of the turbine, hence less GHG emissions for the same power output. Alternatively, manufacturers may use alternative operations that require higher energy output to accommodate less durable non-PFAS products. Both scenarios would ultimately result in increased greenhouse gas emissions. For example, cooling filters and the Heat Exchanger Laminate are deployed at mobile stations and data centres to maintain operating temperatures, while generating PUE (power usage effectiveness) and/or WUE (water usage effectiveness) savings compared to other cooling solutions.

Filters without PFAS are less durable than their PFAS-containing counterparts. Switching to non-PFAS alternatives will thus result in equipment needing to be repaired and replaced more often, ultimately reducing the use life of the equipment. This consequently increases raw material demand and energy demand to manufacture replacement equipment, which ultimately results in increased greenhouse gas emissions from manufacture.

4.5 Social impacts and wider economic impacts

4.5.1 Social impacts

This section explores the social impacts that may occur because of loss of production of Gore's PFAS-containing products due to a possible REACH restriction. Social impacts are impacts which may affect workers, consumers and the public that are not covered under health, environmental or economic impacts (ECHA, 2008). These include impacts on employment, working conditions, job satisfaction and education of workers and social security. This subsection covers employment and working conditions which were identified as the most relevant social impacts to assess.

Employment

Gore buys raw materials from fluoropolymer suppliers and primarily sells its filter products to customers within and outside the EU. The products affected, e.g., filters, serve critical functions in their end-products – for more information, see Section 2.2 and 2.3. A restriction of PFAS may induce impacts on employment along the entire supply chain to the end-use industry. Manufacturers of similar products to Gore's, are

believed to have similar supply and value chains.

Restricting the use of PFAS in products may reduce employment in both upstream and downstream industries, which can induce large impacts since all companies manufacturing similar products to those set out in **Table 2.1** currently also use PFAS (see Section 2.2). It is still expected that some jobs lost will be displaced with new jobs created by manufacturers and users of inferior non-PFAS products, i.e., these effects are considered mostly distributional impacts.

Impacts on EU employment are closely linked to potential production halts and/or relocation of production outside the EU following a PFAS REACH restriction. As set out in the SEAC guidance on calculating costs associated with unemployment (SEAC, 2016), it is assumed that increases in unemployment, due to a restriction on the use of specific chemicals, will be temporary as resources will be redeployed to the production of other goods and services. Furthermore, only lost jobs in the direct supply chain are quantified and included in the comparison of costs and benefits. This is because knock-on effects become increasingly more uncertain further down in the value chain.

The first step in calculating impacts on employment is to model how the number of people employed at the different levels of the value chain develop over time. The underlying assumption used to for these projections is that the number of people employed will grow in line with the market for the products covered within this SEA (see Section 2.5.5). To derive the number jobs at risk it was further assumed that the job losses will occur during the period of production halts (see Section 4.3). The first column in **Table 4.3** below shows the projected number of people employed.

It has not been possible to extrapolate the employment in Gore's direct supply chain to other companies manufacturing similar products. This is because the location of production sites and suppliers of competitors is not known to Gore, and there might some be overlap in the customer base which would lead to double counting. Gore alone is believed to have between 188 and 267 customers in the EU which employ 70,000 to 88,400 people. As a conservative approach it has been assumed that only 10% of Gore's minimum number of customers' employees (70,000) are at risk of losing their jobs if PFAS can no longer be used for the products covered within this SEA. There are also likely to be overlap in the customer base of Gore and manufacturers of similar products, hence no extrapolation has been carried to ensure that a conservative approach is taken. The estimated impacts are therefore likely to be underestimated. The jobs at risks within Gore's direct supply chain in the EU and their associated value to society are set out in **Table 4.3**.

Table 4.3: Impacts on employment in the EU

Impact on employment at...	Number of people employed	Minimum number of jobs at risk	Total value of jobs lost 2022-2041 (PV - € million)	Annuity 2022-2041 (PV - € million/year)
Gore				
Gore suppliers				
Gore direct customers				
Minimum number of jobs at risk				

Notes:

- Jobs at risks have not been extrapolated, which means that the value to society is underestimated.

2. The approach to valuing jobs is in line with SEAC guidance (SEAC, 2016).
3. Average gross annual salary data is used from EU income data (Eurostat, 2022b).
4. Values are given in 2022 prices and rounded to the nearest € million or to the nearest significant decimal if below a million.

As shown in Section 2.5, which presents high-level indicators for end-use industries, the knock-on employment effects may be even higher.

Working conditions

Gore's and similar products are only used to protect against the emission of harmful, aggressive, or hazardous air particles, and there are no known non-PFAS materials that can reliably withstand these operating environments. Without proper filter products, workers could be exposed to chemically aggressive and hazardous materials, which would be in violation of EU workers health and safety directives as directed by the European Pillar of Social Rights (European Commission, 2022a).

In 2017, work-related injuries and illnesses cost €476 billion in the EU (EHS Today, 2017). Increased risk of exposure to chemically aggressive, hazardous fluids and/or extreme temperatures at the workplace could increase these costs over time, which would negatively impact the EU economy.

4.5.2 Wider economic impacts

Sustainability and circular economy

Sustainability and circular economy goals strongly influence the EU economy. A circular economy is an economic model designed to minimise resource input, as well as waste and emission production. Two goals of the European Commission's Circular Economy Action Plan are to normalise sustainable products in the EU and to ensure less waste (European Commission, 2022b). Filter products made without PFAS will not offer the same chemical compatibility, operating temperature range, or cleanliness characteristics which provide high performance and durability in many end-use applications. Products of lower quality and/or durability will increase energy use in downstream production processes, as well as being replaced more often, increasing resource use, increasing risk of exposure to hazardous substances, and generating additional waste. Ceasing the use of PFAS in such products may thus negatively impact meeting EU's sustainability goals. This increased waste will either need to be disposed of via landfill, incineration, or be recycled, which comes at a cost. Furthermore, replacing products more frequently due to using less durable products will also increase resource consumption and greenhouse gas emissions, which conflict the EU's 2050 strategy (EERA, 2022).

Macroeconomic

ECHA's Guidance on Socio-Economic Analysis recommends a consideration of the macroeconomic impacts caused by a restriction, including changes in competition within and outside the EU and changes to international trade. The proposed restriction is not expected to affect competition for products in **Table 2.1** and similar products within the EU, as all manufacturers of similar filter products use PFAS. Gore believes that products that do not contain PFAS will not be able to support industrial uses in situations requiring protection against the emission of harmful, aggressive, or hazardous air particles. The proposed restriction is also not expected to affect competition between EU and non-EU actors placing these products on the market in the EU, as both groups will have to comply with the restriction. However, the use of PFAS enables a high level of efficiency and safety in various filtration processes in the EU, helping industries remain internationally competitive (Wood, 2020). The competitiveness of EU's downstream user industries

may therefore be negatively affected, and there is a risk that non-EU companies (which can continue to use PFAS) will capture a larger share of the market.

Recycling

As noted in a Restriction Task Force note on the approach of Dossier Submitters and Committees on recycling, a REACH restriction on use by default also applies to recycled material (ECHA, 2020b). Accordingly, the note calls for DS to consider how to treat recycled material in a restriction, while balancing the risks associated with continued use and the benefits of recycling (ECHA, 2020b). This is especially important as recycling is of paramount importance in the EU, which is highlighted in the European Commission's Circular Economy Action Plan (European Commission, 2022b).

Gore does not have specific data on downstream users' recycling of its filters. However, as mentioned in Section 2.4.3, (ChemService, 2021) estimated that around 95% of fluoropolymer products are incinerated (80%) or landfilled (15%), i.e., only a small share of the products are potentially recycled. Gore also believes that other factors, such as technical and economic barriers, are the drivers behind the low recycling rate rather than the presence of PFAS. A potential restriction of PFAS is therefore unlikely to significantly affect the recycling rate.

4.5.3 Distributional impacts

As explained in Section 4.3, there will be a redistribution of sales profits from manufacturers using PFAS (i.e., all manufacturers of products similar to those in **Table 2.1**) to those manufacturing products using non-PFAS materials²¹. This will, however, take some time, as the downstream users will have to adapt their production process to account for the lower performance of the non-PFAS products. Similarly, there will be a decrease in employment from those manufacturers using PFAS and an increase in employment for those companies that make industrial filters without PFAS. Unemployment induced by a restriction of PFAS is thus expected to be temporary. The distributional nature of these impacts has been accounted for in the assessment of economic and social impact, where only the loss resulting from temporary production halts and unemployment have been quantified and monetised. Although, the chemical and petroleum manufacturing industries are resilient to small-to-moderate changes, the SMEs within the supply chain might still be adversely affected. A risk is that smaller companies do not have the financial means for investments needed to transition to an alternative, nor withstand periods of production halts. The market therefore may become more concentrated among fewer, larger companies.

Without market restrictions, one would expect that the lower performing filter products without PFAS would be cheaper than the products manufactured using PFAS. The difference in price can be viewed as value downstream users put on increasing the quality of the products. Restricting PFAS will temporarily remove high-quality filter products and increase demand for the lower quality products, allowing the manufacturers of the latter to increase the price of their products although the quality of the product remains the same. A price increase is also expected for products further down the value chain, if cost of substitution and/or adaptation of the production process will be reflected in the price, which means that the end-users would ultimately bear the costs.

²¹ The non-PFAS products (e.g., filters) are not equivalent to products in Table 2.1, but rather products with lower performance.

5. Comparison of costs and benefits

5.1 Introduction

This section collates and compares information on impacts from previous chapters. Section 5.2 presents the total quantified costs of restricting the use of PFAS in the products covered within this SEA and compares these with the emissions used as basis for this SEA. Section 5.3 discusses additional costs and benefits that could not be quantified, whilst Section 5.4 combines the results from the quantitative and qualitative analyses to assess and conclude on proportionality of a potential restriction on PFAS.

5.2 Comparison of quantitative impacts

As highlighted throughout Chapter 4, it has only been possible to (partially) quantify a few of the identified impacts, due to data limitations. This also extends to the calculations of emission and emission reductions, which was detailed in Section 2.5.3. A key aspect to highlight is that a conservative approach has been chosen throughout, in the sense that the monetised costs of a potential restriction have been underestimated and quantified emission reductions have been overestimated. It is not possible to determine the nature of or monetise potential impacts associated with a reduction in emissions and exposure to the PFAS used to manufacture products covered within this SEA. The minimum quantified costs of a potential restriction on the use of PFAS covered within this SEA are summarised in **Table 5.1**.

Table 5.1: Minimum quantified costs in the EU of a potential REACH restriction (no derogation)

Cost element	Minimum costs 2022-2041 (PV - € million)	Minimum costs annuity (€ million/year)
Lost profits		
Substitution costs		
Cost of unemployment		
Cost of lower product performance, e.g., reduced product lifetime		
Total		

Notes:

1. Profits lost are only assumed to occur over 4 years in compliance with (SEAC, 2021)
2. Values are given in 2022 prices and rounded to the nearest € million
3. Present value (PV) has been calculated using a 4% discount rate.

For the comparison of costs and benefits, the minimum costs have been combined with the emission estimates from Section 4.3 to derive 'cost-effectiveness' estimates. Cost-effectiveness is calculated by dividing costs by emissions, then converting the estimates to €/kg which is the preferred unit for cost-effectiveness estimates.

The result, presented in **Table 5.2** shows that despite taking a highly conservative approach, the cost per kg PFAS emission reduced is high – in the range of €4.2 – €6 million per kg PFAS emissions reduced. Furthermore, recognising that PTFE and the other fluoropolymers used meet the criteria for a PLC, the low

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potential risk associated with such emissions should also be taken into account when evaluating proportionality.

Table 5.2: Cost-effectiveness in the EU

	Annuity costs (€ million)	Average annual volumes (tonnes/year)	Cost-effectiveness (€/kg PFAS reduced)
Based on reasonable worst-case emissions	1,152	0.2	5,970,000
Based on worst-case sensitivity emissions	1,152	0.3	4,160,000

Notes:

1. Costs are given in 2022 prices and rounded to the nearest € million.
2. Emissions volumes have been rounded to the nearest tonne first significant decimal.
3. Cost-effectiveness is derived as follows: $(1,152 \times €1,000,000 / (0.2 \times 1,000 \text{ kg}) = 5,970,000$. The same approach is used for both estimates.
4. Cost-effectiveness has been rounded to the nearest €10,000 per kg.

5.3 Non-quantified impacts

Quantification and monetisation of all impacts associated with regulatory interventions are rarely, if ever, achievable. It has already been highlighted throughout previous chapters that it has only been possible to quantify and/or monetise a few select impacts. It is not always the case that the non-monetised effects are less important or have a smaller effect than the monetised impacts, which means that the conclusions of the analysis may be incorrect or inaccurate if non-monetised impacts are not assessed. To avoid this type of 'numbers' bias, a qualitative analysis of the non-monetised effects must be carried out.

Table 5.3 below sets out the non-monetised impacts and their potential effect on the acceptability of the monetised costs. For example, if a known but non-monetised effect is believed to increase the benefits of the restriction scenario, a higher cost per kg PFAS reduced would be more acceptable. The non-monetised effects are listed in the perceived order of importance and the type of impacts (cost/benefit) is indicated as follows:

- **(+)** indicates an increase in benefits or reduction in costs (of restricting the use of PFAS within this SEA), i.e., higher cost acceptability.
- **(-)** indicates an increase in costs or reduction in benefits, i.e., lower cost acceptability.
- **n/a** indicates that there is no or negligible effects on costs and benefits.

Table 5.3 shows that that vast majority of the identified non-monetised impacts will lead to increased costs, which reflects the conservative approach to cost estimation used throughout the analysis. This means that the estimated €/kg of a restriction would be even higher than those estimated in **Table 5.3**. The assessment of non-monetised impacts thus further strengthens the quantitative results presented in Section 5.2, showing that restricting the use of PFAS in products covered within this SEA will come at very high costs to society.

Table 5.3: Overview of non-monetised impacts in the EU and their overall effect on the cost acceptability

Impact	Description of impacts associated with restricting the use of PFAS in products covered by this SEA	Effect on net benefits/costs
Impacts of PFAS on human health and the environment from reduced exposure to PFAS from products in this SEA	The purpose of implementing a restriction on PFAS is to avoid potential adverse impacts on the environment and human health from exposure to PFAS. Because fluoropolymers are not mobile, bioaccumulative or toxic, it is not clear that a restriction would create a significant positive impact on human health or the environment.	
Cost of innovation and R&D for downstream users to find alternative solutions to PFAS-containing products	Downstream users of filters containing PFAS will have to identify alternative non-PFAS (inferior) products and find workarounds for the lower performance of these products. For example, fluoropolymers can protect against the emission of harmful, aggressive, or hazardous air particles. The non-PFAS products cannot be used in business to business (B2B) capital equipment applications that require long lasting materials that demand robust materials to avoid premature failure. Downstream users would therefore need to invest in R&D to find an alternative solution that meets functional properties such as cleanliness, cooling, and filtration of impurities from potentially aggressive and corrosive gas streams. This costly investment in R&D, with uncertain outcomes, would also divert funds that could be invested in product development.	(-)
Investment costs for downstream users	Since the non-PFAS filters will not be identical to the products containing PFAS, minor or fundamental changes in the downstream industrial users' production processes are anticipated, which is expected to induce significant costs. These costs could include altering existing equipment or purchasing new equipment that is suitable to the non-PFAS products being used.	(-)
Lost profits for downstream industrial users	In the estimation of lost profits to downstream users (Section 4.3.4) only some downstream industries have been included, but it was conservatively assumed that only 1% of the sales within this industry would be affected and that the profit margins were only 50% of that of Gore and similar manufacturers. It is believed that a much larger set of industries would be impacted, and the share sales affected could be significant in many of these. This omission may therefore significantly underestimate the costs of the restriction.	(-)
Costs to downstream users of product and process performance testing	When switching to different non-PFAS filters, companies will need to make sure they acquire product and regulatory approval to use different products. Downstream users will incur costs associated with performance testing of new products and production processes to ensure that the non-PFAS alternatives can operate in the harsh environments in which these products are used.	(-)
Maintenance and replacement costs for downstream users	PFAS-containing filters are more durable than their non-PFAS counterparts. If these products were not available, downstream manufacturers would be forced to use lower-performing filters that would need to be replaced more frequently, resulting in costs (time and money) associated with repairs or replacements (e.g., equipment needing to be	(-)

Impact	Description of impacts associated with restricting the use of PFAS in products covered by this SEA	Effect on net benefits/costs
	repaired or replaced more often). Additionally, filters containing PFAS are easier to clean, decreasing energy usage and time needed for maintenance. As explained in Section 4.3.4, fluoropolymers may provide large savings for downstream users increasing the product lifetime, which has not been possible to include in the total cost estimates.	
Worst-case sensitivity emissions assumptions	The worst-case sensitivity emissions are, in addition to being based on upper bound emission factors, based on an extreme assumption that all products being placed on the EU market will also be manufactured in the EU. This is clearly an unrealistic assumption, which is why the resulting emissions are considered a worst-case sensitivity. This does, however, not affect the realistic worst-case emissions.	(-)
Employment	Impacts on employment has only been quantified for a few downstream user industries. It has not been possible to extrapolate the employment in Gore's direct supply chain to other companies manufacturing similar products. This is because the location of production sites and suppliers of competitors is not known to Gore, and there might some be overlap in the customer base which would lead to double counting. Nevertheless, it is expected that the omission of employment impacts beyond Gore's direct supply chain could potentially lead to a significant underestimation of the costs.	(-)
Temporary production halt of downstream user products	If downstream users are not able to redesign and change their production processes to fit the lower performing filters products by the end of the transition period, there is a risk of temporary production halt for products relying on PFAS-containing filters. The EU industrial base, such as the chemical manufacturing, semiconductors, electrical equipment, metallurgy, and petroleum refining industries, would then be faced with significant disruptions, the duration of which is difficult to predict.	(-)
Temporary shortage of supply of filters	Due to the unique properties of PFAS, it is believed that the majority of high-performing filters included in this assessment contain PFAS. Therefore, it is likely that there will be a temporary shortage of non-PFAS filters in the EU, until the production capacity for non-PFAS filters is able to meet the market demand. This would impact the products manufactured by downstream industrial users of such as the chemical, mining and oil & gas industries, and thereby lead to a temporary shortage of the products manufactured by these industries within the EU or increase the import price of such products.	(-)
Risk of worker exposure to hazardous substances	Fluoropolymers enable reliability and functionality during potentially harsh conditions (e.g., 200°C temperatures) and are able to separate harmful particulates from production in such industries as chemical manufacturing and petroleum refining. The use of lower performing non-PFAS filters in downstream industries could increase the risk of hazardous gas or particulate leakages and create health and safety risks for workers.	(-)
Public health risk from exposure to air emissions from industrial activity	PFAS containing filters control harmful gases created during industrial activity and waste incineration as per European regulations. Reducing the reliability and performance of protective air pollution control tools for industry and waste incinerators can expose communities near these facilities to hazardous air emissions such as NOx, fine particulates, heavy	(-)

Impact	Description of impacts associated with restricting the use of PFAS in products covered by this SEA	Effect on net benefits/costs
	metals, and dioxin.	
GHG emissions from resource consumption of raw materials and waste	If filters without PFAS are less durable, this will result in more resources being used to manufacture replacements (parts). This is an inefficient use of resources as well as contributing to increased energy and emissions from increased production. Higher consumption of filters products would consequently increase the amount of waste generated, which itself has environmental impacts both on habitats and greenhouse gas emissions.	(-)
Semiconductor supply chain disruptions	Filters that contain PFAS are used in the production of semiconductor chips. Semiconductors are an essential component within electronic devices, which enable advances in communications, computing, healthcare, military systems, transport, renewable energy, and numerous other applications. As has been demonstrated in the recent semiconductor shortage, a supply chain disruption can have extensive negative socioeconomic impacts on businesses and consumers, creating delays and increasing consumer prices.	(-)
Further increased profits for manufacturers of inferior alternatives	The increased profits of manufacturers of inferior alternatives are already included in the approach set out in the SEAC guidance on assessing changes in consumer surplus loss (SEAC, 2021). However, if downstream users are able to transition to alternatives earlier than 4 years, the increased profits for manufacturers of such alternatives may be higher.	(+)
Increased need for landfill	As filters containing PFAS are used in most waste incinerators for aggressive or hazardous air emissions, a restriction may impact the ability of the incinerator to operate within the limits of their operational permits. Impacts of their operation would likely divert waste streams to landfills where possible, negatively impacting the environment.	(-)
Exclusion of manufacture in reasonable worst-case emissions	The reasonable worst-case emissions were derived using the DS' emission factors for service life and EoL but excludes potential emissions from manufacture of products (Gore purchases fluoropolymer resins from suppliers). According to Gore, who has first-hand knowledge of the manufacturing process and emission from the specific group of products contained in this SEA, the emissions from manufacture of these types of products are negligible, and the overestimation of emissions from service life and EoL will by far outweigh the omission of emissions from manufacture.	(-)
Exclusion of PFAS imported through indirect sales	As explained in Section 2.3.1, some customers of manufacturers of products covered within SEA (that contain PFAS) that are located outside the EU may in some instances import the products to the EU market (e.g., if the customers are distributors). This will lead to a higher volume of PFAS ending up on the EU market that is not captured through direct sales to EU customers. Data limitations did not allow for a quantification of the total PFAS volumes entering the EU, associated with the products covered within this SEA, via indirect sales. This may therefore underestimate the use volumes and subsequent emission volumes. This will not affect the worst-case sensitivity emissions, as these are derived by assuming that all manufacture and potential emissions will occur in the EU.	(+)

Impact	Description of impacts associated with restricting the use of PFAS in products covered by this SEA	Effect on net benefits/costs
Uncertainty related to products manufactured in the EU, but where products are sold outside the EU	Some PFAS-containing products are likely manufactured in the EU and sold outside the EU. This SEA has not considered products sold outside the EU and therefore use and emissions volumes are likely higher than what is reported.	(-)
High emission factors covering a broader set of products	As explained in Section 2.5.3, emissions estimated at the EU level has been carried out using emission factors for a broader set of products that are not fully representative for the products within this SEA. Gore upholds that there are negligible emissions from their products throughout the product life cycle and believes therefore the same should hold for similar products placed on the market. This means that using the emissions factors for the broader product group will likely significantly overestimate the emissions.	(-)
Costs for suppliers	If some PFAS suppliers are able to start manufacturing or supplying alternative substances or materials, this will involve R&D, investments and/or operational. New equipment or production plants may be needed, whilst for importers it is likely that they will have to find new suppliers. The prices of the alternative substances or materials will likely be inflated (i.e., more costly), as new production capacity will be needed in order to meet the new demand.	(-)
Increase in product and regulatory costs	Downstream industrial sectors affected (e.g., chemical manufacturing, waste incineration) will need to ensure continued compliance with regulatory requirements and meet industry standards. New regulatory approvals will likely be needed if products or production processes change.	(-)
Habitat and biodiversity impacts from waste incineration	Using lower-performing PFAS filters during waste incineration reduces the safety of such processing and increases the risk of harmful gas leaks. A NO _x leak would have highly damaging impact on the surrounding habitats.	(-)
Increased waste from landfill	A restriction of PFAS-containing filters used in waste incineration may restrict functionality of this service to properly operate within the limits of regulatory permits. If household and commercial waste generators have less access to waste incinerators to manage these waste streams, the only alternative may be to landfill or export waste. Landfill sites not only generate emissions and increase air pollution (covered above) but also impact the surrounding environment and biodiversity.	(-)
Change in environmental service costs, such as waste treatment and disposal services	If filters without PFAS are less durable, this will also result in more waste being produced at the end-of-life stage (volume basis). This increased waste will either need to be disposed of via landfill, incineration, or be recycled, which comes with waste management treatment costs to downstream industrial users.	(-)
Macroeconomic impacts and changes in EU competition	The use of PFAS enables a high level of efficiency and safety in various chemical or electronic manufacturing processes in the EU, helping industries remain internationally competitive (Wood, 2020). The competitiveness of EU's downstream user industries may therefore be negatively affected, and there is a risk that non-EU companies (which can continue to use PFAS)	(-)



Impact	Description of impacts associated with restricting the use of PFAS in products covered by this SEA	Effect on net benefits/costs
	will capture a larger share of the market.	
Recycling	It is believed that the low recycling rate for fluoropolymer products (<5%) is driven by technical and economic barriers rather than the presence of PFAS. It is therefore considered unlikely that a restriction on PFAS will significantly affect the recycling rate.	n/a

5.4 Proportionality assessment

The socio-economic analysis clearly shows that restricting (and not granting a derogation for) the use of PFAS in products similar to those in **Table 2.1** will have large and wide-reaching impacts on the EU. The adverse impacts induced by a potential restriction includes significant economic impacts throughout the value chain, impacts on employment (lost jobs) as well as adverse impacts on human health and the environment.

The estimated worst-case sensitivity emissions are ~0.3 tonnes/year, and all the types of PFAS used are believed to meet the Polymers of Low Concern (PLC) criteria. It is not clear that a restriction would create a significant positive impact on human health or the environment.

The cost-effectiveness (CE) estimates are based on reasonable worst-case and worst-case sensitivity emissions combined with minimum costs is estimated at €4.2 – €6 million per kg PFAS emissions reduced, which means that the benefits of a potential restriction would need to be very high to outweigh the costs.

A CE estimate does not, in itself, indicate whether benefits (costs) of a restriction outweigh the costs (benefits). For cases where risks and impacts of reducing exposure to a substance are unknown, it is common to compare the cost-effectiveness estimates with some type of benchmark. A study by Oosterhuis et al. published in 2017 found that for PBTs, vPvBs and substances with similar properties (e.g., lead) emission reduction measures with a cost-effectiveness below €1,100²² per kg emission reduced were generally not rejected due to costs i.e., the costs were found to be proportionate. Measures with costs above €56,400²³ per kg, on the other hand, were more likely to be rejected, i.e., costs at this level were found to be disproportionate. Cost in between could be either proportionate or disproportionate – a so called ‘grey zone’ (Oosterhuis et al., 2017).

The Oosterhuis benchmarks (BMs) have been used for the assessment of a number of regulations of PBTs and vPvBs, which are substances of very high concern (SVHCs). These BMs are, however, not necessarily applicable to substances of low concern such as PTFE and other PLCs. The reasoning behind this is that the implied willingness to pay (acceptability of costs) would be higher, the higher the perceived risk of a specific substance.

If the Oosterhuis BMs are to be used for substances of low concerns, it is reasonable to make some indicative, quantitative or qualitative, adjustments. For example, if the ‘grey zone’ for a PBT ranges from €1,100 – €56,400 per kg PBT emission reduced, it is reasonable to assume that upper bound (and likely also the lower bound) would be significantly lower for substances of low concern. For the purpose of this SEA, a grey zone of €1,000 – €10,000 per kg emissions reduced will thus be used for illustrative purposes, alongside the original BMs.

Table 5.4 shows the comparison between the midpoint²⁴ CE estimate derived for a restriction on the use of PFAS in the products within this SEA and the Oosterhuis and (illustrative) adjusted BMs. The results clearly shows that regardless of which BMs are used, the costs derived in this SEA are manyfold higher.

²² €1,000 in original study, uplifted to 2022 prices

²³ €50,000 in original study, uplifted to 2022 prices

²⁴ The midpoint cost-effectiveness (€5.1 million/kg) was derived by taking the midpoint between the reasonable-worst case emission estimate (€6 million/kg) and the worst-case sensitivity estimate (€4.2 million/kg).

Looking at the upper bound BMs alone, any costs above this benchmark value are usually deemed disproportionate. The costs restricting the products covered in this SEA is 90 - 507 times higher than the upper bound BMs, which means that not derogating the products within this assessment would lead to disproportionate costs.

Table 5.4: EU cost-effectiveness and benchmark comparison

Benchmark	Lower bound BM (€/kg)	Upper bound BM (€/kg)	Midpoint cost-effectiveness (€/kg) used for comparison	How many times higher is the CE compared to lower bound BMs	How many times higher is the CE compared to upper bound BMs
Oosterhuis et al.	1,100	56,400	5,065,000	4,605	90
Illustrative adjusted benchmarks	1,000	10,000		5,065	507

Notes:

1. Monetary values are given in 2022 prices
2. BMs are rounded to the nearest €100/kg and cost-effectiveness estimate to the nearest €10,000/kg

There are uncertainties associated with all parts of the analysis and a multitude of impacts could not all be quantified and/or monetised. However, due to the consistent conservative approach taken it is believed that the most significant non-quantified impacts, described in detail in **Table 5.3**, are costs of a possible REACH restriction and would further strengthen the conclusions from the quantitative analysis. Therefore, it is concluded that restricting the use of PFAS in products covered within this SEA will result in highly disproportionate societal costs for the EU.

6. Conclusions and recommendations

The products covered within this SEA includes PFAS-containing filters that serve industries, such as cement production (that underpins most construction works), which require durable filters to contain harmful particulates that are produced during manufacture. These filters can operate in harsh environments where they can be exposed to high temperatures, dust, and hazardous chemical and material gases and particulates. For example, GORE® Mercury and SO₂ Control Modules are used to separate mercury from predominantly aggressive and corrosive gas streams and convert SO₂ into a dilute sulphuric acid. Gore's products are used across many industries, including, but not limited to, chemical manufacturing, semiconductors, electrical equipment, metallurgy, and petroleum refining.

Gore only uses three types of PFAS for the products covered within this SEA, all of which are defined as polymers of low concern (PLC). Around 50% of similar products on the EU market does not contain PFAS, but these are inferior in performance and therefore not used for the same end-use applications. This is because some of these filters containing PFAS are used to protect against the emission of harmful, aggressive, or hazardous air particles.

Gore continually follows external developments of new materials while also pursuing an R&D program to develop novel materials that meet the market's needs. However, no materials have been identified to-date that can replace PFAS in all of Gore's products. As it is chemically resistant and inert and can withstand the operating temperatures required while remaining water and oil repellent. In addition, if it is expanded and laminated to a backing material it can still function as a highly efficient surface filter, which can be cleaned in use. No other known material can provide these unique set of critical properties. However, the industry continues to look for alternative materials for cost saving opportunities but has yet to find any suitable alternative materials that have the same chemical/physical properties.

The cost-effectiveness of a potential restriction for the use of PFAS within the products covered by this assessment is believed to be at least €4.2 - €6 million per kg PFAS emissions reduced, which means that the benefits of a potential restriction would need to be very high to outweigh the costs. These costs are likely to be 90 – 507 times higher than what would normally be considered disproportionate costs within the context of regulating chemicals.

All of the PFAS involved are believed to be PLCs and Gore believes that emissions from product manufacture can be controlled. This, combined with the conservative approach taken throughout the analysis, indicates that the costs of restricting the use of PFAS within the products covered by this assessment will likely, by far, outweigh any benefits.

There are uncertainties associated with all parts of the analysis and a multitude of impacts could not all be quantified and/or monetised. However, due to the consistent conservative approach taken it is believed that the non-quantified impacts lead to net additional costs of a possible REACH restriction and would therefore further strengthen the conclusions from the quantitative analysis.

Considering the lack of any suitable alternative to PFAS, combined with the significant economic and social costs as well as adverse impacts to human health and the environment of using inferior alternatives, it is believed that a derogation is justified for the products covered within this SEA.

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Appendix 1 PFAS volumes and emissions across multiple sectors

The DS published a series of “*investigation report summaries*” in 2021 (National Institute for Public Health and the Environment (RIVM) et al., 2021), where they presented currently available information on the use of PFAS within different sectors which was gathered through a Call for Evidence in 2020 and supplemented with desk-based research. This information has been summarised in:

- Section A1.1: manufacture
- Section A1.2: Use of PFAS
- Section A1.3: End-of-life of products containing PFAS; and
- Section A1.4: Emissions of PFAS.

Disclaimer

The information summarised below is solely based on information published by the DS in their “investigation report summaries” (National Institute for Public Health and the Environment (RIVM) et al., 2021). The below text includes information presented in all the “investigation summaries”, with varying applicability to this SEA. Where the information has been used, this is clearly stated in the main text of the report.

This summary is not an endorsement of the validity nor applicability of the information gathered by the DS, but it is included for completeness and transparency reasons.

A1.1 PFAS manufacture

The production of PFAS is the first stage in the lifecycle of PFAS where PFAS is produced (see [Figure 2.3](#)). [Appendix Table 1](#) details the estimated volume of PFAS produced in the EEA annually according to each PFAS group. Responses to the Call for Evidence survey elicited a wide range of tonnage data, and hence a literature review was used to corroborate the average tonnages of each PFAS manufactured and processed in the EEA.

Appendix Table 1 PFAS and PFAS polymer production

PFAS Group	PFAS manufactured/processed in the EEA (tonnes/year)		
	Minimum (Consultation)	Realistic estimate (literature review)	Maximum (Consultation)
Fluoropolymers	49,458	51,000	101,763
Remaining PFAS	53,902	85,977	118,051
Total	103,360	136,977	219,814

Source: National Institute for Public Health and the Environment (RIVM) et al. (2021)

Notes

1. The minimum and maximum estimates were based on companies’ responses to a survey sent by the DS. Some companies reported exact figures, while others reported ranges. The lower and upper estimates reflect the lower and upper ranges. In some cases, companies reported tonnage data as “greater than x”, with no upper bound included (e.g., “> 1,000 tonnes”). Therefore, the “upper estimate” column is not a true maximum value.
2. It should be noted that the volume of F-gases, including hydrochlorofluorocarbons (HCFCs) and hydrofluorocarbons (HFCs),

manufactured in the EEA were estimated in the 'PFAS and PFAS polymer production' report published by the DS (National Institute for Public Health and the Environment (RIVM) et al., 2021). F-gases have not been included in the production tonnages reported in this table as the registry of restriction intentions for PFAS has been amended to exclude F-gases.

Fluoropolymers make up the second largest proportion of PFAS produced in the EEA. The main fluoropolymers produced for commercial and industrial use are polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF), as well as fluoroethylene propylene (FEP). Ethylene-tetrafluoroethylene (ETFE), perfluoroalkoxy (PFA) and polyvinylfluoride (PVF) follow in terms of volume, whilst perfluoropolyether (PFPE) is a minor use, used mainly for lubrication.

The 'remaining PFAS' category, are defined as PFAS that is neither a fluoropolymer nor an F-gas²⁵. This represents the largest category of PFAS produced in the EEA. This group includes perfluoroether non-polymers with unsaturated bonds. These are the monomers that form the fluoropolymers found in the fluoropolymer group mentioned above. Another group of substances included in this group are perfluoroether non-polymers with only saturated carbon bonds. Information on this PFAS category has been included for completeness but is not relevant to this SEA.

A1.2 Use of PFAS

The "*investigation report summaries*" published by the DS estimated the volumes of PFAS used in products manufactured for a number of different sectors, which are summarised **Appendix Table 2**. The total use of PFAS across all sectors have been calculated as part of this SEA. It has been highlighted that the volumes are likely underestimated as the DS did not have access to a complete dataset for volumes of PFAS used in the EEA/EU.

The estimates show that the 'transportation' sector uses the highest volume of PFAS in the EEA. This sector includes the automotive, shipping, aviation and railway sectors and the use of PFAS in these sectors range from sealing applications to lubricants, fire prevention and protection and HVACAR-systems (including F-gases). A large number of PFAS-containing products in the transportation sector are products which are subjected to harsh conditions like exposure to seawater, heat, UV-radiation or aggressive chemicals. In other cases, PFAS in products are necessary for a defined performance like in firefighting foams or as part of fuels and lubricants (National Institute for Public Health and the Environment (RIVM) et al., 2021). The transportation sector therefore encapsulates a broad range of sub-sectors which require the use of PFAS given the harsh conditions in which the products are used.

²⁵ Data on the volume of F-gases manufactured in the EEA were also published by the dossier submitters but these volumes have not been reported in this SEA based on a change in the registry of restriction intentions for PFAS which now excludes F-gases (ECHA, 2022).

Appendix Table 2 Estimated volume of PFAS used per sector

Sector covered by Risk Management Option Analysis (RMOA)		Volume of PFAS (tonnes/year)			Proportion of total volume (%)
		Low	High	Midpoint or average	
Cleaning agents, polishes, and waxes (non-industrial uses)		No volume data reported			
Construction products		4,203	9,197	6,698	<1%
Cosmetics		No volume data reported			
Electronics and energy		2,600	6,200	4,300	<1%
Food contact materials and packaging		7,327	11,462	9,395	<2%
Lubricants		4,820	4,820	4,820	<1%
Medical Devices		1,500	14,000	8,900	<2%
Medicinal products (active pharmaceutical ingredients, diagnostics, anaesthetics, and intermediates)	ECHA ⁴	26,000	57,000	42,000	<9%
	Call for evidence	5,000	17,000	11,000	-
Metal plating and manufacturing of metal products		960	960	960	<0%
Petroleum and mining		3,671	7,671	5,671	<1%
Ski treatment		No volume data reported			
Textiles, Upholstery, Leather, Apparel and Carpets (TULAC)		41,183	142,694	91,939	<20%
Transportation ⁵		295,234	295,234	295,234	<63%
Total volume used across all sectors		>387,498	>549,238	>469,916	

Source: National Institute for Public Health and the Environment (RIVM) et al. (2021)

Notes:

1. The "Midpoint or average" column lists the midpoint values provided in the 'investigation report summaries' and, where no midpoint was reported the average volume estimated from the high and low volumes.
2. For sectors where only a single value for PFAS volumes was provided, this was used for the low, high and average volumes of PFAS.
3. The ECHA figure for the volume of PFAS in medicinal products was used in estimating the total, as opposed to the call for evidence figure.
4. The ECHA estimate for the volume of PFAS used in medicinal products is assumed to be higher than the volume estimated via the call for evidence (CfE) because only a selection of companies responded to the CfE, and companies may not have recognised their use of PFAS as medicinal.
5. PFAS volumes used in Transportation are given for the EU as opposed to the EEA.
6. These PFAS volumes include all types of PFAS, beyond those relevant to this SEA

The end-use industries for which the Gore products detailed in this SEA (i.e., those listed in **Table 2.1**) are used include chemicals and petrochemicals, mining and minerals and power generation industries (as detailed in Section 2.2.2). These are broadly related to the petroleum and mining sector included in **Appendix Table 2**. The volume of fluoropolymers used in the petroleum and mining sector "investigation report summaries" have been extrapolated and applied in Section 2.5.3.

A1.3 End-of-life of products containing PFAS

The DS also collected and published data on the fate of PFAS in several selected waste streams. The most relevant waste streams for PFAS were selected according to a set of criteria that identified the waste streams likely to have high volumes of PFAS and significant emission risks during waste treatment and/or recycling. This led to the following wastes being chosen for further analysis:

- Textiles
- Food contact material (paper and board)
- End-of-life-vehicles (ELV)
- Electrical and electronic equipment and
- Sewage sludge

Appendix Table 3 details the volumes of PFAS found at the end-of-life of end-use products, whether disposed and recovered, in each waste stream. These volumes have been estimated and reported by the DS. The *“investigation report summaries”* reported estimating the amount of PFAS in each waste stream according to the concentration of PFAS in that waste stream and the amount of waste generated in that stream.

Appendix Table 3 Total amount of PFAS ending up in waste annually in the EEA per use category

Selected waste	Relevant waste stream	Total amount of PFAS (tonnes/year)	
		Disposal (i.e., landfill, incineration, etc.)	Recovery (i.e., recycling, energy recovery, backfilling, etc.)
Textiles ¹	Textile waste	783	7,310
	Household and similar waste	4,949	9,348
	Healthcare and biological waste (medical textiles)	176	133
Food contact material (paper and board)	Paper and cardboard wastes	1	2,230
	Household and similar waste excluding bulky waste in EEA	470	817
End-of-life-vehicles (ELV)	Shredder light fraction (SLF)	7	1
	Shredder heavy fraction (SHF)	0	0.8
Waste electrical and electronic equipment	WEE	Unknown	
Sewage sludge	Sewage sludge from urban wastewater treatment	0.2	0.2 ²
Total emission from waste across the specified use categories		6,387	19,853

Source: National Institute for Public Health and the Environment (RIVM) et al. (2021)

Notes

1. Not all TULAC (textiles, upholstery, leather, apparel and carpets) could be considered within this analysis, as no information

on treatment of technical textiles and “other” is available.

2. Recovery for sewage sludge includes agricultural use and compost and other uses.

Discarded textiles, whether disposed or recovered, have the highest volume of PFAS found in waste streams of all the product categories assessed by the DS. Within the textiles waste stream, household and similar wastes (which includes home textiles, consumer apparel and professional apparel) make up the largest volume of PFAS found in textile waste. This is in line with volume of textiles discarded on an annual basis. For example, the average consumer today buys 60 percent more clothing than 15 years ago, but individual items are kept only half as long (United Nations Environment Programme (UNEP), 2019).

Waste Electrical and Electronic Equipment (WEEE) represents the fastest-growing waste stream in the world (World Economic Forum, 2019), but data on the volumes and concentration of PFAS in (WEEE) waste stream is unavailable.

A1.4 Emissions of PFAS

Section A1.1 to Section A1.3 detailed the volumes of PFAS used at different stages of the PFAS life cycle and across different sectors in the EEA. The “*investigation report summaries*” published by the DS in 2021 (National Institute for Public Health and the Environment (RIVM) et al., 2021), also include information on the PFAS emitted at each stage of the life cycle. These emissions and emission factors have been summarised in this section.

Caveat: *It should be noted that whilst the data presented in this section highlights general PFAS emissions and the effectiveness of different waste treatment methods in removing PFAS, these are not necessarily representative for the products included in this SEA. Even though these emissions are significantly higher than the emissions reported by Gore, they are – following a conservative approach – used as basis for this SEA.*

A1.4.1 PFAS emissions from PFAS manufacture

The emission factors to air and water from the manufacture of PFAS in the EEA were estimated by the DS and are provided in **Appendix Table 4**. These emission factors were derived based on information on emission to air and water from survey respondents, which included some of the biggest producers and processors of PFAS in the EEA. We then extrapolated these emission factors for this SEA and multiplied the total volume of PFAS produced and processed per year (estimated by the DS and detailed in **Appendix Table 1**) by the emission factors provided in **Appendix Table 4**. The emission factors represent the percentage of PFAS which is released to the environment when a certain amount of PFAS is being manufactured or processed (National Institute for Public Health and the Environment (RIVM) et al., 2021). The DS did not consider direct emissions to soils relevant for industrial settings.

As can be seen in **Appendix Table 4**, emissions during PFAS manufacture make up a very small proportion of the total amount of PFAS produced. For the uses in this assessment, Gore purchases fluoropolymer resins from suppliers, therefore PFAS production is not covered. The information on PFAS production published by the DS has been reported for completeness.

Appendix Table 4 Average emission factors and average emissions to water and air from PFAS production for each PFAS group

PFAS Group	Average emission factors (%)		Total emissions from PFAS production in the EEA (tonnes/year)	
	Emissions factor to water	Emissions factor to air	Emissions to water (estimated)	Emissions to air (estimated)
Fluoropolymers	0.01%	0.02%	5	10
Remaining PFAS	0.04%	0.06%	34	52
Total			39	62

Source: (National Institute for Public Health and the Environment (RIVM) et al., 2021)

Notes:

1. The total emissions from PFAS production have been estimated by multiplying the total volume of PFAS produced (average value used) in the EEA by the emission factors.
2. The “investigation report summaries” do not provide any information on the use of emission control technologies and hence it is unknown whether the emission factors reported by the DS include the use of emission abating technologies.

A1.4.2 PFAS emissions from product manufacture and use

PFAS emissions during the manufacture and use of PFAS-containing products varies between sectors. These emissions have been estimated and reported in the “investigation report summaries” published by the DS (National Institute for Public Health and the Environment (RIVM) et al., 2021) and are summarised in **Appendix Table 5**. The emissions reported in **Appendix Table 5** include emissions from all types of PFAS and are therefore not reflective of the fluoropolymer emissions covered in this SEA.

Appendix Table 5 PFAS emissions from product manufacturing and product use per sector

Sector covered by RMOA	PFAS emissions (tonnes/year)			Proportion of total emissions across product manufacturing and use (%)
	Product manufacturing	Product use (service life)	Product manufacturing and use	
Cleaning agents, polishes, and waxes (non-industrial uses)	Unknown			
Construction products	608	796	1,404	5%
Cosmetics	-	12	12	0%
Electronics and energy	740	21	761	3%
Food contact materials and packaging	8,293	72	8,365	28%
Lubricants	50	170	220	1%
Medical devices ³	4,290	1,300	5,590	19%
Medicinal products (active pharmaceutical ingredients,				
Metal plating and manufacturing	Unknown			

Sector covered by RMOA	PFAS emissions (tonnes/year)			Proportion of total emissions across product manufacturing and use (%)
	Product manufacturing	Product use (service life)	Product manufacturing and use	
Petroleum and mining	732	879	1,610	5%
Ski treatment	0.0	0.9	0.9	0%
Textiles, Upholstery, Leather, Apparel and Carpets (TULAC)	7,520	3,998	11,518	39%
Transportation	Unknown			
Total	>68,243	>7,278	>75,521	100%

Source: National Institute for Public Health and the Environment (RIVM) et al. (2021)

Notes

1. The petroleum and mining sector and the TULAC sector provided emissions as a range (low and high estimates). The emissions reported in this table are an estimated average (midpoint) between these low and high emission estimates.
2. Emissions from the manufacture and use of medical devices and medicinal products were provided in a combined table in the “investigation report summaries”.
3. The data provided on PFAS emissions from manufacturing and use of medical devices and medicinal products was unclear and therefore has an additional layer of uncertainty. These emissions have however been reported in good faith.
4. The emissions reported include emissions from all PFAS types as opposed to the types of PFAS relevant to the products covered by this SEA. These emissions are therefore not reflective of the emissions covered in this SEA but have been reported for completeness.
5. The emissions reported are emissions to air and water. The emissions from waste are reported in Section A1.4.3.

As shown in **Appendix Table 5**, the textiles sector has the highest PFAS emissions (of the sectors that data is available for) at both the product manufacturing and use stages. This is expected given that the sector is the second-highest user of PFAS by volume, behind the transportation sector, for which emissions data is not currently available.

In Section 2.5.3 the volumes and emissions from the manufacture and use of fluoropolymer products in the petroleum and mining “investigation report summaries” were used to estimate an upper bound emission factor for the products covered in this SEA. The emissions reported in **Appendix Table 5** include the emissions from all types of PFAS and hence does not distinguish between the emissions from each type of PFAS, which vary greatly. The emissions in **Appendix Table 5** have therefore been reported for completeness but are not reflective of the emissions associated with the products in this SEA.

Across most sectors, the majority of PFAS emissions occur during product manufacturing (i.e., when PFAS is used to make products). Overall, only 25% of the total emissions across these two stages of the life cycle occur during product use (i.e., service life). It can be observed that the products that are fully consumed, such as lubricants and ski treatment, generate the majority of their emissions during the use stage. For example, within the ski treatment sector, most emissions are likely to occur during the application of ski-wax and skiing (i.e. use stage) where the DS assume that 100% of the wax applied is lost to the environment through erosion of the wax (National Institute for Public Health and the Environment (RIVM) et al., 2021).

A1.4.3 PFAS emissions from product end-of-life

The DS has also estimated total PFAS emissions to air, water and soil from three waste streams, namely landfill, incineration and wastewater treatment in the EEA (National Institute for Public Health and the Environment (RIVM) et al., 2021).

For products disposed of via **landfill** the DS assumes that, over time, 100% of PFAS will eventually end up in the environment. This is based on an assumption that contaminants are not destroyed by the storage on a landfill site and will over time be washed out via rain or desorption processes. This assumption does not reflect the landfill emissions associated with PTFE, which is the main type of PFAS covered in this SEA. As detailed in Section 2.5.3, landfilling of PTFE products are not expected to contribute to emissions associated with landfill leachate since PTFE is not water soluble.

For **wastewater treatment** plants (WWTP), the literature analysed by the DS concludes that currently WWTPs are not effective in destroying or removing PFAS. The median removal efficiency of the European WWTP calculated in the "*investigation report summaries*" is 42%, which means that roughly 58% of the PFAS contained in influent would be emitted into the European surface waters (through effluent) or be found in the sludge, which in some cases is spread on land as fertilisers. The products covered in this SEA are not disposed of via wastewater treatment plants at any stage of the product lifecycle. The emissions from wastewater treatment are therefore not reflective of the emissions from waste associated with the products covered in this SEA.

The **incineration** of PFAS containing waste is currently seen as the most effective treatment option for destroying PFAS, however, the remaining bottom and fly ash are typically landfilled in Europe, with smaller proportion being recycled as aggregates for use in, for example, pavements and highway foundations (National Institute for Public Health and the Environment (RIVM) et al., 2021).

Caveats have been included where emissions have not been estimated for each environmental compartment. The volume and share of PFAS emissions estimated by the DS are detailed in **Appendix Table 6**.

Appendix Table 6 Amount and proportion of PFAS emissions in each waste stream

Waste treatment	Amount of PFAS emissions per waste stream (kg/year)			Share of total emissions from waste (%)	
	Low	High	Median	Low	High
WWTP effluent and sludge	-	-	9,884	94%	77%
Landfill	597	2,983	-	6%	23%
Incineration ²	-	-	49	<0.5%	<0.4%
Total	10,530	12,916	-	100%	

Source: National Institute for Public Health and the Environment (RIVM) et al. (2021)

Notes:

1. The low and high estimates for the contribution of each waste treatment to the total amount of PFAS include the median amount of PFAS found in incineration and WWTP effluent and sludge given that the source data does not provide low and high estimated for these waste treatments.

2. Emissions to air not accounted by the DS.

As shown in **Appendix Table 6**, WWTP effluent and sludge has the highest contribution to PFAS emissions into the environment followed by landfill. This is expected given that WWTP effluent represents a direct PFAS emission into the environment and given that some of the landfill leachate is treated in WWTPs and hence is included in the WWTP emissions.

The contribution of incineration to the total PFAS emissions comes via incinerator bottom ash. The share of emissions from incineration are below 0.5% of total emissions across waste treatment options, indicating that this is the best treatment option for the destruction of PFAS.

The emissions reported in **Appendix Table 6** are based on the overall volume of waste in each waste stream, which therefore could not be extrapolated and applied to the emissions from the end-of-life of products covered in this SEA. These emissions published by the DS have therefore been detailed here for completeness.



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