



SEA of restricting use of PFAS in vents

Final Report

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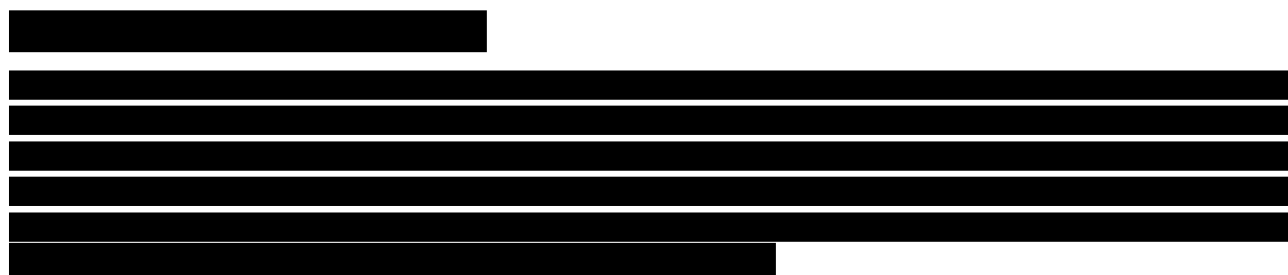
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Executive Summary

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 “**vents**”. 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 automotive, packaging, protective and portable vents and thermal insulation that are long-term reliable and resistant to high temperatures and harsh environments. Automotive vents protect sensitive automotive components from liquid, dust and dirt ingress and prevent degradation or premature component failure. Packaging vents equalize pressure emitted from packaged chemical and agricultural products, preventing leakage and packaging explosion. Protective vents, used in electronic equipment in a wide range of industries, protect electronic enclosures from uncontrolled environmental impacts. Portable vents protect mobile electronic consumer devices and lead to a much longer lifetime of those devices. For example, portable electronics’ battery vents will prevent battery overheating and cell-ballooning by releasing battery gasses. Thermal insulation products insulate and protect heat-sensitive electronic components in mobile devices.

Gore uses several types of PFAS for the products covered within this SEA, most of which on the EU market are defined as polymers of low concern (PLC). Gore believes that around 80% of similar products on the EU market contain PFAS and is manufactured using similar types of PFAS. 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. In addition, industry has been performing trade studies and investing in non-PFAS alternatives that can be used with vents in harsh environments for a number of years. However, no suitable materials have been identified that can replace PFAS in all of Gore’s (and similar) products without a significant drop in performance and an increase in health and safety risk to the end user.

Restricting the use of PFAS in products covered within this SEA may, in fact, result in net costs (rather than benefits) to the environment and human health. For example, vents are used in gas sensors which alert workers to the presence of harmful gases in the air. These gas sensors detect specific gases that, once critical concentration level is reached, can cause a potentially explosive environment. If not detected, the risk of an explosion is more likely and would have harmful impacts on humans and environment. Vents containing PFAS are also used in automotive headlights, fog lights and brake lights, which are critical in ensuring that vehicles are clearly visible to other road users/motorists, and that road users are visible to vehicle drivers at night. Less durable non-PFAS vents could lead to product failure and impact the safety of passengers and pedestrians from an increased risk in road accidents.

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. A key benefit of using vents containing PFAS is their superior durability. Changing to non-PFAS products will therefore increase resource use and waste generation, which results in both costs to the users and adverse impacts on the environment (e.g., through CO₂ emissions).

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 is 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 restricting the use of PFAS in products covered within this SEA is estimated at €1,26 million 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 €130,000 – €1.2 million per kg PFAS emissions reduced. The vast majority of 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.

Contents

1. Introduction	1
1.1 Background	1
1.2 Objective and Scope	2
1.3 Approach	2
1.4 Structure of the report	4
2. Baseline scenario	5
2.1 Introduction	5
2.2 Products and end-uses	5
2.3 Gore sales and direct supply chain	10
2.4 Gore's use of PFAS	15
2.5 EU baseline	26
3. Availability of suitable alternatives	42
3.1 Introduction	42
3.2 R&D undertaken by Gore to date	42
3.3 Technical feasibility	44
3.4 Availability	55
3.5 Cost and timeline for transitioning to alternatives	55
3.6 Hazard comparison	57
4. Restriction scenario	58
4.1 Introduction	58
4.2 Behavioural responses	58
4.3 Economic impacts	60
4.4 Impacts to human health and the environment	64
4.5 Social and wider societal impacts	69
5. Comparison of costs and benefits	74
5.1 Introduction	74

5.2	Comparison of quantitative impacts	74
5.3	Non-quantified impacts	75
5.4	Proportionality assessment	81
6.	Conclusions and recommendations	83
	References	84
	Appendix 1 PFAS volumes and emissions across multiple sectors	88
A1.1	PFAS manufacture	88
A1.2	Use of PFAS	89
A1.3	End-of-life of products containing PFAS	91
A1.4	Emissions of PFAS	92

Figures

Figure 1.1: Indicative timeline for the REACH restriction proposal for PFAS	1
Figure 1.2: SEA approach	2
Figure 1.3: Data sources used in this socio-economic analysis (SEA)	3
Figure 2.1: Products containing PFAS and affected end-uses and industries	8
Figure 2.2: Gore's supply chain for venting products	13
Figure 2.3: Location of the three manufacturing process steps for vents	20
Figure 2.4: PFAS lifecycle (<i>European Commission, 2020</i>)	22
Figure 2.5: PFAS material flow for the EU market for products covered within the SEA	33

Tables

Table 2.1: Commercial Gore Venting products and descriptions	6
Table 2.2: Gore sales of vents containing PFAS, annual average 2016-2021	11
Table 2.3: Gore total sales, direct and indirect, affected by a potential restriction, annual average 2016-2021	12
Table 2.4: Gore raw material suppliers associated with vents	14
Table 2.5: Gore customers (average 2016-2021) associated with vents	14
Table 2.6: Venting applications and specific PFAS uses	16
Table 2.7: Type and volume of PFAS used in Gore products manufactured in EU and non-EU counties	18
Table 2.8: Total volume PFAS manufactured in the EU and placed on the EU market by Gore	21
Table 2.9: Worst-case annual emissions of fluorinated substances from Gore's fluoropolymer manufacturing facility in 2021	23
Table 2.10: PFAS material flow through manufacturing process in the EU	23
Table 2.11: PFAS material flow through manufacturing process outside the EU	23
Table 2.12: Impacted sales and EU market, annual average 2016-2021	27
Table 2.13: EU sales statistics for relevant PRODCOM categories	28
Table 2.14: EU market for fluoropolymers	29
Table 2.15: Economic overview of industries in the EU that use vents containing PFAS	30
Table 2.16: Extrapolation of volumes of PFAS placed on the EU market	31
Table 2.17: Estimates of EU emissions, average 2016-2021	36
Table 2.18: PLC criteria from study by Henry et al. (2018)	38
Table 2.19: Extrapolated projection of sales and volumes for the EU market (2022-2041)	41

Table 3.1: PFAS contained or used (in the manufacturing process) in products and alternatives	42
Table 3.2: Gore venting products and the function they provide in end-products	46
Table 3.3: Gore product portfolio available alternatives and potential suitability	51
Table 3.4: Minimum time frame and costs for Gore to replace PFAS substances in venting portfolio in the EU	56
Table 4.1: Summary of quantified economic impacts in the EU	64
Table 4.2: Reduction in PFAS contained in products and emissions in the EU	65
Table 4.3: Summary of employment impacts in the EU	71
Table 5.1: Minimum quantified costs in the EU of a potential REACH restriction (no derogation)	74
Table 5.2: Cost-effectiveness in the EU	75
Table 5.3: Overview of non-monetised impacts in the EU and their overall effect on the cost acceptability	76
Table 5.4: Cost-effectiveness in the EU and benchmark comparison	82
Appendix Table 1 PFAS and PFAS polymer production in the EEA	88

Abbreviations & Acronyms

ABS	Anti-lock Braking System
ADAS	Advanced driver assistance systems
AoA	Assessment of Alternatives
BM	Benchmark
C	Carbon
CAGR	Compound annual growth rate
CAPEX	Capital Costs
CARACAL	Competent Authorities for REACH and CLP
CE	Cost-effectiveness
CLH	Harmonised Classification and Labelling
CLP	Classification, Labelling and Packaging of Substances and Mixtures Regulation
DS	Dossier Submitters
EAV	Equivalent annual values
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environment Agency
EERA	European Energy Research Alliance
EHS	Environmental Health and Safety
EiF	Entry into Force
ELV	End-of-life vehicles
EoL	End of Life
ETFE	Ethylene-tetrafluoroethylene
EU	European Union
FEP	Fluorinated ethylene propylene
GHG	Greenhouse Gases
GVA	Gross Value Added
H	Hydrogen
HFP	Hexafluoropropylene
ISO	International Organisation for Standardisation
KIT	Karlsruhe Institute of Technology
LGR	Lithium-ion Gas Release
OECD	The Organisation for Economic Co-operation and Development

OEM	Original Equipment Manufacturer
PBT	Persistent Bioaccumulative Toxic
PET	Polyester
PFA	Perfluoroalkoxy alkane
PFAS	Per- and polyfluoroalkyl substances
PFHxA	Perfluorohexanoic acid
PFHxS	Perfluorohexanesulfonic acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic acid
PFP	Product Feasibility Point
PFPE	Perfluoropolyether
PLC	Polymers of Low Concern
ppm	Parts per million
PTFE	Polytetrafluoroethylene
PV	Present Value
PVC	Polyvinyl chloride
PVDF	Polyvinylidene fluoride
PVF	Polyvinyl fluoride
R&D	Research and Development
RAC	Committee for Risk Assessment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	National Institute for Public Health and the Environment
RMOA	Risk Management Option Analysis
RoHS	Reduction of Hazardous Substances Directive
RTO	Regenerative thermal oxidizer
SAGA	Suitable alternatives generally available
SCR	Selective Catalytic Reduction
SEA	Socio-Economic Assessment
SEAC	Committee for Socio-economic Analysis
SHF	Shredder heavy fraction
SLF	Shredder light fraction
SME	Small and medium-sized enterprises
TFE	Tetrafluoroethylene
TFP	Technology Feasibility Point
TULAC	Textiles, Upholstery, Leather, Apparel and Carpets
USD	US-Dollar



UV	Ultraviolet
vPvB	Very Persistent and very Bioaccumulative
WEEE	Waste Electrical and Electronical Equipment
WWTP	Wastewater Treatment Plants

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 “vents”. 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 in all types of vents. The assessment includes Gore products and similar products placed on the EU market by other companies. Types of vents 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**.

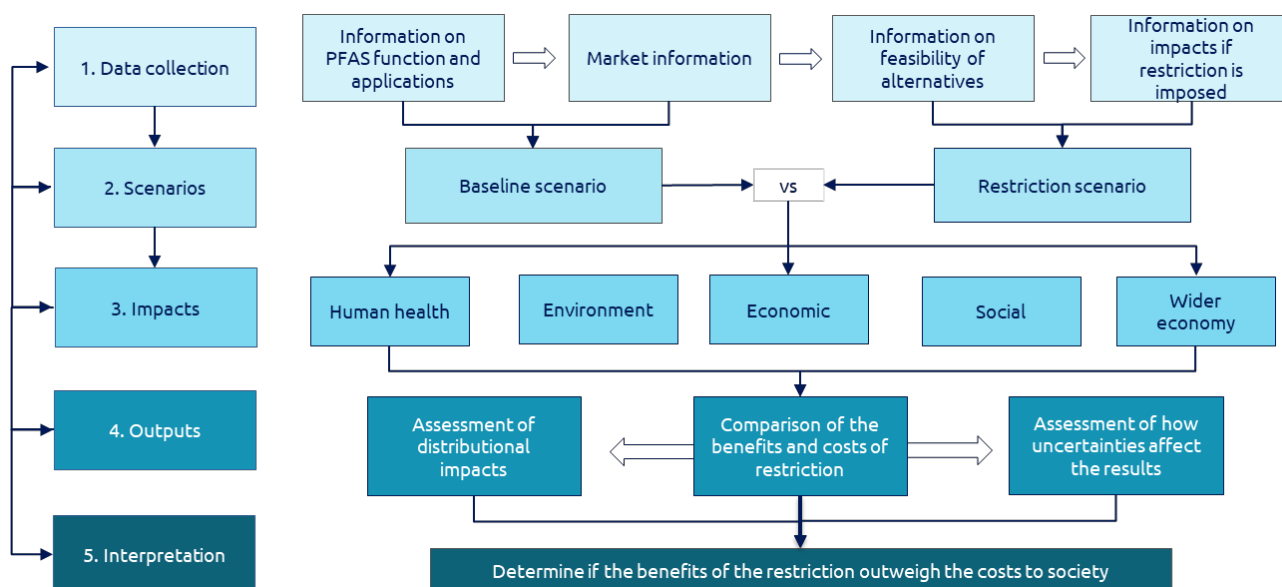


Figure 1.2: SEA approach

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 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 vents 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 ventilation 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 vents 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.

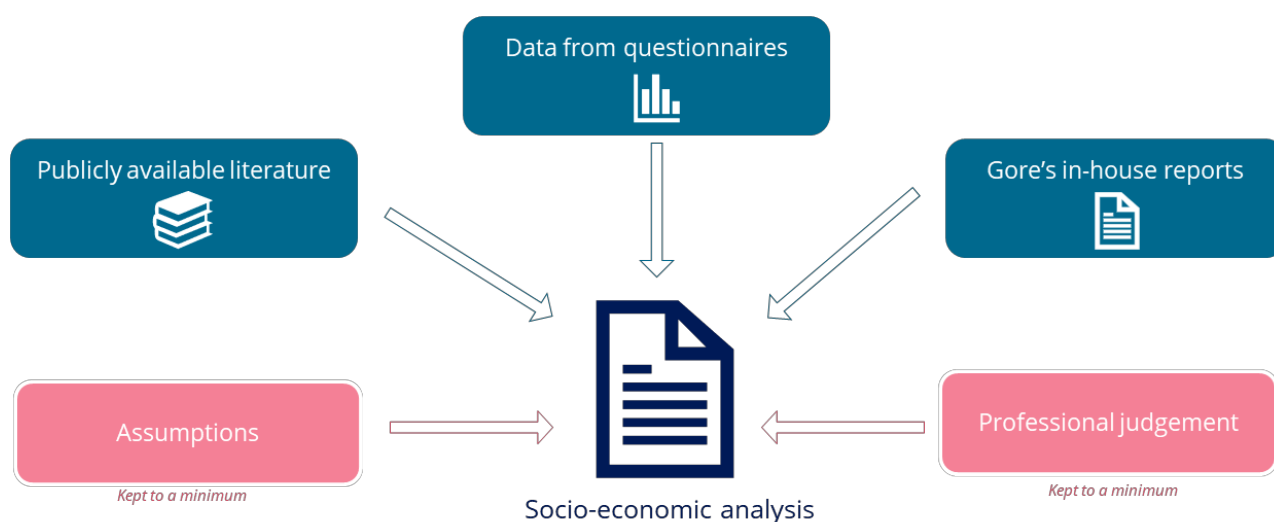


Figure 1.3: Data sources used in this socio-economic analysis (SEA)

1.4 Structure of the report

The remainder of this 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 vents 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

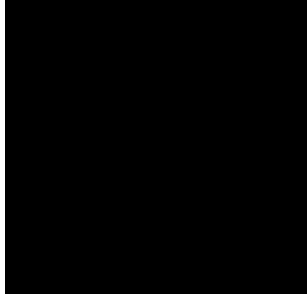
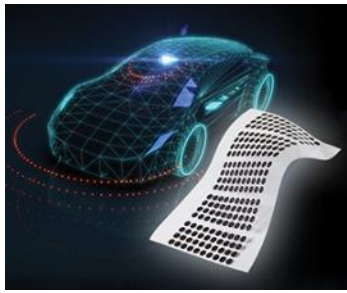
The use category 'venting' relates to GORE® Vents used in:

- automotive applications,
- industrial packaging,
- industrial electronic enclosures, and
- consumer electronic handheld devices.

The vents provide pressure equalization, moisture diffusion and act as a barrier to liquid entry or – in the case of chemicals packaging – liquid outlet, and to particle contaminants, providing protection for the life of the vented devices and increasing reliability of the critical functions the devices perform (Gore, n.d.).

Table 2.1 outlines a full list of Gore's vents and accompanying descriptions.

Table 2.1: Commercial Gore Venting products and descriptions

Product	Illustration	Description
Automotive Powertrain Vents		Gore Powertrain Venting Products provide life of vehicle protection for automotive powertrain components in passenger and light duty trucks against contamination while allowing pressure equalization, reducing design requirements on seals, housings, etc. The vents enable lower weight/fuel, less material usage, and lower vacuum pressures.
Portable Electronic Thermal Insulation		Gore's Thermal Insulation products insulate mobile electronic devices in two ways: first, protecting the device from excess heat created by the device itself, and second, protecting a heat sensitive component inside the device from the heat created by other components inside the device. These vents will constantly and consistently exhaust gas, to maintain cell health enabling cells to last longer.
[REDACTED]		[REDACTED]
Automotive Electronic Enclosure Vents		GORE Automotive Electronic Enclosure Vents durably protect sensitive electronics from damage, degradation, or premature failure in harsh or extreme environments. They rapidly equalize pressure with continuous through bi-directional air exchange through membrane and prevents occurrence of a vacuum and preserves seal's integrity. They offer reliable protection against contaminants over the lifetime of electronic component. They also protect against water splash and spray from automotive fluids, detergents and washing products, dirt, dust, debris, salts
Automotive Battery Vents		Automotive Battery Vents enable the release of gas emissions inside batteries which, if left untreated, can inhibit performance. Thus, the vents improve the performance, longevity, and [REDACTED] technologies: a) Catalytic battery vents for use in traditional lead/acid batteries in start/stop applications in ICEs, BEVs, HEVs, and FCEVs ¹ and [REDACTED]

¹ ICEs, BEVs, HEVs, and FCEVs refer to Internal Combustion Engine and battery, hybrid, and fuel cell electric vehicles, respectively.

Packaging Vents		Packaging Vents are used to equalise pressure in Chemical Packaging, preventing containers filled with hazardous chemicals (e.g., hydrogen peroxide, peracetic acids and bleach) from leaking or bursting (because of unbalanced pressure within the container). As a result, they're an important safety component of chemical storage and transportation, reducing environmental pollution and human harm.
Protective Vents		Protective Vents for Outdoor Electronics are used to equalise pressure in electronic enclosures protecting them from uncontrolled changing environments such as rain, snow, wind, sun, and thunderstorms. Without protection, environmental conditions can cause rapid cooling or heating of electronic devices, thus vents improve the performance, reliability, and longevity of outdoor electronics.
Portable Electronic Vents		Portable Electronic Vents protect sensors, microphones, and speakers in electronic devices such as smartphones, headphones, watches, smart speakers and radios from water, fluid, and dust contamination.

Source: Gore (2022, 2021)

Notes: Images are taken from Gore's website: <https://www.gore.com/products/categories>

2.2.2 End-uses and affected industries

The 9 product categories (henceforth called 'products') that are used in 'vents' can be grouped into three broader use categories:

- Vents used for end-uses in the automotive industry (largest end use category);
- Protective vents across a range of industrial end-uses; and
- Protective vents and thermal insulation used primarily in portable electronic devices.

Figure 2.1 offers a non-exhaustive overview of the downstream end-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 end-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.

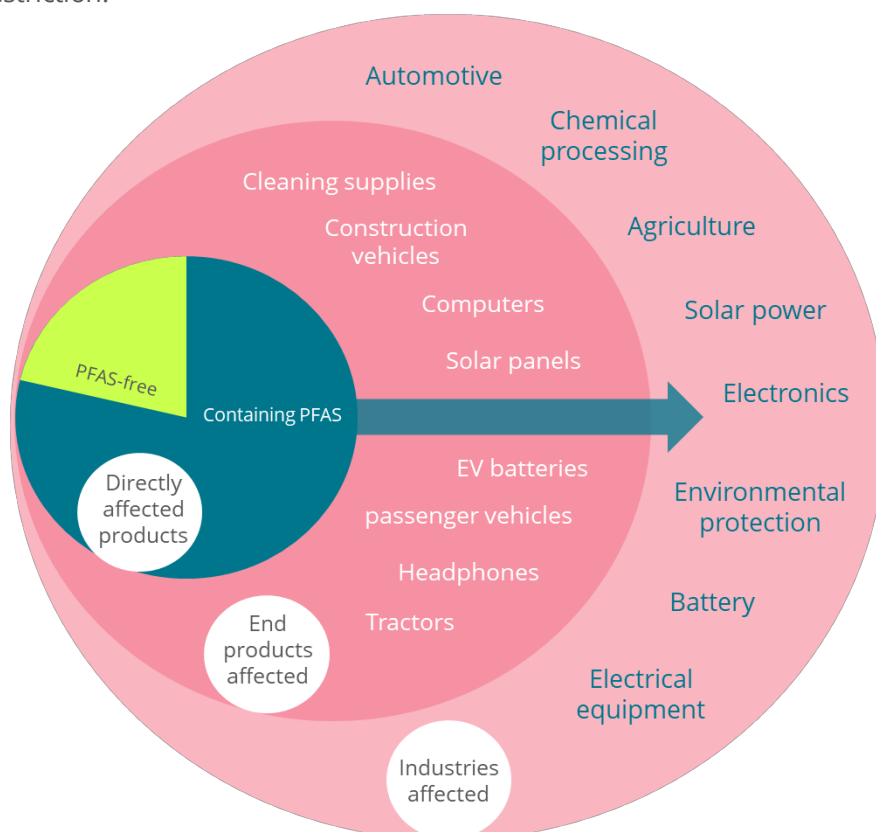


Figure 2.1: Products containing PFAS and affected end-uses and industries

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

Gore believes that approximately 80% of the venting products described in [Table 2.1](#) contain PFAS, about 20% come non-PFAS. PFAS are used because these products are required to be durable and protect against exposure to harsh operating conditions, which protects the health and safety of end-users. The non-PFAS products would not be expected to be used in applications which, e.g., require high temperature stability, effective moisture diffusion and/or protection from water, dust, or aggressive chemicals. Instead, non-PFAS products are rather used in applications which are not exposed to water and dirt, aggressive chemicals or temperatures exceeding 80-100°C.

Vents containing PFAS are used across many end-uses in the automotive industry. This includes Automotive Battery vents that are used in **lead acid** [REDACTED] which are critical components in the functioning of all road vehicles (in both **electric vehicles** and **petrol/diesel powered vehicles**). Automotive Powertrain vents enable lower weight/fuel, less material usage, and lower vacuum pressures. Automotive Lighting vents are used in exterior **vehicle lamps** (e.g., **fog, headlights, brake lights**, etc) which ensure that vehicles are clearly visible to other road users/motorists, and that road users are visible to vehicle drivers at night. Improperly functioning exterior car lights may impact safety of passengers and pedestrians, e.g., when headlamps do not sufficiently illuminate the street at night or when headlamps glare distracts oncoming vehicle drivers. There are also economic savings like avoided accident costs, reduced vehicle insurance costs and avoiding needing streetlights on all roads.

These vents provide safety and durability and are used in **passenger vehicles and trucks**. Without durable functionality the ability of individuals and society to travel and transport goods around the country/economy may be delayed due to safety or technical issues. Supply chains and distribution networks rely on having access to suitable forms of automotive vehicles to transport their goods to market. These supply chains would be affected economically if there were impacts to the transportation sector due to vehicles being out of commission during repairs. This would have further impacts on the movement of goods, services, and people, in particular on those living or working in more remote areas with limited access to public transportation alternatives. **Electric vehicles**, which are important in the transition towards a lower carbon transportation sector, also depend on these vents.

Packaging vents containing PFAS enable packaging of various chemical products (e.g., **household cleaners and agricultural products**) by equalizing pressure emitted from chemical products and ensuring leak proofness over the product life cycle. These vents ensure that the users are protected from their contents. Without suitable packaging and containment, leakage may occur. People and/or the environment may then be exposed to hazardous chemicals, causing adverse impacts to their health.

Portable Electronic thermal insulation containing PFAS protects the surface of **mobile electronic devices** from excess heat created by the device itself. It also protects heat sensitive components inside portable electronic devices from the heat created by other components inside the device.

PFAS-containing vents also help ensure the functioning of sensor systems which identify the presence of fatal gases in buildings (e.g., **carbon monoxide alarms**) or detect the likes of fire and smoke in residential and office buildings. These are crucial for ensuring the safety of individuals whether at home, at work or in public places such as shopping centres and restaurants.

Protective vents containing PFAS are used in outdoor electronic equipment like electronic control units located in **solar panels, weather stations or power lines**. In uncontrolled climate-changing environments such as rain, snow, wind, sun, thunderstorms, reliable performance over lifetime of the electronic device is essential. Functionality in most cases is pressure equalization of electronic enclosures while protecting from uncontrolled environmental challenges (rain, liquids, particles) which would lead to failures, from complete loss of function and damage to related equipment to shorter lifetime of device (increased need for replacement).

Solar panels and related equipment such as inverters utilise protective vents containing PFAS to ensure maximum performance in adverse weather conditions, which helps generate clean electricity. Solar energy production is an increasingly important source of energy within the economy. Solar generation in the EU increased by 15% in 2020, and alongside wind currently generates around 20% of the EU's electricity. This supports the transition to a more sustainable society (Gore, 2021).

Protective vents are typically installed in enclosures of electronic components. They are used in professional **2-way radios** (e.g., used for coordination and communication between different professionals) and **gas sensors** which monitor air quality (e.g., used to ensure safe environment after event of fire). The vents protect device sensors from the ingress of moisture, particles, or other contaminants as a result of uncontrolled harsh environment, condensation, high-pressure cleaning, shocks, vibration, or

other factors. Without these protective vents, the gas sensors would not operate.

Additionally, protective vents ensure functioning of modules within industrial equipment and machinery such as **cranes, forklifts, and agricultural machinery** in various industries. Industrial equipment and machinery ensure the smooth and efficient operation of industrial processes and boost productivity within a multitude of economic sectors, e.g., manufacturing, construction, and distribution.

Automotive battery vents, still in R&D phase, containing PFAS will be welded to the outer packaging material of pouch and prismatic style **lithium-ion batteries** for the purpose of exhausting gases that naturally form within batteries over their useful life while preventing moisture ingress which can be damaging to the cell. Gas generation can be accelerated by stressful device use conditions such as, high temperature, holding cell at a high state of charge, over charge/discharge and aggressive charge rates. These vents will constantly and consistently exhaust gas, to maintain cell health enabling cells to last longer and reduce instances of premature capacity loss and hazardous cell ballooning events. The reliable functioning of these products is critical to the safety of workers and end-users (car drivers) as cell ballooning can result in harm to persons nearby.

Smartphones, headphones, and other wearable devices that are powered by lithium-ion batteries provide important socio-economic benefits to society. They enhance individual's standard of living, while improving productivity and efficiency within the economy. Gore's vents release internal cell gases that naturally form during application.

2.3 Gore sales and direct supply chain

2.3.1 Gore sales of products affected by a potential restriction

[REDACTED]

[illegible]

[illegible]

[REDACTED]						

[illegible][illegible]

██████████

10/1/2011

[REDACTED]

████████████████████

[REDACTED]

[illegible][illegible]

2.3.2 Gore direct supply chain

Gore processes fluoropolymer resins into its finished venting products that serve important uses in:

- Automotive powertrains,
[REDACTED]
- Automotive electronics,
[REDACTED]
- Lead acid batteries,
[REDACTED]
- Mobile electronic devices, and
- Dangerous goods packaging.

533 people are associated with the production and sales of Gore's venting products, 126 of whom are located within the EU. **Figure 2.2** provides a graphical representation of Gore's supply chain.

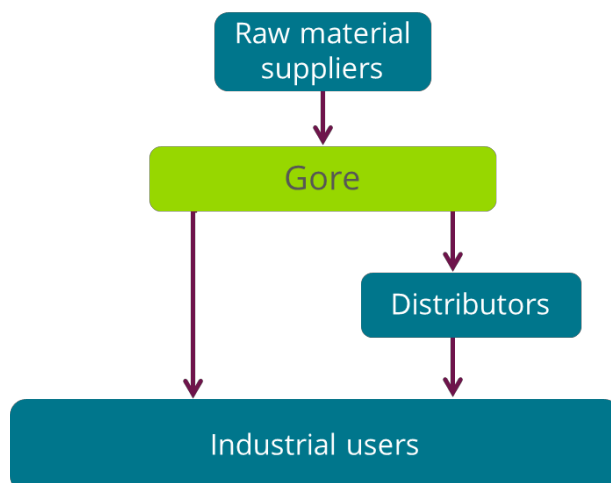


Figure 2.2: Gore's supply chain for venting products

Gore identified moulded parts and die cut parts suppliers as the only "key raw material suppliers" that heavily rely on the continued production of the products set out in **Table 2.1**. 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. **Table 2.4** shows that there are four suppliers within the EU that would be at risk of severe implications (i.e., closure, job losses, etc.) due to a PFAS restriction. Gore estimates there are 360 people employed by these suppliers within the EU. Similarly, two suppliers located outside of the EU, employing 240 people, were identified to be at risk of the same implications. With annual spend on key raw materials from within and outside of the EU of around €11 million and €16 million, respectively, there would be significant implications for upstream suppliers both in the EU and outside the EU.

Gore also purchases polytetrafluoroethylene (PTFE) and other fluoropolymer resin from several global manufacturers and processes the resin into finished products. While the purchases of fluoropolymers for the use described in this analysis are much less than one third of the revenue for such suppliers, 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.

[REDACTED]

[REDACTED]

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

Gore's venting products contain or use (in the manufacturing process) a number of different PFAS substances; these vary based on the Gore venting product in question. However, across all of Gore's venting products, polytetrafluoroethylene (PTFE) is used to provide a thin, high-strength micro-porous substrate (membrane) that has a unique combination of high airflow whilst also exhibiting high liquid entry pressure. Since PTFE has a high melting point and is chemically inert (i.e., stable), it provides unique performance at a broad range of temperatures and harsh chemical environments.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

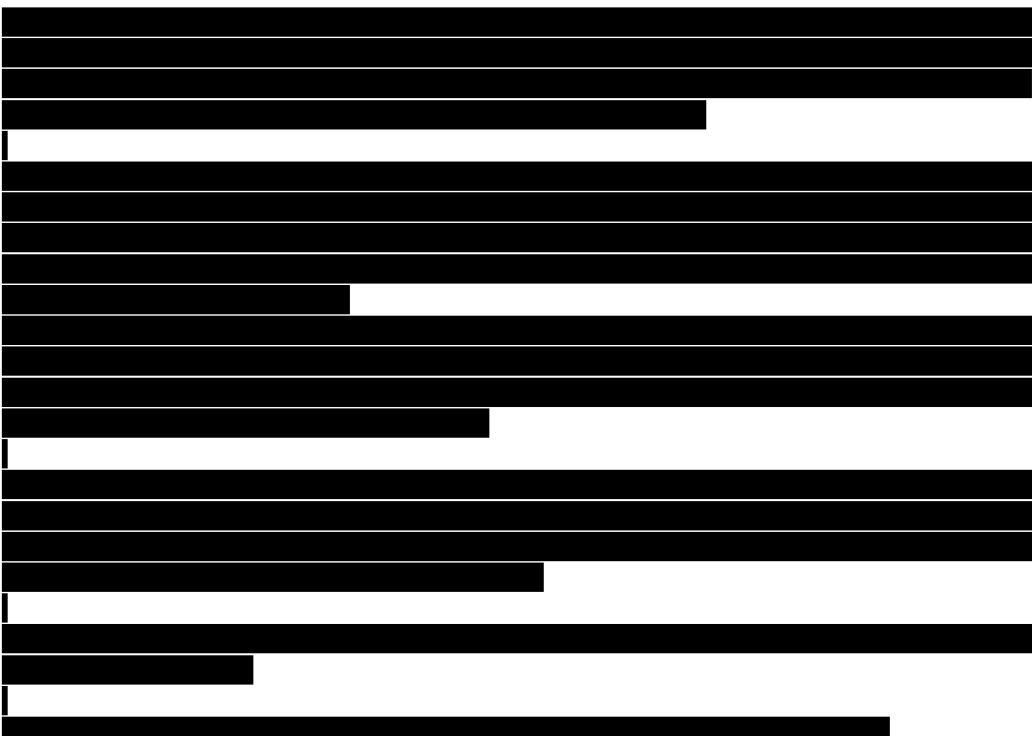
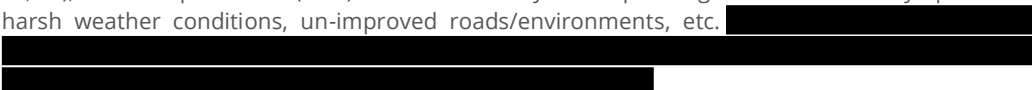
[REDACTED]

[REDACTED]

For certain Gore applications PFAS fulfil performance requirements defined in industry standards. For example, automotive applications must adhere to various product standards defined at either product, national or international level, see **Table 2.6** below.

² Oleophobicity refers to a substance that repels oil and oil-based materials. See: <https://nanoslic.com/oleophobic-coatings/>

Table 2.6: Venting applications and specific PFAS uses

Automotive	
Automotive Electronic Enclosures Vents	Gore's Automotive Electronic Enclosure vents rapidly equalise pressure with continuous bi-directional air exchange through the PFAS membrane, thus preventing the occurrence of a vacuum while preserving the seal's integrity. Moreover, this provides reliable protection against contaminants over the lifetime of electronic component including water splash and spray resistance against automotive fluids and chemicals (oils, greases, washing liquids, etc.), detergents and washing products, dirt, dust, debris, and salts. PFAS substances can withstand high operating temperatures (up to 160°C), which are required and explicitly specified by automotive Tier 1 suppliers³ and Original Equipment Manufacturer (OEMs)⁴. There is a need to reliably seal automotive electronic enclosures to survive harsh operating conditions and by doing so extend the life of the component and ultimately the vehicle. Gore Vents allow pressure equalisation of such components which reduces stress on seals and gaskets. A lack of venting for these components would lead to failure of the seals and let water, liquids, and dust enter the enclosure, leading to pre-mature failure of the component and finally the vehicle (until the component is replaced).
Automotive Powertrain Vents	Automotive Powertrain Vents use the micro-porous structure and hydrophobicity (i.e., water repellent nature) of PTFE as this allows gases to pass through the membrane while keeping out solid and liquid contamination. Furthermore, this serves as a structure for oleophobic treatment enabling repellence of low surface tension fluids commonly used in automotive applications. The PTFE provides high temperature resistance, chemical resistance, water protection (both submersion and high-pressure spray; with the following Ingress Protection (IP) ratings - IPx7, 8, 4, 6k, 9k), and dust protection (IP6x). This functionality allows passenger vehicles to safely operate in harsh weather conditions, un-improved roads/environments, etc. 
Automotive Battery Vents	Functions for Catalytic Device: Production of thin film sheets of precious metal catalysts with highly efficient reactivity; long-term protection of catalyst sheets from sulfuric acid electrolyte. The catalytic device efficiently recombines the hydrogen and oxygen generated inside automotive lead-

³ Tier 1 suppliers are companies that supply parts or systems directly to OEMs (AMATECH, 2017).

⁴ OEMs are the original producers of a vehicle's components (Kharatit and Kvilhaug, 2021).

	acid batteries to produce water. This reduces the electrolyte loss and maintains the performance of the lead battery for a long time. [REDACTED] [REDACTED] [REDACTED] [REDACTED]
Packaging Vents	PFAS enables Gore's products to be [chemically] compatible with extreme and concentrated chemicals (e.g., 60% hydrogen peroxide). A failure in chemical compatibility means the product would fail due to polymer degradation (i.e. breakdown). The result would be membrane rupture and the leaking/spilling of hazardous chemicals. PFAS enables Gore's products to exhibit liquid repellence, without sufficient liquid repellence, the liquid (e.g., surfactants) would block the membrane. As a result, pressure equalisation would be reduced, the container could bloat, rupture, and finally leak.
Protective Vents	The use of PFAS ensures product functionality over long lifetime (up to 30 years). The long-term performance is based on the PTFE membrane characteristics in combination with oleophobic performance. While normal operating conditions are from -40°C to +125°C even more extreme conditions can be required. For example, -60°C for applications used in extremely cold climates; and up to +150°C in energy sector (e.g., in hot engines). In these challenging conditions other membrane materials with same airflow performance could not survive. The overall combination of high airflow and high-water entry pressure (WEP) is unique to other materials.
Portable Electronic Vents & Thermal Insulation	PFAS enables the construction of unique membranes that are strong while also thin and low mass. These membranes provide: • Environmental protection from dirt, water and other fluids that cause failure of the electronics if exposed. This protection is critical to reliable operation of the device in external environments. • Signal transmission – Allow acceptable level of signal (sound, pressure, humidity, etc.) transmission while protecting the electronics. Without acceptable transmission device is inoperable. • Constant and consistent gas exhaust. This is required to maintain health of electronic components and battery cells, enabling cells to last longer and reduce instances of premature capacity loss and hazardous cell ballooning events. Thermal Insulation products utilise a PTFE tape as scaffolding to hold the silica aerogel particles in place in the matrix.⁵ The matrix is consistent and does not shed aerogel particles when handling/converting material into other forms which means the performance of the product is consistent and the thickness is consistent (i.e., allows the devices to operate at higher power without increasing surface temperature and allows the devices to be thinner without reducing device power). This allows for a consistent blocking of heat from getting to the surface of the mobile device, protecting the end user from burns associated with prolonged skin contact on a hot device.

Source: Gore (2022; 2021)

2.4.2 Types and volumes of PFAS used

The 9 Gore product categories affected and assessed within this SEA (see [Table 2.1](#)), [REDACTED]

[REDACTED] The types and volumes of PFAS used for each product manufactured by Gore inside and outside the EU are detailed in [Table 2.7](#). By 2025, 100% of the various types of PFAS used in manufacturing these products in the EU will be Polymers of Low Concern (PLCs). Currently, Gore still uses a side chain fluorinated polymer, which is not classified as PLC. By 2025, the side chain fluorinated polymer will be replaced by Gore with PFA. Since the side chain fluorinated polymer will not be used anymore when

⁵ In this instance, the matrix refers to a chemical substance.

the PFAS restriction is expected to enter into force, the focus of the SEA will be the status in 2025 and onward. 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).

The volume of PFAS used in the EU on an annual basis, as reported in **Table 2.7**, includes the PFAS volumes used in the manufacturing (steps) of vents in the EU, both PFAS in substance form and PFAS imported to the EU in intermediate goods which then undergo the final manufacturing step in the EU. Further details on the manufacturing process within and outside the EU for the products covered in this analysis is provided below.

Final Report | September 2022 Page 19

- [REDACTED]
- [REDACTED]
- [REDACTED]
2. Volumes are rounded to the nearest tonne, or to the first significant decimal if below a tonne. Totals may therefore not sum up.

Gore's manufacturing process for venting products is broadly divided into three steps that involves PFAS:

- The raw material (PTFE), which comprises the final products, is formed into a tape or a membrane during the first step.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

- Finally, shapes are cut out of the final treated tape or membrane. No additional PFAS is added at the last step, but there is some production waste generated.

These three steps are not necessarily carried out in the same manufacturing plants, and they may occur in different regions, i.e., within or outside the EU. Notably, there are no production facilities that carry out step two in the EU, so products are shipped outside the EU to undergo this step. Step one and step three may occur in the EU (as well as outside the EU).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Table 2.7 above only shows the volumes of PFAS that is used in manufacturing steps occurring within the

Table 2.8 shows an approximate breakdown of the PFAS volumes used in the EU based on manufacturing origin and final markets. The total volume PFAS used in the EU for Gore's venting products is estimated at around 39 tonnes per year, of which 97% are PLCs. Around 30 tonnes of these are contained in products placed on the EU market (including products manufactured within and outside the EU).

[illegible]

2.4.3 PFAS material flow

Final Report | September 2022

solvents for the uses in this assessment from suppliers, therefore production of these PFAS are not covered.

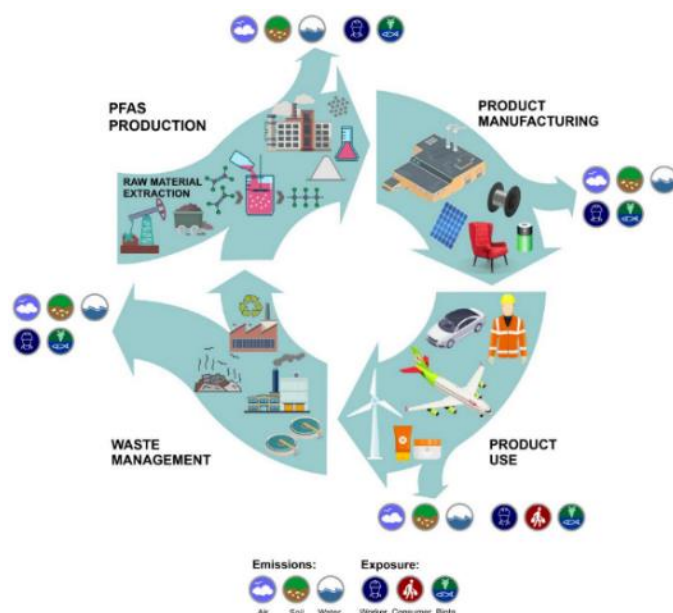


Figure 2.4: PFAS lifecycle (European Commission, 2020)

PFAS production

Gore manufactures a small amount [REDACTED] of PFA in the EU for the use described in this SEA. PFA is then exported to the United States for further processing into intermediate articles. Gore's small-scale polymerization facility is equipped with state-of-the-art environmental controls⁶ including:

- Capture and recycling of monomers;
- A regenerative thermal oxidizer (RTO) with a caustic scrubber for air emissions;
- Activated carbon adsorption beds to treat water effluent.

The spent activated carbon beds are collected and thermally treated in a certified facility to regenerate the media. The facility continuously performs air monitoring with specialized maintenance restart leak testing, pursuant to a documented leak detection program. Wastewater samples are collected and analysed daily in the on-site laboratory and a bi-weekly report is sent to the chemical park central wastewater treatment plant and to the local authorities. The fluoropolymer scrap materials are shipped for thermal destruction at a certified treatment facility. Strict procedures are followed throughout the manufacturing process to eliminate residual monomers from the fluoropolymer. These are industry standard practices and have been shown to result in monomer content of less than 0.01 ppm in the fluoropolymer (the limit of detection for test). A summary of the annual emissions of Gore fluoropolymer manufacturing facility in 2021 is shown in **Table 2.9**. The emissions shown in **Table 2.9** are worst-case scenario emissions calculated by Gore. Since on-site emissions often are below analytical detection limits, the worst-case scenario is based on the assumption that emissions are just below detection limit. Actual emissions are expected to be significantly lower. Additionally, further water treatment is carried out in the central wastewater treatment plant of the

⁶ As recommended in the EU BREF for polymer production (European Commission, 2007)

chemical park where the manufacturing site of Gore is located, which has not been accounted for in the emission estimates.

Table 2.9: Worst-case annual emissions of fluorinated substances from Gore’s fluoropolymer manufacturing facility in 2021

Emission Source	Volume (tonnes)–worst-case	Control Device	Monitoring
Air	< 0.0005	RTO, Scrubber	Temperature > 1000°C
Water	< 0.00095	Activated carbon filters & site wastewater plant	Routine lab analysis
Annual total	< 0.001	-	-

Notes: Volumes given in tonnes and rounded to the first significant decimal. Total may not therefore sum up.

Manufacture of products containing PFAS

As explained in Section 2.4.2, Gore’s manufacturing process for venting products containing PFAS involves multiple stages occurring both within and outside the EU. The manufacturing steps occurring within the EU mainly use PTFE, which is a PLC. The parts of the products process involving non-PLCs (fluorinated solvents) thus solely occurs in facilities outside the EU. The fluorinated solvents used at this stage constitute part of the process but largely do not remain in the products themselves – at least 95% of the solvents are recycled and reused. The final products that are sold in the EU contain very small quantities of these PFAS. For transparency, the material flow through the manufacturing process is presented for the parts of the production process occurring within the EU (Table 2.10) and outside the EU (Table 2.11) separately.

As shown in **Table 2.10** the amount of PFAS released into the environment due to Gore's production of vents inside the EU are negligible due to existing emission control technologies in place. 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 Gore's processes and thermal oxidizers are used to treat air emission from the fluoropolymer processing operations. The production waste from EU manufacturing process is disposed of via municipal incineration.

Product service life

Gore does not have quantitative data on emissions of PFAS from service life of its vent products because they are used as components within a wide range of end-products by different end-users. However, Gore believes that emissions during their service life are negligible. In larger quantities, only the three fluoropolymers (PTFE, PFA, FEP) are used in venting products. According to Gore, for these fluoropolymers neither the release of relevant quantities of non-polymeric residuals nor the release of degradation products during service life is to be expected for the following reasons:

- The concentration of short-chain residual fluorinated polymerization aids in the intermediate fluoropolymer 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 (3 ppb). Other fluoropolymers purchased by Gore for this use do not require polymer processing aids during manufacturing.

- Fluoropolymers are specifically used in venting applications because they do not react, degrade, or erode, even when exposed to aggressive chemicals or relevant application temperatures. Additionally, Thermal Gravimetric Analysis, one indicator of degradation potential, indicates no weight loss of PTFE below 549°C. The use of the venting products takes place according to the product specifications significantly below the specified temperatures.

Disposal of end products

The venting products covered in this SEA are used in several end products, including automotive vehicles, portable electronics and other industrial end uses. The majority of the PFAS volume contained in venting products covered within this SEA (~90%) is found within automotive vents. The disposal of automotive vehicles is therefore the most pertinent in understanding the end-of-life stage for products relevant to this SEA.

End-of-life vehicles are processed as waste and are, in practice dismantled, shredded or otherwise disposed (Eurostat, 2021). The end-of-life process of a vehicle involves:

Dismantling, depollution, and part removal. Some parts of the vehicle are reused and others are recycled or sent for energy recovery (Non-published industrial association study, 2019). At this stage, hazardous waste, such as oil, coolant, and other vehicle fluids, are removed from the vehicle and are disposed of appropriately.

Shredding. At this stage magnets and other methods are used to pull out the steel, which makes up

approximately 70% of a vehicle's weights, and the non-ferrous metals, allowing these metals to be recycled (Non-published industrial association study, 2019).

Auto shredder residues (ASR). These residues either undergo energy recovery (~60%), are disposed of via landfill (~35%) or are sorted for mechanical recycling (~5%) (Non-published industrial association study, 2019).

The waste treatment of ASR is the most relevant stage for the automotive vents covered by this SEA since it has been reported that the vast majority of fluoropolymers found in vehicles remain in the auto shredder residue (Non-published industrial association study, 2019). It has therefore been assumed that, as presented above, that 60% of the fluoropolymers found in automotive vents are incinerated for energy recovery, 35% are disposed of via landfill and the remaining 5% are sent for recycling.

The disposal of fluoropolymers contained within vents used in portable electronics and other industrial applications are assumed, based on information provided in a study published by an industrial association (2019), to have higher rates of incineration with energy recovery (>80%) and lower levels of waste being disposed of via landfill (<15%), with a small proportion being recycled (<5%)⁷. These estimates are based on the disposal of the fluoropolymers contained within end products, as opposed to the disposal route for the end products themselves. For example, photovoltaic cells are regulated as waste from electrical and electronic equipment (WEEE) and are dismantled for the recovery of aluminium and other metals (which make up 10-15% of the total PV module weight) and glass (which makes up for 70-75%). The share of fluoropolymers is below 1% of volume and is therefore not separately collected and recycled (Non-published industrial association study, 2019).

Based on a weighted estimation of the different disposal routes and volume PFAS found within the respective use categories (automotive and other uses) it is assumed that 63% of vents are sent for incineration with energy recovery, 32% are disposed of via landfill and 5% are recycled.

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 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. In addition, PTFE is not a precursor and is a stable substance that does not degrade across a wide range of conditions, suggesting that it would not break down into any other PFAS when in a landfill.

⁷ These estimates are based on the end-of-life of products used in 'chemical and power' applications and 'other' applications in the non-published industrial association (2019) study.

The stability of PTFE is further highlighted in the varied applications for which it is used, including its use in outdoor environments, in high and low temperatures, and with exposure to many harsh chemicals.

Further information on the degradation potential of PTFE 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 (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 information⁸

EU market for affected products

It is challenging to derive an accurate market size estimate for the type of products similar to the ones listed

⁸ 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

Gore believes that around 80% of venting products similar to those listed in **Table 2.1** that are placed on the EU market by other companies also contain PFAS.

Age Group	All respondents	Non-union respondents	Union respondents	Non-union respondents	Union respondents
18-24	28%	22%	25%	20%	23%
25-34	22%	18%	20%	15%	17%
35-44	18%	15%	17%	12%	14%
45-54	12%	10%	11%	8%	9%
55-64	8%	5%	6%	3%	4%

Broader product categories

(product or geographic) for antitrust purposes, and shares may be incomplete and not reflect all competitive sales or all competitors

Final Report | September 2022

Table 2.13: EU sales statistics for relevant PRODCOM categories

Broader product group	PRODCOM code	Average market size 2015-2020 € million	Gore product(s) within this product group
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Parts of electrical ignition or starting equipment, generators, and cut-outs for internal combustion engines	29313030	4,352	- Automotive Vents for Electronic Enclosures - Automotive Battery Vents
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Articles for the conveyance or packaging of goods, of plastics (excluding boxes, cases, crates and similar articles; sacks and bags, including cones; carboys, bottles, flasks and similar articles; spools, spindles, bobbins and similar supports; stoppers, lids, caps and other closures)	22221950	9,467	Packaging Vents
Telephones for cellular networks or for other wireless networks	26302200	241	- Portable Electronic Vents - Protective Vents - Portable Electronics Thermal Insulation
Headphones and earphones, even with microphone, and sets consisting of microphone and one or more loudspeakers (excl. airmen's headgear with headphones, telephone sets, cordless microphones with transmitter, hearing aids)	26404270	227	Portable Electronic Vents
Other wristwatches, pocket-watches and other watches, including stopwatches	26521200	199	- Portable Electronic Vents - Thermal Insulation Material
Photosensitive semiconductor devices; solar cells, photodiodes, phototransistors, etc.	26112240	1,521	- Protective Vents - Automotive Electronic Enclosure Vents
Electronic pressure gauges, sensors, indicators, and transmitters	26515271	1,004	
Multichip integrated circuits: processors and controllers, whether or not combined with memories, converters, logic circuits, amplifiers, clock and timing circuits, or other circuits	26113003	3,266	
Total	All	27,982	

Notes:

- The values are given in 2022 prices
- n.e.c. is an abbreviation of 'not elsewhere classified'

3. The broader product group titled 'Equipment, n.e.c., for internal combustion engines' (ICE) underestimates the size of the market by excluding battery electric, hybrid and other non-ICE vehicles.
4. In cases where the product group was not available in PRODCOM, data on the end product was collected from PRODCOM and included. It should be noted that the end products included are not exhaustive and Gore's products are used beyond only those listed

Products highlighted in *italic* currently have no sales in the EU, either due to direct customers being outside the EU or the product has not yet reached the sales stage.

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 2.14** 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 2.14: 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
Transport	15,500	18,500	298	345
Renewable energy	500	500	21	6
Total relevant industries	30,500	39,000	607	662
Total EU market	39,500	52,000	799	881

Notes:

1. Transport is a wide industry and only a small share is likely relevant.
2. Values are given in 2022 prices and rounded to the nearest € million. Totals may therefore not sum up.
3. The figures are for the fluoropolymer market at large, of which Gore's and similar products are a proportion.

The automotive industry is a key sector that utilises vents containing PFAS because of the aggressive operating conditions in which vehicle components are expected to work error-free over more than 10 years and the significance of the applications. The availability of durable vents is essential for the EU automotive industry and is interlinked with many downstream industries serving automotive manufacturing. The automotive sector provides direct and indirect jobs to 13.8 million Europeans, representing 6.1% of total EU employment (European Commission, n.d.). Gore believes that vents containing PFAS are used in all passenger vehicles that are on the EU market. Any disruptions in EU automotive production would flow from initial production through all downstream industry applications (e.g., transportation, construction, etc.) of the material, and amplify the economic disruption effect.

As discussed in Section 2.2, vents containing PFAS are also used in a broad range of other industries. Packaging vents are used in the packaging of many end-uses across industries, including agriculture and

chemical manufacturing. Protective vents are present in a wide array of electronic devices. Portable Electronic Thermal Insulation is used to protect portable electronic components (and device end users) from uncontrolled heat exposure. Portable Electronic Vents containing PFAS will be found in most cell phones and laptops in the EU. Portable electronic devices are used across every industry and by consumers. Therefore, it is expected that impacts on the electronics industry supply chain may have wide-reaching economic impacts.

Table 2.15 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 vents industry. These figures also include value added that is not reliant on vents, but it is expected that all these industries and more will to some extent be affected if vents containing PFAS were no longer available. Note that the list is non-exhaustive, i.e., not all affected industries are covered in the table.

Table 2.15: Economic overview of industries in the EU that use vents containing PFAS

Industry	Annual turnover (€/billion)	Employment (million)	Year of publication	Source
Agriculture	190	9.7	2020	(Eurostat, 2022a)
Automotive	968	2.6	2020	(Eurostat, 2022b)
Chemical manufacturing	641	1.2	2019	(Eurostat, 2022b)
Electronics	310	1.0	2014	(Eurostat, 2022b)
Electrical equipment	335	1.5	2020	(Eurostat, 2022b)
Solar power	16	unknown	2018	(Statista, 2020)
Total	2,460	16		

Notes:

1. There is likely some overlap between solar power and electrical equipment.
2. Value for agriculture is given in gross value added (GVA)
3. Monetary values are given in 2022 prices and rounded to the nearest € billion.

2.5.3 PFAS use and emissions in the EU

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 80% 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 80% of the similar products (not manufactured by Gore) are manufactured using PFAS. It is not known whether other companies have their manufacturing sites within or outside the EU, which means Gore's use of PFAS in manufacturing cannot be reliably extrapolated to the EU market. Similarly, it is not possible to derive potential volumes PFAS placed on the EU market through indirect sales (i.e., downstream user imports). Instead, the analysis focuses on the PFAS contained in the products themselves (i.e. excluding PFAS being recycled in the production process, PFAS ending up in production waste and potential indirect sales).

Gore places around 30 tonnes of PFAS on the EU market in products through direct sales, which include

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** that are sold in the EU regardless of the location of where they are manufactured. The second estimate also contains the additional volume used by Gore in their EU-based manufacturing facilities, which does not end up in the products sold in the EU (i.e., production waste and exported products). The EU use volumes presented in **Table 2.16** may therefore slightly underestimate the total PFAS volume placed on the EU market.

[REDACTED]			
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED]	[REDACTED]
[REDACTED] [REDACTED]			
[REDACTED] [REDACTED]			
[REDACTED] [REDACTED] [REDACTED]		[REDACTED]	
[REDACTED]	[REDACTED] [REDACTED] [REDACTED]		

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 purchases the vast majority of PFAS from suppliers for the manufacture of products covered within this SEA, 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.

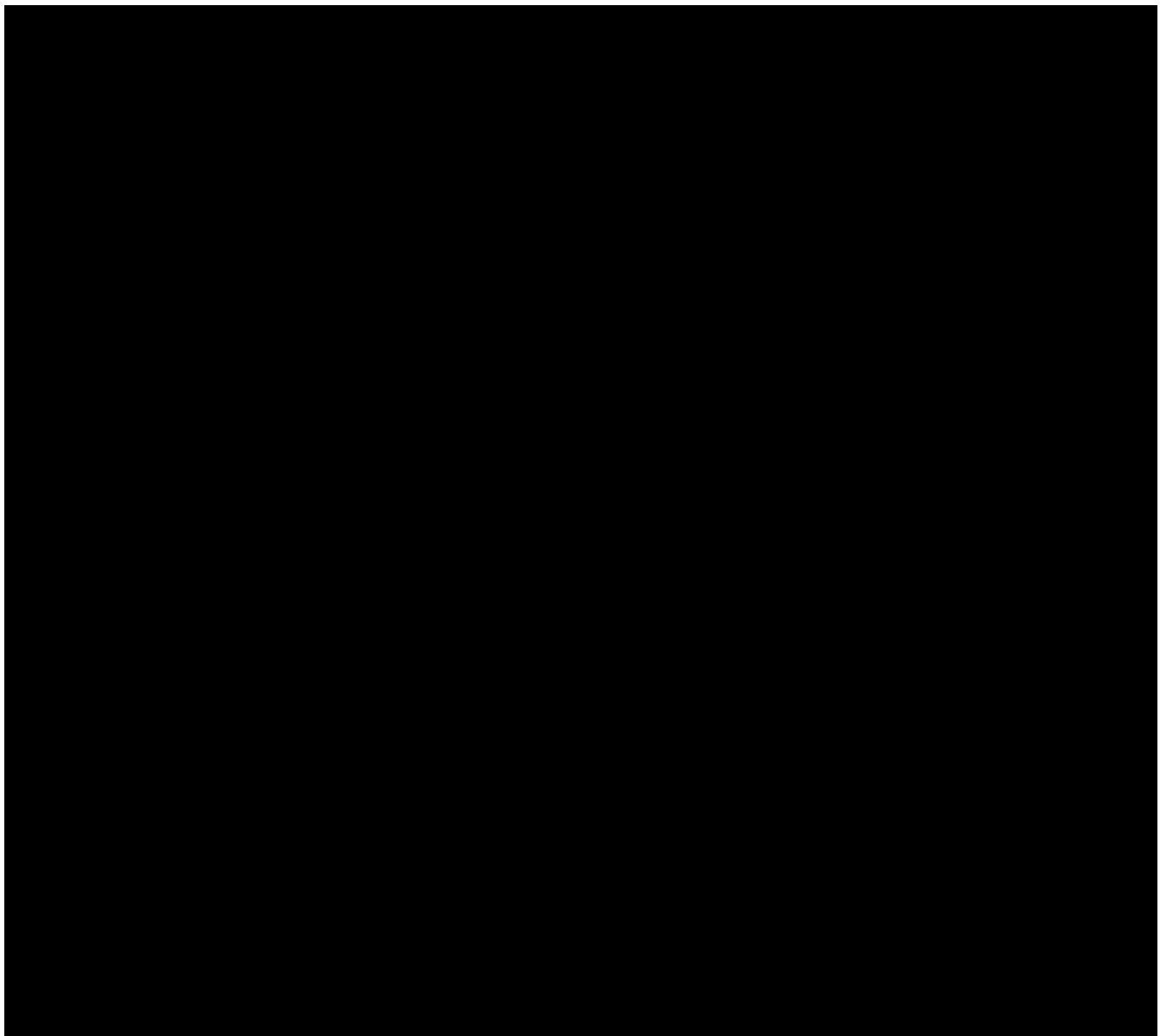
¹⁰ This implicitly assumes that other companies manufacturing similar products do not have significantly higher PFAS waste volumes during the product production process. This is considered a reasonable assumption since PTFE is a relatively expensive raw material (See Chapter 3).

summaries are much higher than the emissions reported by Gore. **In the opinion of Gore, the emissions provided 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 provided by the DS for the service life and end-of-life of PFAS-containing products are overestimated. This is because, as explained in Section 2.4.3, **PTFE 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 the relevant information from the "investigation report summaries" is presented in **Appendix 1 PFAS volumes and emissions across multiple** sectors.

Figure 2.5 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 Figure 2.5 and detailed in the proceeding section are based on information from the DS and do not reflect Gore's data on emissions**. The EU use volumes¹¹ derived in the previous section (PFAS use volumes), was extrapolated from information provided by Gore. The share of PFAS ending up as production waste (5%) is 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 (63%), landfill (33%) and recycling (5%) is based on information from a study prepared for Plastics Europe on fluoropolymer products (Non-published industrial association study, 2019b). The estimates presented in **Figure 2.5** are associated with a high level of uncertainty. The approach and assumptions used to derive the estimates are further detailed below **Figure 2.5**.

Figure 2.5 shows that of the 102 tonnes PFAS that is estimated to be placed on the EU market via direct sales (of products similar to those in **Table 2.1**), and almost all of this remains in the products until end of life. More than half of PFAS in waste streams (relevant for this SEA) is believed to be incinerated, for which emissions are likely negligible (Aleksandrov et al., 2019), with approximately a third being disposed of via landfill. The "investigation report summaries" also indicates that overall emissions from fluoropolymers in waste streams is low (<1%).

¹¹ Note that PFAS used in production that is not contained in products placed on the EU market is only shown for Gore, i.e. these have not been extrapolated to the EU – see further explanation in the previous section. Volumes manufactured outside the EU that is placed on the EU market by the manufacturer of the product (i.e. not the DU), is, however, included.



Manufacture of products containing PFAS

Gore manufactures these products both within and outside of the EU, however, the locations of the production sites of other companies manufacturing similar products are not known. This means that there is no basis for reliably deriving total volumes used for the manufacture of products similar to those set out in **Table 2.1** in the EU, beyond what ends 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, although the EU volumes are unknown.

- Gore states that there are negligible (~0%) PFAS emissions from the manufacturing of their products, due to the use of emissions control technologies in manufacturing sites. Gore believes that if similar or equally efficient emission control technologies are used by other companies (which may have production sites located in the EU). Emissions from product manufacture are 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 PFAS volumes and emissions across multiple sectors), provide estimates for PFAS volumes and emissions in the electronics and energy sector¹². This report covers a different and significantly broader range of products than the products covered 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 products¹³.

The DS estimated that the upper bound for emissions from fluoropolymers is around 1.5% 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 around 5% (see Section 2.4.3). 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.

Lastly, the share of PFAS that compromises the products after the production process waste was derived by subtracting the share ending up in waste (5%) reported by Gore and the DS' emission share from product manufacture (1.5%). Since the locations of manufacturing sites for other companies are not known, the PFAS used for manufacturing in the EU that do not end up in products (primarily production waste) could not be estimated.

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. Due to the reason stated above in Section 2.4.1, 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.
- Based on the *"investigation report summaries"* for the electronics and energy sector, it was estimated that an average of 0.04% of fluoropolymers compromising products used in these industries are emitted during the products' service life. This emission factor is based on emissions from fluoropolymers in the energy sector and is therefore unlikely to be fully representative of the

¹² The DS also published reports on the transport sector and on cleaning agents, which are relevant to the end-use industries of the products detailed in this SEA. However, these reports did not provide emissions or waste data and hence could not be used in the relevant calculations.

¹³ The emission factors have been extrapolated from the *"investigation report summaries"* based on the volumes and emissions of fluoropolymers. These emission factors have been applied to all the PFAS types covered in this SEA, including fluorinated solvents. Fluorinated solvents have higher emissions factors but due to their high recycling rate (95%) and the low concentrations in the final products on (<500 ppm), any emissions of these will be negligible compared to other estimated emissions.

emissions from service life of products covered within 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 0.04% (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%¹⁴, the volume of PFAS from the products similar to those in **Table 2.1** that ends up in waste streams is estimated at just [REDACTED]. The majority of PFAS volume (~90%) is contained in vent products placed on the EU market are installed in automotive vehicles. A significant share of land-based vehicles is exported or sold outside the EU after deregistration, both legally and illegally, estimated at around 30-40% (Non-published industrial association study, 2019b; Taylor, 2020). PFAS contained within these vehicles will therefore end up in waste stream outside the EU. The PFAS values entering EU waste stream is therefore believed to be significantly lower than [REDACTED], likely closer to [REDACTED] per year in total. However, to ensure a conservative approach for estimating emission, the full [REDACTED] per year has been taken forward as the volume ending up in EU waste streams. It is believed that around 63% of the end-products are incinerated ([REDACTED]), 32% are landfilled ([REDACTED]), whilst the remaining 5% is recycled (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 do not estimate the emissions associated with each waste stream but the emissions from fluoropolymers across all waste streams are reported at around <1% 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 at <1 tonne 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 of 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

¹⁴ Exact number is 99.96%.

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

Table 2.17 presents the two emission estimates alongside the best estimate for EU PFAS contained in products. If vents manufactured by other companies comprise similar types of PFAS as Gore's vents, the share of PLCs in the reasonable worst-case emission scenario would be >97%. In the worst-case sensitivity emission scenario, it is assumed that all manufacturing occurs within the EU, and thereby implying a higher share of non-PLCs. However, since 95% of the non-PLCs are recovered and reused, it is estimated that the share of PLCs within the emissions of PFAS would still be >90% (assuming that Gore's production process is to reasonably representative for EU manufacture of similar types of vents). It should also be highlighted that due to upcoming restriction on PFHxA and related substances, the side chain fluoropolymers will be phased out in the EU. This means that the share of PLCs used in the EU will be even higher in the future.

Based on the argumentation presented above, the volumes and emissions presented in **Table 2.17** 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 2.17: 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).	■
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.	■
Worst-case 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).	■

Notes: Volumes are rounded to the nearest tonnes.

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 et al., 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 the six types of PFAS to manufacture the venting products covered in **Table 2.1**:

Similar to other PFAS, PTFE, PFA and FEP are persistent, but data demonstrates that they do not meet the criteria for being mobile, bioaccumulative or toxic (Henry et al., 2018). PTFE, PFA and FEP 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, which 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, PFA and FEP are PLCs based on widely accepted criteria¹⁵ one of which being that they do not breakdown into degradants of concern. **Table 2.18** sets out the criteria used and key results from this study, where the conclusion is that PTFE, ETFE, FEP and PFA are PLCs.

A more recent study (Korzeniowski et al., 2022), building on the research conducted by Henry et al. (2018) found that 14 additional fluoropolymers¹⁶ (including polyvinylidene fluoride (PVDF) and ethylene-chlorotrifluoroethylene (ECTFE)) are also PLCs, having passed the same 13 criteria (tests) outlined in the original 2018 study.

¹⁵ 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.

¹⁶ 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, tetrafluoroethylene, and perfluoroalkyl-vinyl-ether (CPT); and terpolymer of tetrafluoroethylene, hexafluoropropylene and vinylidene fluoride (THV), tetrafluoroethylene-propylene co-polymer (FEPm); hexafluoropropylene-vinylidene fluoride co- and terpolymers (FKM); and a tetrafluoroethylene-perfluoromethyl vinyl ether perfluoroelastomer (FFKM).

Table 2.18: PLC criteria from study by Henry et al. (2018)

Assessment criteria	Fluoropolymers			
	PTFE	ETFE	FEP	PFA
	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 ¹⁷	241 000–575 000 ¹⁷	200 000–450 000 ¹⁷
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 ¹⁸ (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 ratio to MW)	<1 (see section Reactive functional groups and RFG ratio to MW)
FGEW ¹⁸ (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 ¹⁹ (121 °C)	No active leachables by USP class VI ¹⁹ (121 °C)	No active leachables by USP class VI ¹⁹ (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

¹⁷ Molecular weight is weight average molecular weight.¹⁸ 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).¹⁹ 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	PTFE	ETFE	FEP	PFA
Structural similarities to RFG of concern (increases potential risk of adverse effects)	None	None	None	None
Reference standards 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
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, A., Saidi, s., Santos, L. R., And Mudga (2015).

Gore also uses [REDACTED] to provide enhanced oleophobicity on the surface of the PTFE membrane. The enhanced oleophobicity is necessary to resist contamination and provide the levels of protection needed in the applications. [REDACTED]



[REDACTED] The technical work and customer validation for this transition will be completed by June 2025.



The fluorinated solvents are manufacturing aids [REDACTED]. These solvents that are solely used in production steps occurring outside the EU and only a very small amount of residual solvent left on the final product (Gore estimate the levels of fluorinated solvent in the final product to be <500 ppm). Neither of these fluorinated solvents have a harmonised hazard classification (CLH) and has no hazard classifications based on available information.

Risks

PFAS is, as mentioned, a large group of substances (>6,000) which is being proposed for a REACH restriction due to persistence. Gore predominantly uses fluoropolymers that are categorised as PLCs, in the manufacturing steps carried out within the EU. The fluoropolymers used by Gore do not have a harmonised classification (CLH) and data demonstrate that they do not meet the criteria for being mobile, bioaccumulate or toxic and they have been categorised as a PLC (Henry et al., 2018; OECD, 2009). The side chain fluorinated polymers used by Gore in manufacturing in the EU are not categorised as a PLC, but these make up a small proportion of the PFAS volume used in manufacturing in the EU and Gore will be phased out by 2025, ahead of the PFAS restriction entering into force.

98% of PFAS used by Gore within the EU are PLCs. Outside the EU there is a higher share of non-PLCs used in manufacturing of vents, specifically fluorinated solvents, but 95% of these are recycled and only traces (<500 ppm) of the non-PLCs end up in the final products. In total it is estimated that 97% of the PFAS used (including imports in products) by Gore in the EU are PLCs. Even though small amounts of non-PLCs are used, emissions to the environment throughout the lifecycle are considered to be negligible by Gore.

Although information on the type of PFAS used by other companies is not available, Gore considers it likely that similar types of PFAS are used by other companies manufacturing comparable products. Therefore, the risks from PFAS associated with the products covered by this SEA are considered limited.

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 2.2% 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 vents are not restricted during the assessment period.

Age Group	Gender	Vaccinated (%)
18-24	Male	~10
	Female	~10
25-34	Male	~15
	Female	~15
35-44	Male	~25
	Female	~25
45-54	Male	~35
	Female	~35
55-64	Male	~45
	Female	~45
65+	Male	~55
	Female	~55

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 (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 has performed technical and scientific R&D for more than 50 years to be able to manufacture and sell PTFE-based products that are on the market today. However, Gore has started conducting R&D with the aim of identifying potential alternatives to PFAS for their venting product group.²⁰ More specifically, over the past year, Gore has been intensifying work on substitutes for PFAS used in their venting portfolio. **Table 3.1** lists the PFAS used in Gore's venting products and includes the rationale as to why substitution of PFAS is difficult or not possible.

Table 3.1: PFAS contained or used (in the manufacturing process) in products and alternatives

Gore product	PFAS used in product	Reasons why substitution is difficult/not possible
Automotive Powertrain Vents	PTFE, PFA and fluorinated solvent	No in-kind solutions exist, but non-PFAS tube vents and various one-way valves/tortuous paths exist. However, there are issues with these non-PFAS products that could reduce the lifetime of drivetrains and/or complicate design of drivetrains by adding additional materials (volume), weight, etc. High levels of drivetrain protection and the ability for the component to be tightly packaged are critical for adoption of newer e-Drivetrains – where minimising space and weight are core requirements to minimize energy consumption.

²⁰ Gore have been conducting R&D into non-PFAS containing replacements for PTFE, PFA and side chain fluorinated solvent since July 2021, February 2017 and November 2019, respectively.



Gore product	PFAS used in product	Reasons why substitution is difficult/not possible
Automotive Electronic Enclosure Vents	PTFE, PFA, fluorinated solvent, side chain fluorinated polymer ²¹ and perfluoroalkylether carboxylic acid dispersant	Alternatives to Gore Vents for automotive electronic enclosures do not always meet all the requirements, i.e., specifications that are mandatory to be met by OEMs and Tier 1s, mainly related to chemical resistance, durability (ingress protection) and high temperature resistance up to +150°C. In case reduced application requirements allow the use of an alternative, the automotive industry is still in general very hesitant of changing an existing and working system. Not only because of the technical risk, but also the validation efforts (time, resources, investments) and the communication towards and approval by the OEM.
Automotive Battery Vents ²²	PTFE and FEP	Fluoropolymers are the only known material capable and compatible with the end application. As explained in Section 2.4.1, PTFE is required to produce a thin, high-strength micro-porous substrate (membrane) that has a unique combination of high airflow whilst also exhibiting high liquid entry pressure. These characteristics are required for Gore's Automotive Battery Vents to function effectively.
Packaging Vents	PTFE, PFA and fluorinated solvent	No alternative polymer resin has the same (or close to the same) chemical compatibility. Any alternative resin might be degraded in the presence of highly concentrated chemicals and hazardous liquids could leak as a result.
Protective Vents	PTFE, PFA, fluorinated solvent and side chain fluorinated polymer ²¹	Protective Vents are mostly used in environments where functionality matters, and failures can lead to (in some cases potentially catastrophic) failures. The temperature during use ranges from -60°C to +125°C (some applications even reach +150°C). Due to long lifetime requirements (of 10-15 years) and harsh end-use cleaning, high pressure spray resistance is needed. Fluoropolymers are the only group of substances that can function in these conditions without suffering from premature failure, no other material is known to Gore that can replace them for this function.
Portable Electronic Vents	PTFE, PFA, fluorinated solvent, side chain fluorinated polymer ²¹ and perfluoroalkylether carboxylic acid dispersant	While alternative materials exist, they do not deliver the same combination of performance characteristics. Substitution will result in compromising/accepting lesser performance / inferior products and reduce the durability and lifespan of each device.

²¹ Currently, the side chain fluorinated polymer is used for oleophobic coatings. However, Gore aims to replace any use of side chain fluorinated polymer with PFA (which is already used in Gore's Venting products) and have the technical work and customer validations completed by June 2025.

²² Gore have been trying to substitute PTFE and FEP in Automotive Battery Vents for between 6 months and 1 year (as of Q1 2022).

Gore product	PFAS used in product	Reasons why substitution is difficult/not possible
[REDACTED] [REDACTED] [REDACTED]	[REDACTED]	[REDACTED] [REDACTED]
Portable Electronics Thermal Insulation	PTFE	The use of PTFE and the unique microstructure enables the desired low thermal conductivity in an extremely thin material. There is no known non-PFAS based material that meets this performance attribute.

Source: Gore (2022; 2021)

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

This notwithstanding, Gore has no other indication or proof that any non-PFAS alternative material exists to replace PFAS substances in the vast majority of Gore venting product portfolio. For example, Gore has not been able to identify any non-PFAS materials that provide the oleophobic performance of PFA's. However, [REDACTED]

[REDACTED]
[REDACTED]

[REDACTED] These approaches have shown some initial promise on the laboratory-scale but are many years away from commercially viable and high-volume production capability. A commercial viability process can take over 6 years. Currently, Gore is far away from developing a commercial product for automotive vents that does not use a solvent. There is a difference between developing the first commercially available product and being able to offer all of Gore's products without a solvent. Gore has no technical proof that alternative materials would be capable of replacing PFAS in their entire product range. Nevertheless, using an alternative material for some applications might be possible; however, such applications are currently unknown. In addition, industry efforts and standardisation will be required on all products that use an alternative material.

Establishing the laboratory-scale evaluations of these alternative treatment technologies alone is unpredictable, time consuming and costly, and even after the technical feasibility and product performance for the alternative (for each PFAS used) has been verified – the second challenge is establishing the reliable high-volume manufacturing capability; this is further explained in Section 3.5.

3.3 Technical feasibility

Due to the high cost of PTFE and other fluoropolymers relative to other materials, both upstream and downstream users have spent several decades (incentivised by cost reduction) minimising their use of

²³ Gore have been trying to substitute PTFE and FEP in Portable Electronics Battery Vents for between 6 months and 1 year (as of Q1 2022).

PFAS. Despite these strong economic incentives to substitute, Gore has not identified any suitable alternatives for vents which offer the same technical performance as the products listed in **Table 2.1**. The PFAS [REDACTED]

[REDACTED] in Gore's venting products are used for their unique chemical properties, that are outlined in Section 2.4.1 and cannot be replaced by non-PFAS alternative materials.

Any fundamental change to the core material of Gore's venting products, such as substituting PFAS materials with non-PFAS alternatives, is a massive challenge and is expected to require intense and long-term scientific and technical developments. Fundamentally substituting PFAS materials in vents is not only a matter of R&D / reformulation costs and time, but also making sure that any substitute technology is fit for end-use in every single venting application.

In order to maintain a reliable performance of the end-product that contains Gore's venting product, the raw materials used by Gore need to satisfy the most challenging demands with regards to chemical and/or physical resistance and longevity/durability. These include (but are not limited to) having a high melting point, being chemically inert and providing high levels of oleophobicity. Section 2.4.1 discusses the PFAS used by Gore in their venting products and the technical function(s) of the raw materials. The technical performance of the raw materials directly impacts the performance of the end-product (that contains Gore's vents). **Table 3.2** shows the Gore venting products, the end-products that they are used in and the function that the Gore venting products exhibit (within the end-product).

Table 3.2: Gore venting products and the function they provide in end-products

Gore products and the end product they are used in	What function(s) does the Gore product play in the end product?
Gore's Automotive Powertrain Vents are used in automotive light duty powertrain components and Selective Catalytic Reduction²⁴ fluid reservoirs – which are included in passenger- and light duty vehicles.	• Gore's Automotive Powertrain Vents have a number of different functions: • Protect Powertrain components from water (rain, snow, car wash/pressure spray) and salt mist, keeping the component tight/sealed. For example, axles/transfer cases/transmissions are subject to submersion during flooding, off road driving, launching watercraft, etc., the membrane allows protection of the component during water exposure and then fast pressure/vacuum release when back in contact with air. High pressure car wash sprays are also often used on vehicle undercarriages. • Equalise pressure over lifetime, avoiding vacuums and pressure on Powertrain component seals to ensure reliable component tightness. For example, axles/transfer cases/transmissions/etc., are subject to heavy temperature differentials as the component heats up during power transfer and then is cooled after use. The most extreme case being a hot component contacting cold water, rapidly generating a vacuum pressure. The membrane enables pressure equalisation unless submerged and continuous contamination protection. Without this protection seals could be compromised or require heavier designs. • Repel aggressive automotive fluids (e.g., gasoline, power steering fluid, tar remover, windshield washer fluid, antifreeze), preventing damages to Powertrain components. For example, axles/transfer cases/transmissions/etc., can be located at the lowest points and are subject to both vehicle and road level fluids, oils, fuels, etc. • Guarantee tightness against dust, keeping Powertrain components dust tight. For example, axles/transfer cases/transmissions/etc. are subject to dust/dirt/mud exposure during driving in harsh environments/unimproved roads/off roading/etc. The membrane allows constant pressure equalisation during these events while keeping any solid contamination out of the component. • Withstand extreme temperature ranges over vehicle lifetime – from freezing to under-the-hood heat (-40C to +125C). For example, axles/transfer cases/transmissions/etc. can operate at high temperatures and be in

²⁴ The process of Selective Catalytic Reduction (SCR) can require adding AdBlue to diesel during combustion. The AdBlue (ureic acid) is stored in a separate chamber in the car. Gore vents prevent the aggressive acid to stream into the car (but remain in the reservoir) and they equalise pressures in those AdBlue reservoirs, for example, created through temperature changes.

[REDACTED]

proximity to other high temperature components (exhaust, engine, turbo, etc.) this requires a high temperature resistance.

[REDACTED]

[REDACTED]

Automotive Electronic Enclosure Vents are present in electrical and electronic modules that are mounted under the (automotive) hood. Examples are control units (engine CU, transmission CU), Anti-lock Braking System, sensors for drive assist and passenger / pedestrian safety systems, actuators, hybrid / electric vehicle components (inverters, on board chargers), motors, pumps, etc.) in passenger vehicles and light duty trucks.

Gore's Automotive Electronic Enclosure Vents keep control units, sensors and actuators, motors and hybrid/electric components functioning accurately and reliably for the long term, despite ongoing exposure to harsh operating conditions. Whether mounted under the hood, or near the undercarriage, these electronic modules require reliable protection from extremes of temperature and pressure; from water splashes, sprays, or deep wading; and from damaging automotive fluids and dust, dirt, and road debris. Gore Vents for electronic enclosures reliably withstand these hazards, durably protecting sensitive electronics from damage, degradation, or premature failure in harsh or extreme environments.

They effectively block ingress of rain, sleet, snow, dust, dirt, and debris. They rapidly and continuously respond to pressure differentials, quickly equalising over-pressures and vacuums. This protects the integrity and longevity of seals, as well as preventing water and contaminants from being drawn into the module.

[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
Gore's Packaging Vents are used as part of packaging containers / enclosures in Chemical Packaging (for example, Dangerous Good Packaging, Professional Cleaning, Disinfectants, Household Chemicals (Drain Cleaner, pipe clog remover), Agro Fertilizer, Agro Biostimulants and Agro Pesticides).	The primary function is to equalise pressure in hazardous chemicals packages such as hydrogen peroxide, peracetic acids and bleach. The pressure in the container can increase up to a point where the container bloats, however, if this continues, the container could leak or even burst. In worst cases this could harm people or pollute the environment. Gore Packaging Vents enable pressure balancing and ensure leak-proofness over the product life cycle.
Gore's Protective Vents are typically installed/enclosed in electronic components. These electronics are essential for the functionality of a final device or end-product, for example heavy duty equipment, traffic lights, etc. In gas sensor applications Gore products are used for environmental protection as well as integrated components which allow the gas sensors to function.	Gore Protective Vents are used in a variety of applications in uncontrolled changing environments such as rain, snow, wind, sun, thunderstorms where reliable performance over lifetime of the device is essential. The primary function in most cases is pressure equalisation of electronic enclosures as well as protection from uncontrolled environmental challenges (rain, liquids, particles) which would lead to failures, up to catastrophic failures and shorter lifetime of device (increased need for replacement). In addition, rapid cool down or heating up can occur due to uncontrolled environmental conditions (sun, rain, wind, thunderstorms, etc.), so Gore's vents must regulate temperature and pressure.
Gore's Portable Electronics Thermal Insulation can be used on antennas, Computer Processing Units, Graphics Processing Unit, batteries, or any other component inside a mobile electronic device.	Gore's Portable Electronics Thermal Insulation protects the surface of mobile electronic device from excess heat created by the device itself. Additionally, it protects heat sensitive components inside the device from the heat created by other components inside the device.
Portable Electronic Vents are used in device case pressure vents, speaker and microphone vents in consumer and industrial electronics (including smartphones, speakers, earbuds, headphones,	Gore's Portable Electronic Vents are used in the protection of sensors, microphones, and speakers in electronic devices (i.e., smartphones, headphones / earbuds, watches, smart speakers, radios, etc.). Protection from water and contaminants enables the use of these electronic devices in external environments contaminated with dust, water, and other fluids. Water and dust ingress can prevent accurate sound transfer in or out of devices. It can damage devices,

SEA of restricting use of PFAS in vents

[REDACTED]

watches, 2-way radios, and all voice activated electronics).

including small microphones and speakers. Adhesion of water or dust to the exterior of vents can affect sound quality and make the device not fit for use. Device specifications require acoustic performance after exposure to contaminants.

[REDACTED]

[REDACTED]

Source: Gore (2022; 2021)

Gore indicated that, to the best of their knowledge, there are no drop-in alternative substances that can replicate the use of PFAS in their products. As mentioned in Section 3.2, PE substrates are still undergoing R&D to see whether they can replace the use of PTFE in a small number of 'low performance' products. Gore notes that there are some non-PFAS microporous membrane materials on the European market. However, these materials have already been explored by Gore, and while such non-PFAS materials were found to provide adequate performance for some vents used in 'non-harsh' conditions, these materials were not viable for products used in harsh environment applications as currently served by Gore. These (harsh) uses require vents made with the combination of temperature stability and chemical resistance (inherent in PTFE) that can be processed into a thin, microporous substrate. Despite Gore's efforts to date, it has not been possible to successfully validate sufficient performance (based on customer specifications) of a non-PTFE based vent in their current market applications / products. Furthermore, as Gore do not sell any non-harsh venting products, no substitution of PTFE has taken place.

Fluoropolymers are known to provide the highest level of oleophobicity based on their inherently low surface energy (3M, 2022).²⁵ It is unlikely that a non-PFAS substance will meet the required low surface energy, however a variety of surface treatment technologies are being explored by Gore. Oils or harsh chemicals in the application's environment would contaminate the surface leading to the ingress of moisture and other materials that would degrade the performance and lifetime of the end-use device.

Assuming that a new non-PFAS material in the future may meet performance, manufacturing, and regulatory requirements, it may easily not meet cost and profitability targets. If material costs are increased, or productivity is reduced / limited economies of scale, and market conditions mean that it is not possible to pass these costs onto the customer, then these non-PFAS materials may not be economically viable.

The challenges with finding alternatives to PFAS in Gore's venting products used in the automotive sector is also highlighted by the German Association of the Automotive Industry (2021: pg 3) which states that *"without PFAS, both existing vehicles and future automotive technologies would be inconceivable"*. The reasons given by the Association is that components containing PFAS *"satisfy high standards and quality requirements"*, including *"guaranteed vehicle safety, reliability under large temperature fluctuations, flame retardancy and high durability over the whole lifecycle of 15 to 22 years"* (German Association of the Automotive Industry, 2021).

Table 3.3 details some of Gore's venting applications, their non-PFAS alternatives available currently on the market, and their suitability compared to PFAS-containing vents.

²⁵ Low surface energy refers to materials with a surface energy below 36 dunes/cm. These materials are very difficult to bond to and are often used as 'non-stick' surfaces.

Table 3.3: Gore product portfolio available alternatives and potential suitability

Type of vent	Availability of alternatives without PFAS available on the market today	Which applications are the alternatives used in?	Suitability of available alternative products without PFAS
[REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
Automotive Electronic Enclosures Vents	Open venting solutions (like tubes) do equalise pressure but cannot protect against liquid intrusion, which would lead to component failure. There are a few PTFE membrane style alternatives (using polymers such as polyether sulfone (PES) and polyethylene terephthalate (PET)) which cannot meet the combination of attributes that PTFE exhibits - specifically around chemical resistance, temperature stability, mechanical robustness, and durability.	Membrane alternatives are used in less challenging environments (for example, temperature requirements) or systems (for example, Tire Pressure Monitor systems) or less safety critical electronic applications. Open venting solutions are not an option for electronic enclosures.	Automotive Electronic components need to be protected in a reliable and durable way. Open venting solutions (like tubes) do equalise pressure but cannot protect against liquid intrusion, which would lead to component failure. They are currently no viable alternative to PTFE.
Portable Electronic Battery Vents	There is currently no alternative product to Gore's Electronic Battery Vent,	No alternative exists.	No alternative exists.
Automotive Battery Vents (including	There is currently no alternative product to Gore's catalytic device (which is used in traditional lead/acid batteries in	No alternative exists to Gore's vents. However, an alternative technology to lead-acid batteries is 12v lithium-ion	No alternative exists to Gore's vents. However, 12v lithium-ion batteries have cost and recyclability issues compare the lead acid batteries.

Type of vent	Availability of alternatives without PFAS available on the market today	Which applications are the alternatives used in?	Suitability of available alternative products without PFAS
Gore Automotive Electronic Enclosure Vents)	start/stop applications). The only alternatives to an automotive battery are other driving technologies (e.g., combustion engine or fuel cell engine). Currently no alternative product available for Li-ion gas release (LGR) vent. Alternative technologies would involve the use of different battery chemistries or the acceptance of reduced vehicle range and battery life.	batteries (which can be used in traditional internal combustion engines, Battery EVs, Hybrid EVs, and Fuel Cell EVs).	
Automotive Powertrain Vents	Tube (snorkel) vents / rubber valves – these are typically, long (~1m) rubber tubes. Jiggle cap vents (one-way valves) – these are typically metal with a spring-loaded elastomer. Rattle caps – these are typically, plastic, only protects from large solid contamination.	Lubricant filled powertrain applications that have the space to route long tubes or are not concerned with vacuum or risk of contamination.	Have an increased cost, require additional rubber (which increases weight), increases installation labour, and can restrict design freedom. Without the (PFA) oleophobic coating the oleophobicity is reduced and the rubber valves are not chemically resistant and have a shorter lifespan. Also, EV vehicle architecture makes packaging a long tube increasing difficult, while EV traction motors can be sensitive to vacuum pressures. Require the addition of a vacuum to the system. Are more likely to leak than Gore's alternatives which can lead to contamination entering the component. Are not viewed as a replacement / alternative to Gore vents as any water / liquid / dust contact is possible and therefore the performance is not similar.
Packaging Vents	Almost 100% of the targeted end uses contains PFAS. An alternative product without PFAS could be a mechanical valve, which was considered a state-of-the-art product around 20-25 years ago,	Alternative no longer used.	Mechanical systems such as rubber valves could also compensate for overpressure. There are a few negative aspects, why these products are not used (anymore): • Packaging would require a much higher weight, which is

Type of vent	Availability of alternatives without PFAS available on the market today	Which applications are the alternatives used in?	Suitability of available alternative products without PFAS
	but these are no longer used because of economic and safety reasons.		economically and ecologically a challenge. With PFAS products the weight could be reduced between 10-30% (depending on size of the packaging). Alternatives are economically and ecologically worse because packaging has to be designed heavier (higher wall thickness). The Total Cost of Ownership (TCO) of the packaging includes higher raw material costs, higher processing cost and higher recycling costs. • Alternatives cannot compensate under pressure, which is needed during shipments in different climates. • Alternatives have a wide opening pressure range. A low opening pressure could result in leakage and a high opening pressure could bloat the container. When mechanical systems open during pressure release, they could spill chemical content and expose people (or the environment) to potentially dangerous substances. • Mechanical valves lose performance over product life cycle and the risk of leakage increases over time. Liquid typically dries out in the sealing area of the valve. The result is leakage or higher opening pressure, which then finally leads to dangerous bloating.
Protective Vents	“Hydrophobic-only” membranes are available but do not pass the challenges of lower surface tension liquids and do not meet lifetime expectations. Thus, they are not suitable for harsh environment applications.	For demanding applications no non-PFAS materials have been identified to meet requirements on low surface tension liquids and lifetime. Allowing ingress of low surface tension liquids is a no-go, compromising on lifetime does	There is an ongoing investigation regarding the suitability of PE membranes. However, the typical application requirement is to withstand temperatures up to 150°C (for engines). Gore is not aware of other materials that could withstand those requirements (other than PTFE). Thus, alternatives cannot meet long-time performance requirements which will lead to reduced lifetime of electronic

Type of vent	Availability of alternatives without PFAS available on the market today	Which applications are the alternatives used in?	Suitability of available alternative products without PFAS
	For Acoustic protection alternative materials are precision woven materials with defined openings. However, the water / liquid retention and dust-proofness show a much lower performance level.	not meet economic reality and has negative impact on environmental footprint (more frequent replacements)	components. As a result, devices will need to be replaced more often and thus, disposal rates would increase and the consumption of materials for electronics would be greater, which has a negative impact on the environment.
Portable Electronic Vents	There are alternative protective materials that deliver a lower level of protection and eliminate the ability to deliver the performance expected in higher performing portable electronic devices.	No, non-PFAS materials have been identified for these applications. While non-PFAS based materials are being considered, no non-PFAS materials have been identified yet that meet all the current performance requirements of these applications.	Alternative materials come at the expense of reduced performance in both sensor performance and protection level. Lower protection levels can cause end products to fail faster resulting in devices needing to be replaced more often, increased recycling of electronics, higher consumption of ingredients / materials which has a negative impact on the environment. Furthermore, IP68 water protection has become the standard for waterproof claim. No non-PFAS materials have been identified for these applications.
Gore's Thermal Insulation products	Non-PFAS Thermal Insulation products, which utilise a PET textile (non-woven or PET film) substrate or fibre glass substrate, where the aerogel particles are coated onto and/or into these substrates.	The alternatives have been used in mobile handset and laptop applications that are mid-tier in performance, meaning that they generate less heat, and therefore have less need for high quality thermal solutions.	They are very inconsistent in their aerogel particle loading and thickness distribution. The consequences of this are that a company could have manufacturing problems when they receive an insulation product that is too thick, or, have heat problems if the insulation product is too thin, or the aerogel is too unevenly distributed – which would lead to potential burn injuries to end users. Furthermore, the particles also are not well bound to the alternative substrates, so any flexing of the material can cause the particles to flake / fall off. This can lead to even more inconsistent performance (as described above) and can also cause damage to the internal components of the device as most are dust sensitive. Lastly, this inconsistency can lead to the injury of the manufacturing person(s) applying the part if the dust is inhaled.

Source: Gore (2022; 2021)

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 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.

■ may replace the use of PTFE for very few of Gore’s venting products, but the technical feasibility is uncertain. However, ■ this will only be possible for a small (<10%) fraction of Gore’s venting portfolio, and it is therefore assumed that the increased demand ■ will be limited, and Gore will be able to obtain adequate volumes of ■.

3.5 Cost and timeline for transitioning to alternatives

Gore perceives the likelihood of technically replacing PFAS in Gore Vents and succeeding commercially as very low, i.e., it is highly unlikely that substitution of PFAS will be technically and economically feasible for the vast majority of their vents. Gore note that it is only technically feasible to estimate the cost of substitution of PFAS materials (to non-PFAS materials) after 2032 (7 years after the proposed Entry into Force (EiF) of 2025). After 7 years, Gore estimate that 10% of their venting portfolio can be substituted – this is estimated to cost €70 million. This assumes that R&D into PE (discussed in Section 3.2) replacing PTFE as the base-substrate for some venting products is technically feasible.

Following this, 10 years after the proposed EiF, Gore estimate that a further 40% of their PFAS-containing venting portfolio can be substituted – provided that alternative materials and production processes are identified, which are not apparent yet. This is projected to cost over €100 million. Furthermore, in Gore’s experience of developing and commercialising replacement products, it is believed that increasing investments would not reduce the timeline for substitution.

Table 3.4 details Gore’s estimates for time frames and costs (alternative development investments) required for transitioning away from the use of PTFE, PFA and fluorinated solvent to non-PFAS alternatives. This includes the time required to find alternatives and integrate them into the Gore production process – summarised below in a five-step substitution plan required for Gore’s products to be reformulated successfully:

1. **Planning** - This involves initiating the substitution or reformulation project internally.
2. **Development** - This involves an iterative stage of R&D, (re)formulation and lab testing.
3. **Qualification and/or Validation** - This involves testing and validation with customers and/or external testers.

4. **Certification** - This involves review and testing by standard setters and/or regulators. For example, all Gore products sold into the Automotive applications must meet IATF standards. Additionally, all Gore products have many application-based standards that must be met, such as ISO, REACH, RoHS, and others.
5. **Production** - This would involve implementing the manufacturing plan for the alternative, including a possible pilot phase, regulatory approval and/or updates to the production line.

Furthermore, within this, the internal substitution milestones are the same for each substance: (1) Reach TFP²⁶, (2) Reach PFP²⁷, (3) Design and build commercial equipment, and (4) Internal validations. The costs below include resources costs (employees), capital costs (CAPEX) and non-capital costs. Examples of non-capital costs include non-saleable consumable materials, labour costs, and other costs not directly associated with design and building equipment.

Table 3.4: Minimum time frame and costs for Gore to replace PFAS substances in venting portfolio in the EU

PFAS Substance	Time frame (Years)	Capital costs (€ million)	Resource investment (€ million)	Non-capital costs (€ million)	Total costs (€ million)
PTFE	>11	50	20	5	75
PFA	>12	25	25	5	55
Fluorinated solvent	>8	20	10	5	35
All venting products (minimum)	>15	95	55	15	165

Source: Gore (2022; 2021)

Notes:

1. The costs of replacing PFAS are highly uncertain, due to the fact substitution may not be feasible. The numbers have been rounded to nearest €5 million.
2. The numbers in **Table 3.4** are estimates made by Gore for this SEA report. These should not be viewed as accurate representations of the cost of substituting PFAS from Gore's venting portfolio.

In addition, in all of the above cases, customer approvals (or, validations) would add at least 1-3²⁸ years to the timeline set out in **Table 3.4**. For example, in the automotive industry, a supplier cannot decide to substitute one product with another without authorisation from direct (tier) customers as well as OEM vehicle manufacturers. Instead, before any supply to an automotive customer can start, the supplier and customer are requested to enter in a Production Part Approval Process (PPAP).

As all paths/substances would need to be pursued simultaneously due to degree of overall uncertainty, the total time and investments to remove PFAS from the venting portfolio is estimated to be at least 15 years and cost at least €165 million. Adjusting these estimates to include customer validation process the final estimate would be at least 16-18 years, although this is dependent on the discovery of a viable alternative

²⁶ TFP is the Technology Feasibility Point which is the point at which prototypes (materials or processes) have satisfied the few properties of largest technical uncertainty for the product or product family.

²⁷ PFP is the Product Feasibility Point which is the point at which functional prototypes have repeatedly achieved the key product performance criteria and reduced remaining uncertainties for commercial product development.

²⁸ Gore estimates that customer validations are expected to be extensive and longer than average since a product performance trade-off is likely to occur.

material, which has not become apparent yet.

This notwithstanding, the current state-of-the-art technologies used to produce Gore vents containing PTFE have taken more than 50 years to develop and optimise. Gore expects that even if 15 years of effort is put into the substitution of PFAS, the majority of venting applications will still not have any viable replacements for materials containing PFAS, as no alternative material has been found that can replicate the performance of fluoropolymers.

3.6 Hazard comparison

As there are no identified 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 venting products that contain PTFE, PFA, FEP, fluorinated solvent, side chain fluorinated polymers, and non-polymeric PFAS dispersant, it is not possible to compare the hazard profile of a potential alternative substance (or substances) to the PFAS mentioned.

Substrates may replace the use of PTFE for very few of Gore's venting products, but the technical feasibility is uncertain. However, if the R&D is successful, it would be viewed as a non-hazardous, non-fluorinated polymer with no harmonised or self-classifications. However, these vents would still require the use of a PFA to meet the application performance requirements, so would not be non-PFAS products. The feasibility of replacing the application of the PFA without the use of a fluorinated solvent is more difficult and time-consuming process (as set out in earlier in this section).

4. Restriction scenario

4.1 Introduction

This chapter assesses impacts of a potential REACH restriction on the use of PFAS in venting products 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 venting 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 possible²⁹), 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

²⁹ A change in service would be to remove the need for the product itself. For example, instead of using a BPA in thermal paper receipt, electronic receipt could be used instead. The paper receipt would then no longer be needed, but it requires other broad-reaching societal changes.

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:

- *Gore and manufacturers (importers) of similar 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**
- *Industrial 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 (see Section 3.5). Without a derogation, the only options therefore involve ceasing the production of such products in the EU, and the sales into and within 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 moulded parts and die cut parts and suppliers of fluoropolymers, adhesives, coatings and manufacturing aids will be heavily affected by a restriction of PFAS, since they manufacture and sell these parts containing PFAS, or manufacture and sell intermediates required to manufacture vents containing 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 and PFAS-containing parts 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/parts that can be used to produce similar, albeit 'inferior', products. This could theoretically allow some upstream suppliers to reduce some of the profit losses, but this would not occur 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 (10+ years). 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 that rely on vents that can operate in harsh environments with a high degree of reliability. These downstream users manufacture products that are important for a large number of end-use industries, described in Section 2.2 and Section 2.5.2. It is not realistic that the downstream industries or consumer markets relying on vents will collapse (Option 3 and Option 4), but the industrial downstream users as well as some companies in end-use industries may temporarily need to cease production until they are able to find alternative solutions (Option 2). Since no

alternatives with equal performance are available (and unlikely to become available), they will have to redesign products, supply chains and production processes to use lower performing alternatives, which will take some time.

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 manufacturers of vents

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 Section 3.5, no suitable alternatives exist on the market, and it is not anticipated that alternatives will be found within the next 15 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 and the sales into and within the EU, which will lead to large financial losses for society.

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 impact.

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 alternatives 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

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, with a total time needed of at least 15 years after an alternative material has been identified (see **Table 3.1**). It is important to recognise that it is unknown what alternative could be used, so the 15-year transition period would only apply from when an alternative has been identified and onwards. 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 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

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. Gore has four key raw material suppliers (i.e., Gore comprises at least a third of total sales for each of these suppliers) and spends a total of €11 million on raw materials within the EU (associated with venting products alone). These will lose Gore sales and thereby at least a third of their business if no derogation is granted for the products covered within this SEA. If manufacturers similar to Gore purchase from these and or other suppliers within the EU, the actual impact to suppliers in the EU will be much higher. The only option 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 is 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 baseline volume of PFAS placed on the EU market in products covered by this SEA was estimated at an annual average of 102 tonnes between 2016-2021, which excludes production waste and indirect sales. The total volume of fluoropolymers sold in the EU for relevant industries uses³⁰ (See **Table 2.14**) 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 vents in the EU comprise a relatively small share. The total profits lost for these fluoropolymer suppliers, associated with venting 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 venting products is that it provides reliability and durability in harsh operating conditions. 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 vents are on the market. If PFAS can no longer be used, downstream users will therefore need to modify their processes and products to compensate for reduced performance such as protection from water, dust, or aggressive chemicals and durability of vents made without PFAS. Furthermore, they will need to acquire product and regulatory approval to use different products 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 is not possible to estimate such substitution/compliance related costs for downstream users.

If downstream users are not able to redesign and change their production processes to fit the lower performing venting products by the end of the transition period, there is risk of temporarily halting production for products relying on PFAS-containing venting products. The EU industrial base, including but not limited to the automotive, chemical manufacturing and electronics industries, would then be faced with significant disruptions, the duration of which is difficult to predict.

It is also uncertain if manufacturers of lower performing non-PFAS venting products 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 venting products 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 as 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 sectors can give an indication of the minimum order of

³⁰ Relevant industries include Automotive, agriculture, chemical manufacturing, electronics, electrical equipment, and solar power

magnitude of profits loss due to production halts in downstream user sectors. As shown in **Table 2.15**, the turnover in these industries was close to €2,460 billion in 2019 and employed around 16 million people in the same year. To keep the example even more conservative, one can assume that only 1% of sales in this industry is affected and that the profit margins are 50% lower than for Gore and similar manufacturers. Again, using the no-SAGA approach (SEAC, 2021) as there are no suitable alternatives on the market, the resulting loss amounts to over €7 billion (PV) over the period 2022-2041 which annualised is €523 million per year.

Due to the lack of suitable alternatives downstream users will incur additional costs including, but not limited to replacement costs for electronic devices due to higher incidences of pre-mature failures, costs of more frequent auto repair also due to pre-mature component failures, and the costs and supply chain disruptions of more complex packaging for hazardous chemicals. These hard to quantify indirect costs could easily exceed the direct costs estimated above.

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 other materials, potentially yielding savings in the order of €100 million annually (Fluoropolymer Product Group of PlasticsEurope, 2017). Amongst other benefits, fluoropolymers 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 on the EU*

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 in **Table 4.1** 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 industries³⁰ 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.

[illegible]

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	2,365	118
Reduction in emission (worst-case sensitivity)	190	10
Reduction in emission (reasonable worst-case)	21	1

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 human health and the environment

Other impacts on the environmental and health may include the potential for higher safety risks from vehicle or aircraft failure, increased risk of exposure of workers to hazardous substances, and increases in emissions arising from technical regression (in transport, for example this includes inferior car emission sensors, inferior internal seals, increased fugitive emissions or weight increases). 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 hazardous chemicals

A potential REACH restriction on the use of PFAS in vents could increase the health and safety risks of workers in downstream industries, such as chemical processing industries. For example, packaging vents are used to equalise pressure in hazardous chemical packaging, preventing containers filled with hazardous chemicals (e.g., hydrogen peroxide, peracetic acids and bleach) from leaking or bursting (because of unbalanced pressure within the container). As a result, they're an important safety component of chemical storage and transportation.

In the example of chemicals packaging vents, the loss in product effectiveness, and potential product failure, from non-PFAS vents could lead to workers being 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). Another example are vents used in gas sensors which alert workers to the presence of harmful gases in the air. These gas sensors are also used to detect specific gases that, once critical concentration level is reached, a potentially explosive environments are present. If not detected, the risk of an explosion is more likely and would have harmful impacts on humans and environment. Further, these vents can operate in uncontrolled environments that may be potentially exposed to moisture, particles, or other contaminants that may harm the sensor's ability to function, and therefore, its use as a safety instrument to protect workers in a range of scenarios. Durable and reliable vents are therefore a fundamental enabling technology for safe production.

The human health risks associated with coming into contact with harsh chemicals during chemical processing span the range from minor irritation to death. Exposure to hazardous chemicals have been connected to chronic illness, respiratory problems, cancer, liver diseases and many other conditions that threaten health. Industries processing harsh chemicals have extensive regulation associated with reducing the health risk posed by accidental chemical exposure or release.

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

Automotive Powertrain Vents provide protection for automotive powertrain components in passenger and light duty trucks against contamination while allowing pressure equalization. A failure of the powertrain vent system can, for example, cause water or contamination entry into transfer cases, e-axles or e-motors, and, in extreme cases, this can cause component failure and disable the vehicle, thereby placing drivers and passengers in potentially dangerous situations.

Similarly, PFAS-containing automotive electronic enclosure vents durably protect sensitive electronics from damage, degradation, or premature failure in harsh or extreme environments. These vents are used in critical drive assist systems and are becoming increasingly dominant in advanced driver assistance systems (ADAS), given the rapid developments in the future of autonomous driving. Failure of these systems due to ingress of liquids, for instance, from the use of less effective non-PFAS products could lead to increased safety risks in critical situations during the vehicles operation.

Protective vents for outdoor electronics are used to equalise pressure in electronic enclosures caused by uncontrolled changing environments such as rain, snow, wind, sun, and thunderstorms. These environmental conditions cause rapid cooling or heating of electronic devices, which leads to increased stress on installed seals and eventually to failure of the seal leading to ingress of water and dust. Protective vents ensure constant pressure equalization while protecting from liquid and dust ingress and thus improve the performance, reliability, and longevity of outdoor electronics. These protective vents are used for example in the control units of traffic lights. A malfunction of these control units could lead to uncontrolled traffic and an increased risk of road accidents, thereby endangering motorists and pedestrians. The use of less durable non-PFAS products would increase the risk of failure over time. Protective vents are also used in the control unit of brake systems for trains. Product failure in the brake

control system from the use of less durable non-PFAS products could lead to catastrophic accidents and endanger human lives.

Reduced public safety from telecommunication failures

As detailed above, protective vents are used in outdoor applications and provide protection against uncontrolled environments. These vents are used in the backbone of telecommunication infrastructure, which are the sets of paths that local or regional networks connect to for long-distance interconnections. A failure in this infrastructure and the related transmission of the transmitter mast would halt cell phone reception, which could have far-reaching public safety implications, including the inability to communicate with emergency services.

These public safety risks from telecommunication failures can also be caused from failures in portable electronic vents, which protect sensors, microphones, and speakers in electronic devices such as smartphones from water, fluid, and dust contamination. The use of less durable non-PFAS vents could lead to increased risk and rate of product failure and have safety implications for those that require emergency assistance.

Increased risk to consumers and

[REDACTED]

Additionally, non-PFAS vents put workers who assemble electronic components and devices at risk of breathing in aerogel particles, as the non-PFAS vents shed the aerogel particles much more readily than PFAS containing vents.

Environmental impacts

Increased risk of chemical emissions into the environment

PFAS-containing packaging vents are used by downstream industrial users, namely the harsh chemical industry, as they equalize pressure within chemical containers and are able to withstand aggressive chemicals. Non-PFAS products would not be expected to be used in applications which require protection from aggressive chemicals. The next best alternative to vents containing PFAS is a mechanical valve. Although a mechanical valve can provide pressure equalization, this has an environmental impact in the sense that with every pressure peak the system opens and by this may release hazardous chemicals from within the container. When the container drops, it's likely it will leak. In addition to increasing the risks to human health detailed above, non-PFAS mechanical valves increase the risk of hazardous chemicals being released to the environment. This could increase risk of threat to all environmental receptors, including air, water, and soil.

Increased resource used and waste

PFAS-containing vent products are more durable than their non-PFAS counterparts. The products containing PFAS protect against exposure to harsh operating conditions, have a high temperature stability and effectively diffuse moisture, offering high quality performance important for the function of certain high performance uses. PFAS-containing vents are used by downstream industrial users, such as the harsh chemicals industry, in capital equipment applications that demand robust materials to avoid premature failure. If these products were not available, downstream users would be forced to use lower-performing vents which could increase the risk of damage industrial equipment that would need to be replaced. A shorter product life puts further strain on the environment by increasing the volume of raw materials needed to manufacture the vents themselves and to manufacture replacements for damaged industrial equipment. Increased resource use may include an increased use of chemicals, water, and energy. The increased use of energy to extract raw materials and manufacture a higher volume of vent products and damaged industrial equipment has the subsequent impact of emitting greenhouse gases.

By providing durable and effective protection against heat, aggressive fluids and fuels, humidity, vibrations and compression, fluoropolymers prolong the useful life of various components critical for performance, emission control and safety in the automotive industry (Fluoropolymer Product Group of PlasticsEurope, 2017). Automotive electronic enclosure vents are used in systems, such as sensors and control units, which would need to be entirely replaced rather than repaired if they were to fail. Using less durable non-PFAS vents in these applications would increase the amount of raw material used to manufacture these systems and the waste generated. Similarly, the use of less durable non-PFAS automotive powertrain vents could lead to the unnecessary replacement of vehicle parts such as gearboxes and axels, which would not only increase raw material use but would also increase the amount of solid waste and fluid disposal, such as gear oil and hydraulic fluid, increasing the risk of these fluids leaking into the environment.

Similarly, automotive battery vents are intended to improve the performance and lifespan of the batteries, reducing the frequency with which the batteries need to be replaced and therefore reducing the amount of raw materials used and energy consumed in the manufacturing process. The catalytic device efficiently recombines the hydrogen and oxygen generated inside automotive lead-acid batteries to produce water. This reduces the electrolyte loss and maintains the performance of the lead battery for a long time.

Increasing the lifespan of automotive batteries is of particular strategic importance to the EU. The EU expects that by 2030 there will be 30 million electric vehicles on the road, with a corresponding number of batteries being produced, for which access to raw materials is becoming critical (European Commission, 2022a). Europe remains heavily dependent on supplies from third countries for critical materials used in batteries, such as lithium, cobalt, and graphite, which makes extending the lifespan of batteries geopolitically important as well as being environmentally beneficial (European Commission, 2022b).

PFAS-containing Portable Electronic thermal insulation protects the surface of mobile electronic devices from excess heat created by the device itself. It also protects heat sensitive components inside portable electronic devices from the heat created by other components inside the device. PFAS-containing vents,

though relatively small in size and material usage, extend the life of much larger and heavier components/devices (such as a cellphone or car battery), and thereby reduce the build-up of waste into the environment. Use of non-PFAS insulation products may result in shorter lifecycles for electronic devices if internal device components experience higher temperature than what the electronics were designed to withstand based on the desired insulation performance. In this situation, devices would be used for shorter lifecycles, which would mean excessive material usage compared to devices using PFAS-containing vents.

This consequently extends the lifespan of mobile electronic devices compared to less effective non-PFAS alternatives, and thereby reduces the consumption of raw materials and corresponding electronic waste generated in the EU. This reduces the land area used for material extraction and landfilling of waste, as well as reducing the associated GHG emissions from manufacture and waste. The amount of waste electrical and electronic equipment (widely known as WEEE or e-waste) generated every year in the EU is increasing rapidly (European Commission, n.d.). It is now one of the fastest growing waste streams (European Commission, n.d.). The EU has introduced the WEEE Directive and the RoHS Directive to tackle the issue of the growing amount of WEEE. One of the primary priorities of these Directives is to prevent the creation of WEEE (European Commission, n.d.). This is achieved by extending product use life.

Increased greenhouse gas emissions

As highlighted above, PFAS-containing vents are durable and extend the lifespan of the equipment in which they operate, such as chemical containers, automotive batteries, and advanced driver assistance systems. Extending the lifespan of this equipment used by downstream industrial users and consumers reduces the greenhouse gas emissions generated from raw material extraction and manufacturing replacements for this equipment.

PFAS-containing vents are used in a number of zero-emission technologies, including electric vehicles and solar panels. In automotive vehicles, fluoropolymers contribute to safety, engine efficiency, weight reductions and emission control, thereby improving fuel efficiency and reducing leaks and fugitive emissions (Fluoropolymer Product Group of PlasticsEurope, 2017). For example,

Electric vehicles, which are important in the transition towards a lower carbon transportation sector, depend on these vents.

Solar panels and related equipment such as inverters utilise protective vents containing PFAS to ensure maximum performance in adverse weather conditions, which helps generate clean electricity. Solar energy production is an increasingly important source of energy within the economy. Solar generation in the EU increased by 15% in 2020, and alongside wind currently generates around 20% of the EU's electricity. This supports the transition to a more sustainable society (Gore, 2021).

4.5 Social and wider societal 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.

4.5.1 *Employment*

In Europe, Gore buys materials from, e.g., manufacturers of moulded parts and die cut parts and sells its venting products to customers both within and outside of the EU. The products affected serve important functions in the production and final stage of a large variety of 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-product. 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 approximately 80% of companies manufacturing similar products³¹ 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, which would be considered 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. The SEAC approach thus accounts for the distributional effects, which become increasingly uncertain further down 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 be overlap in the customer base which would lead to double counting.

Gore alone is believed to have between 980 and 1,541 customers in the EU, and these customers employ around 2.0 million - 5.5 million people in the EU. As a conservative approach it has been assumed that only 10% of these (using the lower bound) 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 overlaps 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 risk within Gore's direct supply chain in the EU and their associated value to society are set out in **Table 4.3**.

114

4.5.2 Working conditions

4.5.3 Energy supply

reach the EU's energy and climate objectives (European Commission, 2022d). The Commission recently presented Europe's new 2030 climate targets, including a proposal to increase the current target to at least 40% renewable energy sources in the EU's overall energy mix by 2030 (European Commission, 2022e). The ambition to transition to renewable energy and to diversify the EU's energy supplies has also been driven by Russia's invasion of Ukraine, which has spurred the Commission to set out a number of measures to rapidly reduce EU's dependence on Russian fossil fuels well before 2030 by accelerating the clean energy transition (European Commission, 2022e). Minimising supply chain disruptions in the supply of solar panels and maximising the efficiency of power lines allows the EU to meet its climate and geopolitical targets and ensures a reliable supply of energy to EU customers.

4.5.4 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, 2022f). Ventilation products made without PFAS will not offer the same chemical compatibility, operating temperature range, 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 approximately 80% of manufacturers of similar venting products³¹ use PFAS. 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 ventilation 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 Dossier Submitters (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).

Gore does not have specific data on downstream users' recycling of its vents. However, as mentioned in

Section 2.4.3, The majority (90%) of the vents covered by this SEA is in automotive vehicles. End-of-life vehicles are processed as waste and are, in practice dismantled, shredded or otherwise disposed (Eurostat, 2021). It is assumed that 60% of the fluoropolymers found in automotive vents are incinerated for energy recovery, 35% are disposed of via landfill and the remaining 5% are sent for recycling. 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.

Distributional impacts

As explained in Section 4.3.3 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 materials³¹. This will, however, take some time, as the downstream users will have to adapt their product designs, production processes and supply chains 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 vents 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, large industries such as the automotive industry are resilient to small-to-moderate changes, 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.

³¹ The non-PFAS products (e.g., vents for automotive parts) 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 (i.e., whether a derogation is warranted).

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 shown in **Table 5.1** 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, which means that it is not possible to directly compare costs and benefits. Instead, a cost-effectiveness analysis has been carried out, for which the results are shown in **Table 5.2**.

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	7,242	533
Substitution costs	463	34
Cost of unemployment	9,472	697
Cost of lower product performance, e.g., reduced product lifetime	significant	significant
Minimum total economic impacts	17,177	1,264

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 derived in Section 4.4 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 is high – in the range of €130,000 to €1.2 million per kg PFAS emissions reduced. Furthermore, recognising that PTFE and other fluoropolymers meet the criteria for a PLC, the low potential risk associated with such emissions should also be taken into account when evaluating proportionality.

Table 5.2: Cost-effectiveness in the EU

	Minimum annuity costs (€ million)	Average annual volumes (tonnes/year)	Cost-effectiveness (€/kg PFAS reduced)
Based on reasonable worst-case emissions	1,264	1	1,230,000
Based on worst-case sensitivity emissions	1,264	10	130,000

Notes:

1. Monetary values are given in 2022 prices and rounded to the nearest € million.
2. Emissions volumes have been rounded to the nearest tonne.
3. Cost-effectiveness is derived as follows: $(1,264 \times €1,000,000 / (1 \times 1,000 \text{ kg})) = 1,230,000$. The same approach is used for both estimates.
4. Cost-effectiveness has been rounded to the nearest €10,000/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. A ranking system has been used to indicate the size of the effects:

- **(+)** indicates an increase in benefits or reduction of costs (of restricting the use of PFAS within this SEA), i.e., higher cost acceptability.
- **(-)** indicates an increase in costs or reduction of 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 the 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 5.2**. 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 vents and thermal insulation containing PFAS will have to identify alternative non-PFAS (inferior) products and find workarounds for the lower performance of these products. For example, Gore's Automotive Electronic Enclosure Vents keep control units, sensors and actuators, motors and hybrid/electric components functioning accurately and reliably, despite ongoing exposure to harsh operating conditions. There are no known materials which can achieve the level of durability provided by PFAS. This will require investments in costly R&D with uncertain outcomes, which also will divert funds that could be invested in product development.	(-)
Investment costs for downstream users	Since the non-PFAS vents will not be identical to the products containing PFAS, minor or fundamental changes in the downstream industrial users' production processes, product designs and supply chains 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, or it could involve changes to the production process and/or product design.	(-)
Lost profits for downstream industrial users	In the estimation of lost profits to downstream users (Section 4.3) only a few downstream industries ³⁰ were included, and it was conservatively assumed that only 1% of the sales within these industries would be affected and that the profit margins were 50% of that of Gore and similar manufacturers. It is believed that a larger set of industries would be impacted by a restriction on PFAS in products covered within this SEA, and the sales share affected could be significant in many of these. This conservative approach 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 vents, companies will need to make sure they are compliant with product and operational requirements. 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	Gore's vents and thermal insulation products support a multitude of end uses, including processing equipment within power generation sites, whilst garnering environmental benefits by protecting equipment and extending its	(-)

	use life. Vents without PFAS are less durable than their PFAS-containing counterparts. Switching to non-PFAS alternatives will thus result in costs (time and money) associated with repairs or replacements (e.g., equipment needing to be repaired or replaced more often). For example, components within electronics may over-heat without proper insulation between components but PTFE's durability decreases component degradation due to over-heating.	
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.	(-)
Impacts on employment in downstream user industries	Impacts on employment were only quantified for Gore's direct customers/downstream users. The lower bound estimate for the number of people employed by Gore's customers were used and it was assumed that only 10% of these jobs would be affected by a potential restriction. The impacts on employment are therefore likely underestimated. 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.	(-)
Risk of worker exposure to hazardous chemicals	A potential REACH restriction on the use of PFAS in vents could increase the health and safety risks of workers in downstream industries, such as chemical processing industries. Packaging vents are used to equalise pressure in chemical packaging, preventing containers filled with hazardous chemicals from leaking or bursting. As a result, they're an important safety component of chemical storage and transportation. Non-PFAS vents do not have the characteristics needed to protect against aggressive chemicals. The loss in product effectiveness, and potential product failure, from non-PFAS vents could lead to workers being exposed to chemically aggressive and hazardous materials or high temperatures, which would be in violation of EU workers health and safety directives.	(-)
Risk of environment exposure to hazardous chemicals	PFAS-containing packaging vents are used in storing and transporting chemically aggressive and/or hazardous fluids. A possible REACH restriction would increase the use of non-PFAS vents, which are less durable and not well-suited to harsh environments, which would increase the risk of these chemicals being released to the environment through leakage and product failure.	(-)
Emissions related to products manufactured in the EU, but where products are sold outside the EU	The worst-case sensitivity emissions estimate does not include emissions related to products manufactured in the EU, but where products are sold outside the EU. This will not affect the proportionality per se (as it is more appropriate to base this on the reasonable worst-case scenario), but it means that the worst-case emissions are less overestimated if there is significant export.	(+)
High emission factors covering a	As explained in Section 2.5.3, emission calculation estimated at the EU level has been carried out using emission	(-)

broader set of products	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, which means that using the emissions factors for the broader product group will likely significantly overestimate the emissions.	
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. 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.	(-)
Reduced road and transportation safety	PFAS-containing vents are used in multiple automotive and transportation applications, providing product reliability and safety. Less durable non-PFAS vents could lead to product failure and increase the risk of road and/or transportation accidents. For example, automotive electronic enclosure vents are used in critical drive assist systems, protecting sensitive electronics from damage, degradation, or premature failure. Failure of these systems due to ingress of liquids, for instance, from the use of less effective non-PFAS products could lead to increased safety risks in critical situations during the vehicles operation.	(-)
Increased risk to consumers from hazardous cell ballooning	Battery vents used in consumer electronics and car batteries release the gas generated inside a battery to maintain cell health and to reduce instances of hazardous cell ballooning events. The reliable functioning of these products is critical to the safety of consumers as swollen batteries can explode if not properly dealt with, resulting in serious injury and harm to persons nearby.	(-)
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.	(+)
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 new operations. 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.	(-)
Temporary shortage of supply of	Due to the unique properties of PFAS, it is believed that the majority of vents included in this assessment contain	(-)

industrial vents	PFAS. Therefore, it is likely that there will be a temporary shortage of non-PFAS vents in the EU, until the production capacity for non-PFAS vents is able to meet the market demand. This would impact the products manufactured by downstream industrial users, including products such as cars, batteries, semi-conductors, portable electronics and could lead to a temporary shortage of these products within the EU or could lead to the import of such products at an elevated cost.	
Increase in energy consumption costs for downstream users	Gore's vents support a multitude of end uses, including portable electronic devices and automotive vehicles, and extend their use life. Lower-performing products would decrease efficiencies and increase energy costs. For example, without proper thermal insulation, electronic devices would overheat and cause inefficiencies during use and require more frequent charging (i.e., energy usage).	(-)
Increase in product and regulatory costs	Downstream industrial sectors affected ³⁰ 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.	(-)
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.	(+)
Reduced public safety from telecommunication failures	PFAS-containing vents are used in telecommunication applications, including network infrastructure and in portable electronic devices. The use of less durable non-PFAS vents could lead to product failure and have safety implications for those that require emergency assistance.	(-)
Resource and energy use	If vents 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 the contributing to increased energy and emissions from increased production.	(-)
Increased greenhouse gas emissions	If vents without PFAS are less durable, this will result in an increased volume of raw materials being used to manufacture replacement products and increased waste being disposed of via landfill or incineration, which would increase the GHG emissions. PFAS-containing vents are also used in a number of zero-emission technologies, including electric vehicles and solar panels, ensuring maximum performance in adverse conditions. Using non-PFAS alternatives would hinder the performance of these technologies and impact the GHG savings provided by these products.	(-)

Change in environmental service costs, such as waste treatment and disposal services	If vents 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 across various industries 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.	(-)
Ecological and biodiversity impacts from increased waste	If vents without PFAS are less durable, this will also result in more waste being produced at the end-of-life stage, therefore increasing the amount of waste disposed of in landfill. Landfill sites not only generate emissions and increase air pollution (covered above) but also impact the surrounding environment and biodiversity.	n/a
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 reasonable worst-case emissions are 1 tonne/year. The vast majority of types of PFAS used by Gore and believed to be used in similar products covered by this SEA meet the Polymer of Low Concern (PLC) criteria.

The cost-effectiveness (CE) estimates, based on reasonable worst-case and worst-case sensitivity emissions combined with minimum costs, are estimated at €130,000 to €1.2 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 €1,100³² per kg emission reduced were generally not rejected due to costs i.e., the costs were found to be proportionate. Measures with costs above €56,400³³ 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 midpoint³⁴ 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

³² €1,000 in original study, uplifted to 2022 prices

³³ €50,000 in original study, uplifted to 2022 prices

³⁴ The midpoint cost-effectiveness (€680,000 million/kg) was derived by taking the midpoint between the reasonable-worst case emission estimate (€130,000 million/kg) and the worst-case sensitivity estimate (€1.2 million/kg).

clearly shows that regardless of which BMs are used, the costs derived in this SEA are manyfold higher. 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 between 12 and 68 times higher than the upper bound BMs, which means that not derogating these products would lead to disproportionate costs.

Table 5.4: Cost-effectiveness in the EU 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	680,000	618	12
Illustrative adjusted benchmarks	1,000	10,000		680	68

Notes: Monetary values are given in 2022 prices and the estimated cost-effectiveness has been rounded 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 are costs of a possible REACH restriction and would therefore further strengthen the conclusions from the quantitative analysis. It is therefore concluded that restricting the use of PFAS in products covered within this SEA will result in highly disproportionate societal costs for EU.

6. Conclusions and recommendations

The products covered within this SEA include automotive, packaging, protective and portable vents and thermal insulation that are long-term reliable and resistant to high temperatures and harsh environments. Automotive vents protect sensitive automotive components from liquid, dust and dirt ingress and prevent degradation or premature component failure. Packaging vents equalize pressure emitted from packaged chemical and agricultural products, preventing leakage and packaging explosion. Protective vents, used in electronic equipment in a wide range of industries, protect electronic enclosures from uncontrolled environmental impacts causing failure and shorter lifetime of electronics. Portable vents protect mobile electronic consumer devices and lead to a much longer lifetime of those devices. For example, portable electronics' battery vents will prevent battery overheating (cell-ballooning). Thermal insulation products insulate and protect heat-sensitive electronic components in mobile devices.

There are currently no non-PFAS alternatives on the EU market with comparable performance to these products, and Gore upholds that no such alternatives are likely to be found in the foreseeable future. If high-performance vents become unavailable because of a restriction of PFAS, the downstream users will then be forced to redesign their own processes and products to use inferior products. In addition to costs associated with R&D and investments to adapt their production processes, the downstream users will be faced with costs arising from the need to replace parts more frequently and obtain new product and regulatory approval until suitable alternatives have been found. Process changes may be time-consuming and expensive, and temporary production halts in industries relying on vents containing PFAS can be expected.

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 €130,000 – €1.2 million per kg 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 12 - 68 times higher than what would normally be considered proportionate costs within the context of regulating chemicals. PTFE is not mobile in the environment, is demonstrated to be non-toxic and extremely stable, and is also identified as PLCs. Gore believed that other companies manufacturing similar products also use 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, 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 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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Appendix 1 PFAS volumes and emissions across multiple sectors

The dossier submitters (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: PFAS manufacture
- Section A1.2: Use of PFAS
- Section A1.2: End-of-life of products containing PFAS; and
- Section A1.3: 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 2.4**). **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 in the EEA

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-gas³⁵. 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 in **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.

³⁵ Data on the volume of F-gases manufactured in the EEA were also published by the DS 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 in the EEA

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, amongst others, the electronics and semiconductor and automotive industries (as detailed in Section 2.2.2). These are broadly related to the electronics and energy and transportation sectors included in **Appendix Table 2**. The volume of fluoropolymers used in the electronics and energy sector³⁶ “*investigation report summaries*” have been extrapolated and applied to 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 by the DS 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 electronical 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
	Paper and cardboard wastes	1	2,230

³⁶ The “*investigation report summary*” for the transportation sector was not extrapolated in this SEA due to missing emissions data in the summary report published by the DS.

Food contact material (paper and board)	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
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 PFAS manufacture to Section A1.3 End-of-life of products containing PFAS 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 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 in the EEA

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 for several different sectors (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 in the EEA

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, diagnostics, anaesthetics and intermediates) ³				
Metal plating and manufacturing of metal products	Unknown			
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. ‘Medicinal products’ comprise active pharmaceutical ingredients, diagnostics, anaesthetics, and intermediates. 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 electronics and energy “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 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 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 in EEA

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.

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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