SOCIO-ECONOMIC ANALYSIS OF THE IMPACT OF A PFAS RESTRICTION ON THE SEALING DEVICE INDUSTRY AND WIDER ECONOMY

Report for: European Sealing Association

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1. SUMMARY OF THE SEA

This Socio-Economic Assessment (SEA) has been commissioned by the European Sealing Association (ESA). It aims to make an independent assessment of the contribution of fluoropolymer-based sealing devices to the European Economic Area[1] (EEA)'s economy and society. The analysis covers both manufacturers and importers of fluoropolymer-containing sealing devices and their downstream users.

This executive summary summarises the proposed restriction of PFAS under assessment, elaborates on the aims and scope of the assessment, and concludes on the economic impacts on the sealing industry in the EEA that could result from the adoption of a universal restriction of PFAS, specifically focused on the role and effects of the restriction of fluoropolymers in sealing devices, and how this could affect downstream using industries of sealing devices.

1.1 THE PROPOSED REACH RESTRICTION OF PFAS

In July 2021, four European Member States (Denmark, Germany, the Netherlands and Sweden) plus Norway submitted a joint REACH restriction proposal for a universal restriction of PFAS, based on concerns surrounding their persistence in the environment. In February 2023, ECHA published the Annex XV report containing two restriction options for controlling the manufacture, use and placing on the market of PFAS.

The definition of PFAS in the restriction proposal has led to a broad scope, covering at least 10,000 substances, with the definition being based on the OECD definition of PFAS[2], i.e., Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).

Fluoropolymers are polymeric substances that contain fluorine bound to one or both of the olefinic carbon atoms, to form a perfluorinated carbon-only polymer backbone with fluorine atoms attached directly to it[3], and so, under this definition, are classified as PFAS.

The preferred restriction option (RO) within the proposal (RO2) lists several derogations from the restriction based on use and on the availability of alternatives. Derogations that are specific to fluoropolymers include[4]:

a) polymerisation aids in the production of fluoropolymers (except PTFE, PVDF, and FKM) until 6.5 years after entry into force (EiF)
b) Use of fluoropolymers in the following applications:
    a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF;
    b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF;
    c. tubes and catheters in medical devices until 13.5 years after EiF;
    d. coatings of metered dose inhalers (MDIs) until 13.5 years after EiF;
    e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF;
c) fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.

The view within the fluoropolymer industry is that for the majority of fluoropolymer uses, there are no alternatives that meet the required performance[5].

1.2 SCOPE OF THE ASSESSMENT

The objective of this study is to deliver a socio-economic analysis of the impacts of a universal restriction of PFAS in the EEA on the sealing device industry and wider economic impacts, to be submitted to ECHA to

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[1] The EEA comprises the EU-27 (2020) and Iceland, Liechtenstein and Norway.

[2] OECD. Series on Risk Management No. 61, 2021.

[3] Buck, R. C., Franklin, J., Berger, U., Conder, J. M., Cousins, I. T., De Voogt, P., ... & van Leeuwen, S. P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. Integrated environmental assessment and management, 7(4), 513-541.

[4] ECHA (2023) Annex XV Restriction Report: Per- and polyfluoroalkyl substances (PFASs). Available at: https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

[5] UK HSE (2023) Analysis of the most appropriate regulatory management options (RMOA). Available at: https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

inform the restriction process. The focus of the study is fluoropolymer-based sealing devices placed on the market in the EEA, which are captured under the proposed PFAS restriction.

Specifically, this SEA should be regarded as an assessment of the net costs or benefits of the proposed restriction to human health and the environment and the net costs or benefits to manufacturers, importers, downstream users, distributors, consumers, and society as a whole. Potentially, this report will also contribute to a discussion on the scope or conditions of the proposed restriction and whether potential derogations should be proposed on the basis of socio-economic considerations.

The effects on consumers and public authorities will not be of focus. The Study will, however, qualitatively consider how the health of EU residents and the environment may be affected.

Sealing devices are components used to prevent or minimisethe leakage of media, such as fluids, gases, or powders, from a system or equipment. They are used in various industries and applications where containment and sealing integrity are essential, as they are often inserted in a hostile operating environment involving exposure to abrasion, radiation, and temperature and pressure extremes, and for applications requiring the containment of hazardous, toxic, flammable, corrosive, and reactive chemicals. For sealing applications in aggressive environments, many plastics and elastomers cannot meet the required level of performance. In these instances, fluoropolymers are used due to their unique combination of properties, including thermal stability, and chemical resistance; low coefficient of friction; flame resistance; insolubility; excellent weatherability; and purity, amongst others[6]. A REACH restriction of all PFAS could significantly impact the sealing device sector, by prohibiting the use of fluoropolymers in the EU. Such a restriction could pose several risks and challenges which are explored in this SEA. Key challenges include:

- Fluoropolymer sealing devices are used in a number of applications that are of high importance to the European Commission's priorities, such as delivering on commitments under the Green Deal and achieving the economy's digital transition. Any restriction could threaten progress in working towards those objectives.
- Fluoropolymer sealing devices are used in applications that make a significant contribution to Europe's economy, and any restriction would cause an immediate impact on GWP.
- Fluoropolymer sealing devices are used in applications that are critical for ensuring a high level of protection for workers, consumers, and the environment. Any restriction could therefore increase environmental emissions of harmful chemicals and human exposure if suitable alternatives are not found.
- In response to the restriction, fluoropolymers may be substituted with non-PFAS alternatives, or sealing devices manufactured without fluoropolymers (which are PFAS). Non-fluoropolymer-based sealing devices may generate other concerns for human health and the environment if they are less safe to use, or if they do not prevent leakage of harmful substances, thereby leading to regrettable substitution.

1.3 RESULTS

A targeted consultation with sealing device manufacturers and importers, and with sealing device downstream users from various application sectors, allowed the socio-economic analysis of impacts of a restriction of PFAS that includes fluoropolymers, a key component in many widely used sealing devices. Fluoropolymer-based sealing devices provide some properties to sealing devices that are considered critical in some uses, such as temperature resistance, chemical resistance, low coefficient of friction, water or moisture resistance, and mechanical strength.

The survey targeted companies in 10 different sectors, with 4 sectors having more than 5 respondents, allowing limited granularity of reporting at sectoral level. The sample coverage of the economic value generated in their sectors was low and below 5% in all cases, and therefore, results from the survey of downstream users will refer to the sample of surveyed companies only, and not their overall sectors. This coverage cannot be considered representative of the whole, and therefore it is not extrapolated to the complete value of the downstream user sectors. Thus, by definition the figures presented entail an underestimation: no extrapolation to sectoral level, no indirect effects (supply chain) and no induced effects on wider EU economy were taken into consideration.

[6] Ebnesajjad, S., & Khaladkar, P. R. (2017). Fluoropolymer applications in the chemical processing industries: the definitive user's guide and handbook. William Andrew.

A targeted consultation with sealing device manufacturers and importers, and with sealing device downstream users from various application sectors, allowed the socio-economic analysis of impacts of a REACH restriction of PFAS. As outlined in Section 2.1.1, the restriction proposal includes fluoropolymers, which are a key component in many widely used sealing devices. Fluoropolymer-based sealing devices provide properties to sealing devices that are considered critical in some uses, such as temperature resistance, chemical resistance, low coefficient of friction, water or moisture resistance, and mechanical strength.

The economic analysis reveals that the proposed restriction is likely to have significant impacts on the EEA sealing device manufacturers and importers, on their downstream users, and the wider economy. In particular, **EEA sealing device manufacturers and importers are estimated to experience an annualised loss of between €1.6 billion and €3.7 billion per year on average between 2024 and 2042, compared to baseline projections, as a result of the proposed restriction**. For sealing device manufacturers, there is limited scope to substitute fluoropolymers in their sealing devices with alternatives, as these are application-specific materials, selected on the basis of their ability to maintain a consistently tight seal, often in extreme conditions. Derogations will allow for more time and resources to innovate. However, even then, in 2042, sectoral turnover has been estimated to range between 18% and 21% lower than in the baseline projections, depending on the derogation scenario for sealing devices.

For EEA sealing device downstream users, their loss would result from the inability to continue their manufacturing activities without the properties that fluoropolymer-based sealing devices confer to their products and/or manufacturing processes**. These downstream users are estimated to lose between 11%-33% of their baseline sales turnover, ultimately depending on the extent and duration of time-limited derogations** and the ability of these companies to develop, test and introduce alternative manufacturing processes and/or products that no longer have fluoropolymer-containing sealing devices.This estimated loss, is estimated to range between €6.1 billion to €19.5 billion in annualised terms between 2024 and 2042 , compared to the baseline projections[7], for a sample of surveyed sealing device downstream users. Whilst the sample represents a small percentage of sales turnover within the selected sectors, it is not possible to conclude whether it is representative and, thus, sectoral extrapolations cannot be concluded.

These estimated losses of business activity against the baseline are significant despite already accounting for actions that businesses would take to mitigate the effects of the legislative changes, such as substitution, reformulation and other innovation. For example, sealing device manufacturers and importers have reported that they might be able to substitute and/or reformulate around 20% of the portfolio of products that could be affected by the proposed policy changes and, a similar scale of substitution, reformulation and/or redesign would be expected from downstream users, around 22% .

These estimates are uncertain. For example, baseline product characteristics and performance are not guaranteed by these strategies, nor is customer demand. The approval process for sealing device manufacturers takes varying amounts of time (7.6 years on average, for survey participants), in order to fully understand the capability of the material before recommending it for an application, and this process would need validation to thousands of applications individually, with a non-zero risk of failure. The outcomes of innovation might constitute the placing on the market of entirely new products that may be more costly, with uncertainty in how this translates further down the value chain and the rest of the economy.

The proposed restriction would also affect the jobs supported by the sealing device manufacturers and downstream users. It is estimated that, **by 2042, between 10,700 and 12,500 jobs would be lost against the baseline scenario in the sealing device industry,** which is equivalent to approximately 17% to 20% of the overall employment in EEA sealing device producing and importing businesses. Based on the multiplier effects of this economic effect, it is estimated that the cumulative employment reduction could reach between 13,800 and 16,100 jobs by 2042 against the baseline.

For the set of downstream users surveyed, potential job losses could range between 4% and 13% of the baseline workforce of downstream users in 2042[8]. Based on the sample of respondents, these losses could range between 9,100 and 28,400 by 2042, against the baseline. These cannot be extrapolated because the sample of respondents may not necessarily represent the average effects across the selected sectors.

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[7] The sample of downstream users surveyed consisted of 49 companies pertaining to 5 different sectors, and represented overall less than 5% of their joint sales value. Therefore, extrapolations from the sample to the level of the sector have been avoided, and results will only refer to the sample.

[8] It should be noted that this is an extrapolation based on the known production value of sealing device downstream using sectors and the production value reported only by the surveyed sample, which has a limited representativeness of the whole sectors assessed.

These effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to employment. Given that the sample of sealing device downstream users was not representative of large sector volumes, knock-on implications at the sector level have not been quantitatively assessed in this case.

The direct contribution of sealing device manufacture and import to GVA would be between €0.5 and €0.8 billion lower per year over the period 2024-2042, on average and when compared to the baseline. When adding indirect and induced effects, **the total contribution of the EU sealing device manufacture and import to GVA would be between €1.0 and €1.7 billion lower per year over this period, on average.**

Moreover, the sample of downstream users participating in a survey for this Study would also be negatively. Their contribution to the EU economy would be €0.8 billion to €2.3 billion lower, in GVA terms, than in the baseline per year on average over this period. When we include potential indirect and induced effects, it is estimated that the GDP in the EEA would be €2.4 to €6.8 billion lower on average per year against the baseline. The scale of this impacts is likely to be larger, especially if additional companies within the selected downstream sectors would experience similar impacts. However, the extent to which that might be the case is unknown.

Table 4-1 summarises some of these impacts on key business and economic indicators of the **sealing device manufacturing and import** against the baseline and across the three scenarios considered.

Table 1-1 Annualised impacts on selected business and economic indicators of the EEA sealing device manufacturing and importing sector, against the baseline scenario.

Themes (business or economic indicators)	Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Scenario 3 (Substitution and Reformulation, 13.5-year derogation)
Turnover (first order effects)	A loss of €3.7 billion per year between 2024 and 2042 on average against the baseline	A loss of €2.9 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.6 billion per year between 2024 and 2042 on average against the baseline
Total GVA contribution (*direct, indirect, induced*)	A loss of €1.7 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.5 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.0 billion per year between 2024 and 2042 on average against the baseline
Regulatory burden	An additional annualised burden of €100 million each year between 2024 and 2042	An additional annualised burden of €150 million each year between 2024 and 2042	An additional annualised burden of €200 million each year between 2024 and 2042
Total employment contribution (*direct, indirect, induced*)	16,700 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	14,500 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	10,500 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042

Table 4-2 below summarises some of these impacts on key business and economic indicators of the sample of sealing device **downstream users** against the baseline and across the three scenarios considered.

Table 1-2 Annualised impacts on selected business and economic indicators of the sample of EEA sealing device downstream users, against the baseline scenario.

Themes (business or economic indicators)	Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Scenario 3 (Substitution and Reformulation, 13.5-year derogation)
Turnover (first order effects)	A loss of €19.5 billion per year between 2024 and 2042 on average against the baseline	A loss of €12.8 billion per year between 2024 and 2042 on average against the baseline	A loss of €6.1 billion per year between 2024 and 2042 on average against the baseline
Total GVA contribution (*direct only*)	A loss of €2.3 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.5 billion per year between 2024 and 2042 on average against the baseline	A loss of €0.8 billion per year between 2024 and 2042 on average against the baseline
Regulatory burden	An additional annualised burden of €200 million each year between 2024 and 2042	An additional annualised burden of €300 million each year between 2024 and 2042	An additional annualised burden of €350 million each year between 2024 and 2042
Total employment contribution (*direct only*)	25,100 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	17,300 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	7,900 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042

There is also the need to consider the impact of these restrictions on consumers. Sealing devices are key inputs to many industrial applications that produce and manufacture a wide range of products of everyday use. Without the use of fluoropolymer-based sealing devices there could be a significant impact on the functioning of society, with e.g. food, water and power supplies, transport and safety being impacted. Without fluoropolymer-based sealing devices, such products would either not be able to be made or operate safely, increasing the risk of accidents, or would not be able to be manufactured at all, due to the operating conditions that, at present, can only be facilitated by fluorpolymer-based sealing devices.

Because of the lack of available evidence on more qualitative and quantitative aspects of the fluoropolymer use in sealing devices, it is not possible to draw conclusions on the potential direct health implications from their application. Nevertheless, the health effects from fluoropolymer use in sealing devices is not limited to those associated with direct exposure to PFAS. Fluoropolymer-containing sealing devices play a key role in ensuring the protection of human health across several applications and provide numerous benefits, including safety in the manufacturing process of chemicals, among others.

A full analysis of alternatives was outside the scope of this study, so it is not known whether there are available alternatives that could meet the performance necessary to guarantee the same level of protection afforded by fluoropolymers. If alternatives with lower performance are used, the level of protection of human safety would decrease. If businesses in certain sectors are forced to shut down because of the lack of acceptable alternatives, this too may have an adverse effect on human health. For example, a lack of acceptable alternatives in the pharmaceutical and food industries may threaten food security and the availability of pharmaceuticals, as their supply would be dependent on imports from outside the EU, reducing Europe's strategic autonomy.

Based on the 20% substitution/reformulation rate indicated by the businesses surveyed in this study, it is concluded that **a full restriction on the use of fluoropolymers could have a significant adverse effect of human health as a result of exposure to hazardous chemicals and indirect effects on the availability of products which serve basic needs such as food and healthcare.**

The environmental impacts of fluoropolymer use in sealing devices remain uncertain due to limited available data. The persistence of fluoropolymers, and the formation of microplastics are causes for concern. However, the environmental fate, behaviour, and toxicity of the majority of PFAS, including fluoropolymers, is unknown or supported by little evidence. It is therefore not possible to draw any conclusions on the expected direct environmental impacts from fluoropolymer use in sealing devices.

However, there are indirect impacts to consider. The use of fluoropolymer-containing sealing devices in the chemical industry not only improves worker safety from preventing chemical spills, but also helps to prevent contamination of the environment with hazardous chemicals.

Examples include: the automotive sector, where fluoropolymer-containing sealing devices are used to prevent fuel and fluid leaks, thereby minimizing the release of pollutants into the environment; and the use of fluoropolymer-based sealing devices in renewable energy technologies, such as solar panels and wind turbines also contribute to reducing environmental impacts by facilitating sustainable energy production.

In summary, fluoropolymer-based sealing devices bring environmental benefits from several of their applications. It is not known with certainty whether there are available alternatives that could replace fluoropolymers in these applications, as a full analysis of alternatives was outside the scope of this study. However, business responses to the consultation indicated that 80% of fluoropolymer-containing sealing devices could not be substituted and/or reformulated. On this basis, **a full restriction on the use of fluoropolymers may have an adverse effect on environmental health from emissions as a result of less effective sealing of systems using or containing hazardous substances.**

The results of this assessment highlight that the proposed restriction of PFAS, as it was conceived including all fluoropolymers that are used in the sealing devices in scope of this study, may lead to the reduction in manufacturing and/or use of downstream user applications and increase in costs thereof. Sectors that use sealing devices in their products or in their manufacturing processes need time and resource to make the necessary investment and innovate in non-fluoropolymer-based sealing device alternatives. Without further data on the impact of exposure to fluoropolymers to human health and the environment, a balance of costs and benefits cannot be determined.

1.4 OVERVIEW OF HUMAN HEALTH, ENVIRONMENTAL, SOCIAL, AND ECONOMIC IMPACTS

This section presents an overview of the assessment of the proposed restriction of PFAS carried forward in this Study. Four impact categories are assessed: environmental, human health, economic, and social impacts. Each of these categories are scored against the baseline scenario of no restriction.

A qualitative scoring framework has been used to provide a methodology for comparison of the proposed restrition with respect to the baseline scenario (outcome of the assessment of the 4 impact categories above). The qualitive framework is provided in Table 4-3.

Table 1-3 Qualitative scoring framework for assessment of the proposed restriction through its impact on sealing devices.

Score	Description of impact direction and magnitude
-3	High negative impact on the factor is expected from the implementation of the proposed restriction
-2	Medium negative impact on the factor is expected from the implementation of the proposed restriction
-1	Low negative impact on the factor is expected from the implementation of the proposed restriction
0	Neutral or unknown impact on the factor is expected from the implementation of the proposed restriction
1	Low positive impact on the factor is expected from the implementation of the proposed restriction

Score	Description of impact direction and magnitude
2	Medium positive impact on the factor is expected from the implementation of the proposed restriction
3	High positive impact on the factor is expected from the implementation of the proposed restriction

The table below provides a summary of the direction and magnitude of impacts that are expected following a restriction of the use of fluoropolymers in sealing devices. Following the scoring framework, impacts are scored on a scale from 3 (strong positive impact) to -3 (strong negative impact), with 0 representing a neutral impact, or where lack of data does not allow for conclusions to be drawn.

Table 1-4 Summary of impacts expected from restriction of fluoropolymers in sealing devices under REACH

Impact Category	Score	Level of Uncertainty	Explanation
Environmental heath	0	High	There is insufficient data available to draw conclusions on the impact on environmental health from the breakdown of fluoropolymers and emissions of PFAS throughout. Fluoropolymer sealing devices provide a high level of environment protection against chemical spills and contamination, which would be reduced following restriction of fluoropolymers due to the lower levels of ability to substitute cited by industry. The lower performance of alternatives is expected to lead to more frequent replacement of sealing devices and equipment using sealing devices. It is assumed that if the performance of an alternative is too low or too risky, it will not be used and the activity will cease.
Human health	-1	High	There is evidence to suggest that fluoropolymers themselves are of low concern. However, there is insufficient understanding of direct PFAS exposure throughout the lifecycle of fluoropolymer sealing devices to draw conclusion on their direct impact on human health. Fluoropolymer sealing devices also provide a high level of human health protection against chemical spills and leakage, which would be reduced following restriction of fluoropolymers due to the lower levels of substitution cited by industry. The lack of alternatives is expected to lead to more frequent workplace accidents involving hazardous chemicals and food security incidents because of the important role of sealing devices in food production.
Economic	-2	High	Impacts on various critical applications of fluoropolymer-based sealing devices such as the chemicals industry, aerospace and defence, oil and gas, and the food and drink industry, among others, could be large and preclude their continued production. However, there is large uncertainty in whether there can be suitable alternatives and there is a wide range of opinions among downstream users on whether this could be possible. There is also the risk of relocalisation of economic activities elsewhere.
Social	-1	Medium	In terms of key properties, alternatives seem to perform particularly poorly on chemical resistance, temperature resistance, repellence, low surface tension and low coefficient of friction. Alternatives do not seem to be able provide the same combination of properties and durability, resulting in leakages

Impact Category	Score	Level of Uncertainty	Explanation
			and process contamination risks and as a result, fail to meet performance, customer or industry specifications. Some jobs would be lost following the economic loss for various downstream industries.

Below are the weights assigned to each impact category. Economic impacts have been assigned double weight due to the fact that impacts on downstream users have only been captured at the level of a sample, and not as a whole. Therefore, estimated numbers are expected to be larger, although with uncertainty on whether the sample accurately represents the extent of impacts for each downstream using sector assessed. Additionally, it is understood that more sectors than those assessed in this study would be affected by a restriction of PFAS that bans the manufacture and placing on the market of fluoropolymer-based sealing devices.

Table 1-5 Weightings by impact category.

Impact category	Weight
Human Health	1
Environmental	1
Economic	2
Social	1

The final score is the weighted average across impact categories: -1.5. This score positions the restriction of fluoropolymers in sealing devices in a low-to-medium negative score range.

1.5 RECOMMENDATIONS

As a result of the need for additional data to assess the human health and environmental impacts of fluoropolymers, and the need to mitigate impacts on the EEA economy and wider society through the identification of alternatives, the following recommendations have been drawn from this assessment:

As an exemption does not appear feasible under RO2, it may be appropriate to introduce a derogation for fluoropolymer-based sealing devices to the REACH restriction, which takes into account the proposed derogation for polymerisation aids (RO2 derogation 5a). In light of the absence of alternatives for the large majority (80%) of the fluoropolymer sealing applications, the derogation should include a review period (e.g. 12 years) that allow for reconsideration of the availability and suitability of alternatives in order to prevent significant impacts on the competitiveness of the EU and the ability to meet the objectives of the EU Green Deal. Finally, said derogation and review period should also consider the average useful life of manufacturing equipment containing fluoropolymer seals and gaskets (typically 15-35 years) and the fact that those components must be replaced over the life of the equipment, thereby requiring the availability of fluoropolymers.

2. AIMS AND SCOPE OF THE SEA

This Socio-Economic Assessment (SEA) has been commissioned by the European Sealing Association (ESA). It aims to make an independent assessment of the contribution of fluoropolymer-based sealing devices to the European Economic Area[9] (EEA)'s economy and society. The analysis covers both manufacturers and importers of fluoropolymer-containing sealing devices and their downstream users.

This section elaborates on the aims and scope of the assessment of the economic impacts on the sealing industry in the EU-27 that could result from the adoption of a universal restriction of PFAS, specifically focused on the role and effects of the restriction of fluoropolymers in sealing devices.

2.1 THE AIM OF THE SEA

This SEA will be used to support a response to the European Chemicals Agency's (ECHA) six-month consultation on the restriction proposal on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS) under Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of chemicals (REACH)[10].

The report's structure and approach closely follow ECHA's guidelines[11] for the content and format of an SEA for the purposes of REACH restriction, such that the outputs and conclusions can be readily incorporated into ECHA's review of evidence provided through the consultation.

2.1.1 The Proposed Restriction

In July 2021, four European Member States (Denmark, Germany, the Netherlands and Sweden) plus Norway submitted a joint REACH restriction proposal for a universal restriction of PFAS, based on concerns surrounding their persistence in the environment. In February 2023, ECHA published the Annex XV report containing two restriction options for controlling the manufacture, use and placing on the market of PFAS.

The definition of PFAS in the restriction proposal has led to a broad scope, covering at least 10,000 substances, with the definition being based on the OECD definition of PFAS[12] (see Box 2-1).

Box 2-1 Definition of PFAS in the proposed restriction

Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).

A substance that only contains the following structural elements is excluded from the scope of the proposed restriction:

- CF3-X or X-CF2-X',
- where X = -OR or -NRR' and
- X' = methyl (-CH3), methylene (-CH2-), an aromatic group, a carbonyl group (-C(O)-),
- -OR'', -SR'' or –NR''R''';
- and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH3), methylene (-CH2-), an aromatic group or a carbonyl group (-C(O)-).

Fluoropolymers are polymeric substances that contain fluorine bound to one or both of the olefinic carbon atoms, to form a perfluorinated carbon-only polymer backbone with fluorine atoms attached directly to it[13], and so, under this definition, are classified as PFAS. The only exception for substances covered by this definition

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[9] The EEA comprises the EU-27 (2020) and Iceland, Liechtenstein and Norway.

[10] ECHA (2023) Submitted restrictions under consideration – Per- and polyfluoroalkyl substances (PFAS). Available at: https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term

[11] ECHA (2008). Guidance on Socio-Economic Analysis - Restrictions. Available at: https://echa.europa.eu/documents/10162/2324906/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

[12] OECD. Series on Risk Management No. 61, 2021.

[13] Buck, R. C., Franklin, J., Berger, U., Conder, J. M., Cousins, I. T., De Voogt, P., ... & van Leeuwen, S. P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. Integrated environmental assessment and management, 7(4), 513-541.

is for a small number of fully degradable PFAS subgroups, which are excluded because they do not fulfil the underlying concern of high persistence[14].

The preferred restriction option (RO) within the proposal (RO2) lists several derogations from the restriction based on use. Derogations that are specific to fluoropolymers include[15]:

d) polymerisation aids in the production of fluoropolymers (except PTFE, PVDF, and FKM) until 6.5 years after entry into force (EiF)
e) Use of fluoropolymers in the following applications:
    a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF;
    b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF;
    c. tubes and catheters in medical devices until 13.5 years after EiF;
    d. coatings of metered dose inhalers (MDIs) until 13.5 years after EiF;
    e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF;
f) fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.

The derogation periods are based on the availability of alternatives, with a 6.5-year derogation being applied where there is "*sufficiently strong evidence that technically and economically feasible alternatives are not yet available but potential alternatives are in development, or where known alternatives are available but not on the market in sufficient quantities*". A 13.5-year derogation is applied where there is "*sufficiently strong evidence that technically and economically feasible alternatives are not yet available and potential alternatives are unlikely to become available in the near future, or where certification or regulatory approval of PFAS-free alternatives cannot be achieved within a five-year derogation period*"[16]. The view within the fluoropolymer industry is that for the majority of fluoropolymer uses, there are no alternatives that meet the required performance[17].

The next steps in ECHA's restriction process involve the following:

2.1.1.1 Consultation

A six-month consultation on the Annex XV report began on the 22 March 2023, allowing stakeholders directly affected by the proposed restriction and the wider society to submit comments and/or support documentation. The deadline for submissions is 25 September 2023[18]. A second consultation period begins when the Committee for Socio-Economic Analysis (SEAC) draft opinion and Committee for Risk Assessment (RAC) final opinion are published on ECHA's website. This allows stakeholders to submit comments on SEAC's draft opinion within 60 days of its publication[19].

2.1.1.2 Opinion Development

Within nine months of the publication of the conforming restriction report, the RAC prepares and adopts an opinion based on the restriction dossier, advice received from the Forum for Exchange of Information on Enforcement, and comments and documentation received during the 6-month consultation. The Forum aims to ensure enforcement of EU chemicals legislation (namely Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[20], Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP)[21], Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (PIC Regulation)[22], Regulation (EU)

[14] ECHA (2023) Annex XV Restriction Report: Per- and polyfluoroalkyl substances (PFASs). Available at: https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

[15] ECHA (2023) Annex XV Restriction Report: Per- and polyfluoroalkyl substances (PFASs). Available at: https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

[16] ECHA (2023) Annex XV Restriction Report: Per- and polyfluoroalkyl substances (PFASs). Available at: https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

[17] UK HSE (2023) Analysis of the most appropriate regulatory management options (RMOA). Available at: https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

[18] ECHA (2023) Submitted restrictions under consideration. Available at: https://echa.europa.eu/restrictions-under-consideration

[19] ECHA (2023) Restriction process – II-A Phase: Consultations. Available at: https://echa.europa.eu/restriction-process-phase-2a

[20] See: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006R1907

[21] See: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272

[22] See: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32012R0649

2019/1021 on persistent organic pollutants (POPs Regulation)[23], and the Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)[24]) is harmonised, identifies best practice in enforcement, and develops tools of use to local inspectors. The RAC opinion considers whether the proposed restriction is the most appropriate form of regulatory management for reducing risks posed to human health and the environment.

Also, within the same nine-month period, the SEAC prepares and agrees on a draft opinion of the restriction dossier, an assessment of socio-economic impacts, the Forum's advice, and the comments and socio-economic information received during the consultation on the report. After the second consultation period lasting 60 days from publication of the SEAC's draft opinion, a final opinion is prepared and adopted within 12 months of publication of the conforming restriction report. A three-month delay in adopting the SEAC's final opinion can occur if the RAC's opinion is significantly different from the original proposal. Finally, ECHA sends the compiled opinions of RAC and SEAC along with relevant background documents to the European Commission. These are also published on ECHA's website[25].

2.1.1.3 Decision and Follow-Up

Within three months of receiving RAC and SEAC's compiled opinions, the Commission prepares a draft amendment to Annex XVII of REACH (Restriction List). The Commission submits it to the World Trade Organisation (WTO) to ensure that it does not create technical barriers to international trade.

If there is no opposition from the Council or the European Parliament, the restriction is adopted, and the decision is published in the Official Journal[26].

2.1.2 Objectives of this Socio-Economic Analysis

The objective of this study is to deliver a socio-economic analysis of the impacts of a universal restriction of PFAS in the EEA on the sealing devices industry and the wider economic impacts, to be submitted to ECHA to inform the restriction process. The focus of the study is fluoropolymer-based sealing devices placed on the market in the EEA, which are captured under the proposed PFAS restriction.

Specifically, the study will aim to achieve the following:

1. Identify and assess the social and economic contribution of fluoropolymer-based sealing device products in the EEA, especially through the selected downstream sectors, and qualitatively assess any associated human health or environmental risks, including from their production and/or placing on the market, their supply chains, their use in downstream products by European citizens and in industrial processes, and their disposal.
2. Identify and assess the availability, suitability, technical and economic feasibility of alternatives to fluoropolymer-based sealing devices, as well as selected downstream users of these devices and consider their costs and benefits when compared to the baseline.
3. Evaluate (*ex-ante*) the potential impacts of a universal restriction of PFAS on the sealing device industry, their downstream users and the wider socio-economy. This includes all actors in the supply chain: manufacturers, importers, and downstream users (where possible).

The effects on consumers and public authorities will not be of focus. The Study will, however, qualitatively consider how the health of EU residents and the environment may be affected.

Specifically, this SEA should be regarded as an assessment of the net costs or benefits of the proposed restriction to human health and the environment and the net costs or benefits to manufacturers, importers, downstream users, distributors, consumers, and society as a whole. Potentially, this report will also contribute to a discussion on the scope or conditions of the proposed restriction and whether potential derogations should be proposed on the basis of socio-economic considerations.

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[23] See: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32019R1021

[24] See: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528

[25] ECHA (2023) Restriction process – II-B Phase: Opinion Development. Available at: https://echa.europa.eu/restriction-process-phase-2b

[26] ECHA (2023) Restriction process – III Phase: Decision and Follow-Up. Available at: https://echa.europa.eu/restriction-process-phase-3

A REACH restriction of all PFAS could significantly impact the sealing device sector, by prohibiting the use of fluoropolymers in the EEA Such a restriction could pose several risks and challenges which are explored in this SEA. Key challenges include:

- Fluoropolymer sealing devices are used in a number of applications that are of high importance to the European Commission's priorities, such as delivering on commitments under the Green Deal and achieving the economy's digital transition. Any restriction could threaten progress in working towards those objectives.
- Fluoropolymer sealing devices are used in applications that make a significant contribution to Europe's economy, and any restriction would cause an immediate impact on GWP.
- Fluoropolymer sealing devices are used in applications that are critical for ensuring a high level of protection for workers, consumers, and the environment. Any restriction could therefore increase environmental emissions of harmful chemicals and human exposure if suitable alternatives are not found.
- In response to the restriction, fluoropolymers may be substituted with non-fluorinated substances, or sealing devices manufactured without fluoropolymers. Non-fluoropolymer-based sealing devices may generate other concerns for human health and the environment if they are less safe to use, or if they do not prevent leakage of harmful substances, thereby leading to regrettable substitution.

2.1.3 Methodology Overview

2.1.3.1 Scenarios Under Consideration

This SEA follows ECHA's guidance on performing SEAs for restriction proposals[27] and is structured following the format established in the guidance. A key stage specified in the guidance is the definition of a baseline scenario and a proposed restriction scenario for the purpose of guiding the analysis. The methodology used in this study is as follows:

a) **Baseline scenario:** A baseline scenario is defined to analyse the contribution of the fluoropolymer sealing devices and their associated industries to the economy and wider society. This presents a business-as-usual situation (BAU), i.e., how would the industry and market continue to develop in the absence of the proposed restriction or any further policies to restrict the use of fluoropolymers beyond those which are already in place.

   The baseline scenario seeks to define the current status of the industry (i.e. what the industry and market look like today – or the year for which we have most recent historic data), and then projects forward various indicators to describe how the industry (as well as that of the downstream users) could develop going forward. It also explores the environmental and health risks and wider economic and societal contributions of the sealing industry should no further policy or regulatory action be taken.

   The baseline scenario assumes an absence of legislation controlling the use of fluoropolymers, due to the substances currently being unregulated under REACH.

b) **Restriction scenario:** The restriction scenario refers to the environment in which the proposed PFAS restriction enters into force, restricting the use of fluoropolymers. If the restriction enters into force, the possibility to manufacture and place fluoropolymers on the EEA market will no longer be viable, unless they meet the conditions of the derogation for polymerisation aids (see condition 5a of restriction option 2 (RO2)),or are used in sectors for which additional derogations have been granted e.g., the petroleum and mining industries. Manufacturers and importers of fluoropolymer sealing devices and downstream users will need to respond to such a restriction, and this response by affected stakeholders is used to assess the net impacts of the proposed restriction on their businesses. A summary of such potential strategic actions for different actors is as follows:

   - Manufacturers and importers of sealing devices containing fluoropolymers could: switch to sealing devices made from alternative and compliant substances in order to maintain their business; fostering other business lines almost unrelated to fluoropolymers to mitigate potential losses; where substances are intended for export, shift production outside the EEA; or pursue derogations.
   - Downstream users could: source alternative products for use in downstream equipment (whilst taking into account potential differences between fluoropolymers and the alternatives in terms of

[27] ECHA (2008), Guidance on Socio-Economic Analysis – Restrictions. Available from: https://www.echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d

costs, performance and risk profile); adapt existing technologies to make-use of alternative products; pursue derogations; invest in new alternative technologies making use of alternative substances; abandoning the manufacture of certain products; shift production outside of the EEA, etc.

Additionally, impacts from the proposed restriction of fluoropolymers on human health and the environment are qualitatively assessed in the restriction scenario and consider both the impacts of the restricted substances, and those emanating from the adoption of alternative substances and/or technologies.

2.1.3.2 Mapping and screening of impacts

Impacts within the scope of this assignment can be classified in five main categories: economic, human health, environmental, social, and wider economic impacts (i.e., impacts on trade, competition, and economic development, following ECHA's guidelines for SEA restriction reports[28]). To identify the impacts that will be included in the scope of the SEA, first, a longlist of impact categories was developed. The nature of the business impacts of this proposed restriction may significantly affect manufacturers and importers of sealing devices, and downstream user sectors. Therefore, the economic, social and wider economic impacts are assessed at the level of manufacturers and importers of fluoropolymer sealing devices, and at the level of downstream users thereof.

Table 2-1 Longlist of the impact categories mapped for screening. Developed by Ricardo for ESA.

Impact category	Impact Sub-categories
Economic	• Revenue, operating costs and conduct of business (e.g. substantive compliance costs) • Administrative burdens on businesses (e.g. costs associated with registration obligations or other administrative activities) • Innovation and research (e.g. stimulation or hindrance of investment in alternatives, etc.) • Public authorities (e.g. administrative costs or savings from additional or lessened requirements, etc.) • Size of operations (e.g. production, turnover)
Human health	• Health hazards presented to consumers and professionals associated with exposure to fluoropolymers • Changes in health hazards presented to consumers and professionals (e.g. through substitution with alternative compounds)
Environmental	• Impacts on PFAS emissions and the feasibility of achieving the EU's toxic-free environment targets • Change in environmental emissions of substances through use of alternatives in equipment • Disruption to greener technology markets and their adoption
Social	• Employment (e.g. number of jobs created or lost) • Consumers and households (e.g. ability to benefit from the internal market)
Wider economic	• Knock-on effects (i.e. outside sealings industry) in terms of value added • Knock-on effects in terms of employment • Trade and investment flows (e.g. imports and/or exports effects) • Competitiveness (sectoral) of businesses (e.g. effects on the market share and comparative advantages in an international context) • Position of SMEs (e.g. burden on small firms and impacts on their financial sustainability, etc.) • Functioning of the internal market and competition (e.g. impacts on the free movement of goods)

[28] Ibid footnote 11.

Impact category	Impact Sub-categories
	• Macroeconomic environment (e.g. consequences on economic growth and employment) • Third countries and international (e.g. effects on EU foreign policy)

This mapping is based on the development of impact pathways from the proposed restriction of fluoropolymers. The pathways highlighted how key stakeholders may be affected: enterprises (sealing device manufacturers/importers and downstream users), workers, consumers, EEA citizens, public authorities and third countries.

Following this mapping, a screening exercise was conducted to identify the most significant impact categories for a more in-depth assessment. This exercise focussed on the categories of most relevance for manufacturers/ importers of sealing devices and their downstream users, and considered the following:

- The likelihood or uncertainty of an impact materialising
- Its relation to the proposed restriction on fluoropolymers (i.e. whether it is a direct and/or an indirect impact from the restriction of fluoropolymers)
- The magnitude of the potential impact and whether the impact is more or less significant for certain business stakeholders (i.e. SME vs large firms, different downstream using sectors, etc.)
- The relevance of the impact in meeting the EU's ambitions and commitments (i.e. whether the proposed restriction and its impacts are aligned or not with underlying objectives of the Green Deal and transition to a digital economy).

For this screening exercise, evidence was collected through secondary research and rapid literature review of published reports and papers, and the knowledge and expertise of the project team.

As a result, four 'primary' sub-categories of economic impact were shortlisted as likely to be significant for a more in-depth quantitative assessment. Four additional 'secondary' sub-categories were considered for qualitative exploration and, where possible, quantitative assessment, depending on the evidence available and/or collected via consultation. The relevance of the shortlisted key business and other types of impacts is mapped against the indicators selected for assessment below.

Table 2-2 Shortlist of the socio-economic impacts for more in-depth assessment, and how these are linked to the indicators selected for the quantitative assessment. Developed by Ricardo for the ESA.

Priority	Key Impact sub-categories	Indicators selected as proxies for these key impact sub-categories
Primary economic impacts	• Operating costs and conduct of business (e.g. substantive compliance costs) • Administrative burdens on businesses (e.g. costs associated with notification obligations or other administrative activities) • Position of SMEs (e.g. burden on small firms and impacts on their financial sustainability, etc.) • Innovation and research (e.g. stimulation or hindrance of investment in chemical and/or non-fluorinated alternatives, etc.)	• Sectoral output or production value or turnover (€ millions), where possible by business size (**Turnover**) • Gross investment (€ millions) (**CAPEX**) • Operating expenditure (€ millions) (**OPEX**) • Research and Development expenditure (€ millions) (**R&D**) • Sectoral Gross Value Added (€ millions), approximately capturing the sector's contribution to Gross Domestic Product) (**GVA**)
Other economic impacts	• Trade and investment flows (e.g. imports or exports effects) • Competitiveness (sectoral) of businesses (e.g. effects on the market share and comparative advantages in an international context)	• These sub-categories were considered qualitatively and captured indirectly as part of the analysis of turnover and GVA (since exports contribute to the sectoral turnover and GVA in the EEA).

Priority	Key Impact sub-categories	Indicators selected as proxies for these key impact sub-categories
	• Price and demand effects • Macroeconomic environment (e.g. consequences on economic growth and employment of the whole EEA)	• Reported pass-through capacity and demand elasticity were collected in consultation.
Social impacts	• Employment (e.g. number of jobs created or lost within the sector) • Consumers and households (e.g. ability to benefit from the internal market)	• Number of jobs supported by the sector (Number of jobs) (**Employment**) • Qualitative assessment of product availability
Human health	• Health hazards presented to consumers and professionals associated with exposure to fluoropolymers	• Qualitative assessment of changes in health hazards presented to consumers and professionals (e.g. through substitution with alternative compounds)
Environmental health	• Impacts on PFAS emissions and the feasibility of achieving the EU's toxic-free environment targets	• Qualitative assessment of changes in environmental emissions of substances through the use of alternatives in equipment • Qualitative assessment of the disruption to greener technology markets and their adoption

Although these impact categories are likely the most significant in the face of a fluoropolymer restriction, the specific impacts across these categories would differ in nature, direction, and scale.

Social and environmental impacts that may result from a fluoropolymer restriction are assessed based on secondary research of academic literature. Any second-order social and environmental impacts from a restriction of fluoropolymers, and therefore, the indirect economic impacts driven by these (e.g. the subsequent impact of immediate health effects on productivity or the public and private health systems) were not in the scope of this assessment. However, some second-order economic impacts have been considered in qualitative terms, such as the possibility to outsource production of fluoropolymer-based sealing devices, and impacts on competitiveness from a restriction that is limited to products manufactured, used and sold in the EEA. This can be of special relevance in the maritime sector, due to the enforcement difficulties for ships that operate internationally.

2.1.3.3 Data gathering

The assessment of impacts triangulates evidence from two complementary information-gathering exercises:

- **Stakeholder consultation process**. Data (in particular on the economic profile of the industry) was obtained through survey responses from ESA's direct member companies and related businesses within ESA's network. This sample covered manufacturers and importers of sealing devices and downstream actors in the sectors of focus. This provided an understanding of the manufacture and import of sealing devices and their downstream user markets. Qualitative information on environmental and human health impacts of alternatives according to stakeholders' views was used as supportive evidence to desk-based research on these types of impacts.
- **Data collection through desk-based research**. This focused on reviewing relevant reports, academic literature, and industry reports. This assessment was quantitative to the extent that data was available, and qualitative in the cases where relatively limited quantitative information was contained within the publicly available sources. When assessing business indicators this review provided an indication as to the current market of the sealing device industry and downstream user application sectors to the extent that information was available. For environmental and human health impacts, the main approach to gather evidence was a review of relevant reports, academic literature, and industry reports.

The **stakeholder consultation process** included two separate surveys, which were each live for a period of six weeks:

1) One survey designed for ***manufacturers and/or importers of sealing devices***. Their current business volumes in euros and number of products were assessed in the survey, as well as other economic metrics, including investment, operating costs, and employment. Assessing their expected strategic response to the proposed restriction of fluoropolymers was a central part of the consultation. That comprised assessing the scope and extent of possible substitution and all types of alternatives to the use of fluoropolymers in sealing devices. Finally, manufacturers and importers of sealing devices were also directly asked about their expectations of the scale of impacts of the proposed fluoropolymer restriction on their business and conduct of business. Even though impacts are modelled with the information provided indirectly in other questions, the responses to this direct question were used as a sense check of the model results and as an indication of the precision of the industry in assessing how they will be impacted. 59 sealing device manufacturers and importers were interviewed. This sample was estimated to be highly representative of the totality of the sector, covering around 91% of the sector's turnover value in 2021. Hence, results from the survey to sealing device manufacturers and importers are scaled to the whole sector.
2) One survey designed for ***downstream users of sealing devices*** in their various applications. Their current business volumes in euros were assessed in the survey, as well other economic metrics, including investment, operating costs, and employment. Similarly to the survey of manufacturers and importers, their expected strategic response to the proposed restriction of fluoropolymers was a central part of the consultation, and they were also directly asked about their expectations of the scale of impacts of the proposed fluoropolymer restriction on their business and conduit of business, specifically only through the loss of sealing devices they currently use. The key applications (i.e. end uses for sealing devices) were determined based upon discussion with ESA and an expert understanding of the market. 49 sealing device downstream users were interviewed. This sample targeted companies in 10 different sectors, with 4 sectors having more than 5 respondents, allowing some results to be reported separately for them. The sample coverage of the economic value generated in their sectors was low and below 5% in all cases, and therefore, results from the survey of downstream users will refer to the sample of surveyed companies only, and not their overall sectors. This coverage cannot be considered representative of the whole, and therefore it will not be extrapolated to the complete value of the downstream user sectors.

To assess the quantitative effects (where possible) of the proposed restriction, a model was built to define and project various parameters depicting the fluoropolymer industry going forward, both under the baseline and the restriction scenario. The information collected via the surveys constituted a key input to the model. Data from different questions was triangulated to elicit the potential business impacts of the proposed restriction, and directly reported expectations were combined with economic theory (e.g., concepts of supply and demand, demand elasticity, relationships between production and different types of costs, input-output models, etc.) to model direct business impacts, impacts along the value chain, and wider economic impacts on the overall EEA economy. 2021 is taken as the reference year in all questions. Data was aggregated and complied with statistical rules[29] to ensure anonymity and confidentiality of respondents.

Additional and complementary historical data from public sources was used to independently assess the baseline scenario for the businesses of manufacturers/importers and downstream users, as well as any other business variables to the extent that the quality of the data allowed. Specifically, key sources of evidence were the European Environment Agency (EEA) report on fluorinated polymers[30], ESA and ESA members' data and library of publications[31], the restriction proposal on the manufacture, placing on the market and use of per- and polyfluoroalkyl substances (PFAS) under Regulation (EC) No. 1907/2006 on the Registration, Evaluation,

[29] The aggregated data used always must come from more than five independent companies, the latter being understood as the collection of undertakings whose relations with the company participating to the statistical exercise come within the terms of one or more of the sub-paragraphs of Article 5(4) of the EU Merger Regulation. Any input of less than 5% of the total volume reported by companies cannot be taken into consideration. Even when aggregated, the data must not come from one company with more than 70% of the total volume. No price information is included in the report.

[30] EEA (2021) Fluorinated polymers in a low carbon, circular and toxic-free economy: Technical Report. Available at: https://www.eionet.europa.eu/etcs/etc-wmge/products/etc-wmge-reports/fluorinated-polymers-in-a-low-carbon-circular-and-toxic-freeeconomy

[31] See: https://www.esaknowledgebase.com/

Authorisation and Restriction of chemicals (REACH)[32], and the 2020 ECHA Analysis of the derogations included in the restrictions on the manufacture, placing on the market and use of perfluorocarboxylic acids (PFCAs), their salts and related substances and perfluorocarboxylic acid (PFOA), its salts and related substances[33]. Additional sources included evidence on fluoropolymers from key industry associations (e.g. Plastics Europe, AGC, and Chemicals Europe), scientific studies, and datasets, such as the Structural Business Statistics (SBS)[34] and PRODCOM[35] databases from Eurostat. The latter two sources allow the team of economists to construct a business baseline for all the target economic impact categories, for sealing device manufacturers and/or importers, and for sealing device downstream users from different industrial sectors of interest, projected until 2042 based on historical trends and growth.

2.2 DEFINITION OF THE 'BASELINE' SCENARIO

2.2.1 Policy Context

2.2.1.1 PFAS

Since the 1940s, PFAS have been widely used in industrial, professional, and consumer products due to their unique and desirable physical and chemical properties. Although their properties vary, certain PFAS exhibit stability under high heat, have high chemical resistance, possess surfactant properties, and can even function as refrigerants. Various industries, including aerospace and defence, textiles, electronics, firefighting, medical devices, refrigeration, chemicals, and the sealing device industry heavily rely on PFAS.

The OECD's definition of PFAS includes both polymeric and non-polymeric substances, with much of the regulatory action and academic interest having focused on a small number of the latter[36]. Studies on a select number of PFAS compounds have shown their production and use to have caused severe contamination of soil, water, and food, resulting in potentially harmful levels of exposure for humans, animals, and the environment[37,38,39]. Epidemiological studies have shown associations between exposure to specific PFAS, such as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), and various health effects, including immune and thyroid function alterations, liver disease, lipid and insulin dysregulation, kidney disease, adverse reproductive and developmental outcomes, and cancer[40]. While these health effects primarily affect areas near emission sites, the global use of PFAS and their persistence in the environment make them a worldwide risk to human health and the environment. Additionally, certain PFAS are known to bioaccumulate, further increasing the risks to humans, animals, and whole ecosystems[41].

Fluoropolymers are a distinct subset of polymeric PFAS due to their unique combination of properties and high molecular weight. The most widely used fluoropolymers are PTFE, fluorinated ethylene propylene (FEP), perfluoroalkoxy alkanes (PFA), ethylene tetrafluoroethylene (ETFE), and other tetrafluoroethylene-

[32] Ibid. footnote 10.

[33] ECHA (2020) Analysis of derogations included in the restrictions on the manufacture, placing on the market and use of perfluorocarboxylic acids (PFCAs), their salts and related substances and perfluorocarboxylic acid (PFOA), its salts and related substances. Available at: https://echa.europa.eu/documents/10162/17086/report_pfcas_additional_derogation_en.pdf/527979b6-87ea-c9b7-a504-4ae2a4da73bf

[34] Eurostat, 2023. Available at: https://ec.europa.eu/eurostat/web/structural-business-statistics/overview

[35] **PROD**uction **COM**munautaire (Community Production), Eurostat, 2023. Available at: https://ec.europa.eu/eurostat/web/prodcom

[36] Lohmann, R., Cousins, I. T., DeWitt, J. C., Gluge, J., Goldenman, G., Herzke, D., ... & Wang, Z. (2020). Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[37] Johnson, P. I., Sutton, P., Atchley, D. S., Koustas, E., Lam, J., Sen, S., ... & Woodruff, T. J. (2014). The Navigation Guide—evidence-based medicine meets environmental health: systematic review of human evidence for PFOA effects on fetal growth. Environmental health perspectives, 122(10), 1028-1039.

[38] Post, G. B., Cohn, P. D., & Cooper, K. R. (2012). Perfluorooctanoic acid (PFOA), an emerging drinking water contaminant: a critical review of recent literature. Environmental research, 116, 93-117.

[39] Sunderland, E. M., Hu, X. C., Dassuncao, C., Tokranov, A. K., Wagner, C. C., & Allen, J. G. (2019). A review of the pathways of human exposure to poly-and perfluoroalkyl substances (PFASs) and present understanding of health effects. Journal of exposure science & environmental epidemiology, 29(2), 131-147.

[40] Fenton SE, D. A. (2021). Per- and Polyfluoroalkyl Substance Toxicity and Human Health Review: Current State of Knowledge and Strategies for Informing Future Research. doi:10.1002/etc.4890. Retrieved from: https://pubmed.ncbi.nlm.nih.gov/33017053/

[41] Aditi Podder et al. (2021) Per and poly-fluoroalkyl substances (PFAS) as a contaminant of emerging concern in surface water: A transboundary review of their occurrences and toxicity effects, Journal of Hazardous Materials, Volume 419, https://doi.org/10.1016/j.jhazmat.2021.126361

copolymers, which make up around 75% of the global fluoropolymer market[42]. A recent analytical review[43] of fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data concluded that they meet widely accepted criteria for being considered as "polymers of low concern" (PLC), and thus pose insignificant environmental and human health impacts. Because of the distinct difference to other polymeric and nonpolymeric PFAS, fluoropolymers should be separated from them for hazard assessment or regulatory purposes. As such, grouping fluoropolymers with all classes of PFAS for "read across" or structure–activity relationship assessment is not scientifically appropriate.

The documented adverse health effects from a small number of PFAS has led global manufacturers to start substituting some harmful PFAS with alternative substances. Recognition of PFAS's potential harmful effects on human health and the environment has also increased regulatory scrutiny on the substance group and has led to a global ban on select PFAS, such as PFOA and PFOS, through listing in the Stockholm Convention[44]. The EU has implemented the ban on PFOA and PFOS via the POPs Regulation[45] and has started regulating other PFAS under REACH, such as perfluorocarboxylic acids (PFCAs), which are restricted under Annex XVII[46] and Perfluorohexane-1-sulphonic acid (PFHxS) and undecafluorohexanoic acid (PFHxA), which are proposed for restriction[47].

The European Commission has also outlined options for addressing the use of PFAS and the subsequent environmental contamination[48]. The Staff Working Document highlights the limitations of regulating individual PFAS, such that it allows companies to substitute the widely used long-chain PFAS with a large number of shorter chain PFAS, which may also pose concern for human health and the environment, and may be used in greater quantities. There is also a lack of information on the majority of PFAS, meaning a substance-by-substance regulatory approach is not feasible. There has therefore been calls to regulate PFAS as a group based on concerns related to the high persistence of PFAS, the lack of knowledge on chemical structures, properties, uses, and toxicological profiles of most PFAS currently in use. Industry have opposed this approach, highlighting that the different environmental and human health impacts result from the structural differences of PFAS subgroups, such as fluoropolymers.

A recently published RMOA of PFAS[49] performed by the UK HSE has recommended derogations for PFAS with low hazard or safe uses, with examples including fluoropolymers and PFAS used in sealed/contained systems.

2.2.1.2 Fluoropolymers

Polymers are not currently regulated under REACH, meaning they are exempt from registration and evaluation, but can be subject to restriction and authorisation. However, under Article 6(3), manufacturers and importers of a polymer must submit a registration for the monomer or other substances in the polymer that have not already been registered and meet the following conditions[50]:

- The polymer consists of 2% weight by weight (w/w) or more of the monomer or other substance(s) in the form of monomeric units and chemically bound substance(s);
- The total quantity of the monomer or other substance(s) is 1 tonne or more per year.

Due to their regulatory status, polymers have come under increased scrutiny in recent years. In 2019, the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) developed a Conceptual

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[42] Gardiner, J. (2014). Fluoropolymers: origin, production, and industrial and commercial applications. Australian Journal of Chemistry, 68(1), 13-22.

[43] Henry, B. J., Carlin, J. P., Hammerschmidt, J. A., Buck, R. C., Buxton, L. W., Fiedler, H., ... & Hernandez, O. (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 14(3), 316-334.

[44] UNEP (2023) All POPs listed in the Stockholm Convention. Available at: https://chm.pops.int/TheConvention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx

[45] See: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32019R1021

[46] See: https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e181e91f73

[47] See: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1827f87da

[48] European Commission (2020) Commission Staff Working Document on PFAS, accompanying the Chemicals Strategy. Available at: https://environment.ec.europa.eu/strategy/chemicals-strategy/implementation_en

[49] UK HSE (2023) Analysis of the most appropriate regulatory management options (RMOA). Available at: https://www.hse.gov.uk/reach/assets/docs/pfas-rmoa.pdf

[50] ECHA (2023) Guidance for monomers and polymers. Available at: https://echa.europa.eu/documents/10162/2324906/polymers_en.pdf/9a74545f-05be-4e10-8555-4d7cf051bbed

Framework for Polymer Risk Assessment ("CF4Polymers")[51], which was followed in 2020 by a European Commission contracted study proposing criteria for the identification of polymers requiring registration (PRR) under REACH[52]. Both the CF4Polymers framework and Commission report support the view that fluoropolymers should not be regulated as a group with other PFAS substances and should be considered as polymers of low concern (PLCs), which are likely to be exempt from new polymer registration requirements.

However, it should be noted that the PLC criteria does not cover any concerns during the production and disposal stages. Fluoropolymer manufacture has historically involved the use of harmful short-chain PFAS processing aids, whose emissions would not be considered in determining whether a polymer is a PLC. To address concerns from the potential use of PFAS in the production process, fluoropolymers have been included in the proposed PFAS restriction[53].

All manufacturers, importers, and downstream users in the EU must comply with the CLP Regulation[54] unless exempt under Article 1(2) This includes manufacturers, importers, and downstream users of fluoropolymers.

a) Classification

Manufacturers, importers, and downstream users are required to 'self-classify' their substances under the CLP Regulation. Self-classification is required when a substance, which has hazardous properties, is not listed under Annex VI of the CLP Regulation with a harmonised classification or if an additional hazardous property is identified, not covered by the harmonised classification. The classifications may include exposure considerations however an exposure assessment is not required for classification, the hazardous properties of the substance are the deciding factor in classification. The self-classifications resulting from the application of Titles I and II of the CLP Regulation should be included in REACH registration dossiers. Manufacturers, importers, and downstream users are responsible for keeping their notifications up to date according to scientific advances in testing and new information on their substances. None of the fluoropolymers typically used in sealing devices that are within the scope of this study are classified under CLP (see Table 2-3 below).

Table 2-3 The harmonised and self-classified hazard codes of the fluoropolymers typically used in sealing devices. Source: REACH and CLI[55].

Trade Name	CAS Number	Classification
PTFE	9002-84-0	Not Classified
FKM	9011-17-0 / 25190-89-0 / 56357-87-0	Aquatic Chronic 2 (25190-89-0)
FFKM	26425-79-6	Not Classified
FEP	25067-11-2	Not Classified
FEPM	27029-05-6	Not Classified
PCTFE	9002-83-9	Not Classified
PFA	9002-83-9	Not Classified
PVDF	24937-79-9	Not Classified

b) Labelling

The identified hazardous properties of a substance must be communicated according to the labelling and packaging requirements under the CLP Regulation. The following information must be included on the product label if the product includes substances with identified hazards:

[51] Cummings, I. (2019). The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers)-Technical Report No. 133-1.

[52] Wood (2020) Scientific and Technical Support for the Development of Criteria to Identify and Group Polymers for Registration/ Evaluation under REACH and Their Impact Assessment. Final Report. Available at: http://publications.europa.eu/resource/cellar/1cc811ff-d5fc-11ea-adf7-01aa75ed71a1.0001.01/DOC_1

[53] Plastics Today (2023) Proposal to Ban Fluoropolymers Has European Industry on Edge. Available at: https://www.plasticstoday.com/legislation-regulations/proposal-ban-fluoropolymers-has-european-industry-edge

[54] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures. ELI: http://data.europa.eu/eli/reg/2008/1272/oj

[55] Data sourced from the C&L Inventory - ECHA (europa.eu) in June 2023.

- The identity and contact information of the supplier;
- the nominal quantity of the substance or mixture in packages made available to the general public;
- the identity of the hazardous substance;
- the relevant hazard pictograms and statements, signal words, precautionary statements and any additional information as dictated by complementary legislation[56].

There are also strict packaging requirements to ensure safe containment and transport of substances. The packaging of hazardous substances must be strong, resistant to damage and possible to open and reseal without the substance escaping. Additional requirements under CLP restrict the packaging design to prevent attracting children to the hazardous product. None of the fluoropolymer have hazard classifications so none are subject to the labelling and packaging requirements mentioned.

2.2.2 Background

2.2.2.1 What Are sealing devices?

Sealing devices are components used to prevent or control the leakage of media, such as fluids, gases, or powders, from a system or equipment. They are used in various industries and applications where containment and sealing integrity are essential. Sealing devices come in different forms, shapes, and materials, depending on the specific requirements of the application.

To contain media within non-moving equipment, static seals are used, whereas dynamic seals are used to contain media within moving equipment, such as bearings, pistons, and gearboxes. Five of the main sealing device types are:

- **Gaskets** – flat or moulded sealing devices used to create a seal between two or more stationary surfaces. They can be made of various materials, such as rubber, fibre, metal, or composite materials. Gaskets are commonly used in piping systems, flanges, pumps, and heat exchangers.
- **Mechanical seals** - devices used to provide a seal at the point of entry or exit of a rotating shaft, which typically prevent leakage of one high pressure fluid into a lower pressure fluid[57].
- **Compression packing** –a common sealing process where a gland follower along the top ring is tightened, and the packing compressed onto the surface to be sealed[58]. They are typically made of braided fibres and used to seal valve stems and shafts of reciprocating compressors.
- **Expansion joints** – installed in piping systems to absorb vibration and shock[59]. They provide a flexible connection between flanges or pipe ends and other equipment.
- **Elastomeric and polymeric seals** – static and dynamic seals made from elastomeric and plastic materials that are typically custom moulded or machined components.

Sealing devices made from high performance materials are required for applications with a hostile operating environment involving exposure to abrasion, radiation, and temperature and pressure extremes, and for applications requiring the containment of hazardous, toxic, flammable, corrosive, and reactive chemicals. The material is only deemed suitable if it does not damage the equipment in which the sealing device is housed and is compliant with the equipment surface to achieve a high level of efficiency. The sealing material therefore needs to be softer than the equipment surface they are in contact with, which is why graphite, plastics and elastomers are preferred materials[60].

For sealing applications in aggressive environments, many plastics and elastomers cannot meet the required level of performance. In these instances, fluoropolymers are used due to their unique combination of

[56] Labelling and packaging - ECHA (europa.eu)

[57] IMECHE (2014) 12th Fluid Machinery Congress – 6-7 October 2014. DOI https://doi.org/10.1016/C2014-0-01730-3

[58] GlobalSpec (n.d.) Compression Packing Seals Information. Available at: https://www.globalspec.com/learnmore/mechanical_components/seals/compression_packing_seals#:~:text=Compression%20packing%20seals%20or%20gland,to%20various%20temperatures%20and%20pressures.

[59] Sotoodeh, K. (2022). Pipeline Valve Technology: A Practical Guide. CRC Press.

[60] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.esaknowledgebase.com/wp-content/uploads/2022/03/ESA-Position-Statement-on-proposed-PFAS-regulation-March-2022-1.pdf

properties, including high melting point, thermal stability, and chemical resistance; low coefficient of friction; flame resistance; insolubility; excellent weatherability; and purity, amongst others[61].

The chemical resistance of fluoropolymers increases in line with their fluorine content. Therefore, fully fluorinated polymers, such as PTFE, FEP, FFKM, and PFA, have superior chemical resistance to partially fluorinated polymers, such as ETFE, ethylene chlorotrifluoroethylene polymer (ECTFE), FKM, FVMQ, and PVDF[62].

2.2.2.2 *What Applications Are They Used In?*

Fluoropolymer-based sealing devices have applications in a wide range of sectors. Key sectors are outlined in more detail below.

Aerospace & Defence

Fluoropolymer sealing devices are used in gas turbine engines because of the high operating temperatures that are needed to achieve maximum thermal efficiency. High efficiency helps to reduce fuel consumption and make commercial aviation affordable[63].

As engine temperatures have risen, High Temperature Stability (HTS) lubrication oils are used to cool down engine parts and lubricate bearings. These are passed through a complex circuit and are subject to large temperature variations as well as strong vibration[64].

Sealing devices are used in gas turbine engines to prevent the oil leaking from its intended path of flow. Two of the main types of sealing devices used are labyrinth and helical, with the labyrinth sealing device usually being pressurized to minimise leakage, while the helical sealing device depends solely on reverse threading[65]. Fluoropolymer devices are also used in rotary systems in helicopters[66].

O-rings are also used in gas turbine engines, as well as hydraulic systems, fuel systems, and braking and landing gear systems to seal out environmental contaminants, retain critical fluids and keep surfaces separate for friction mitigation[67].

Petroleum & Mining

Fluoropolymer sealing devices are used in wellhead equipment, pipelines, compression systems, flow meters, hydraulic couplers, and pumps in both subsea and onshore sour oil and gas exploration and production. Fluoropolymers are the material of choice because of the extreme operating temperatures and pressures and harsh nature of the chemicals[68,69]. Fluoropolymers such as PTFE,, PCTFE, PFA, FKM, FFKM, and other non-fluorinated polymers such as ultra-high-molecular-weight polyethylene (UHMWPE), HYTREL®, and FEP[70,71,72] are all used in oil and gas industry and have different combinations of properties that make them the best option for specific applications.

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[61] Ebnesajjad, S., & Khaladkar, P. R. (2017). Fluoropolymer applications in the chemical processing industries: the definitive user's guide and handbook. William Andrew.

[62] Ebnesajjad, S., & Khaladkar, P. R. (2017). Fluoropolymer applications in the chemical processing industries: the definitive user's guide and handbook. William Andrew.

[63] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.europeansealing.com/esa-position-statement-on-proposed-pfas-regulation/

[64] Omniseal Solutions (n.d.) Omniseal Polymers. Available at: https://www.omniseal-solutions.com/components/omniseal-polymers/omniseal-spring-energized-seals

[65] Aeronautics Guide (2023) Aircraft Gas Turbine Engine Bearings and Seals. Available at: https://www.aircraftsystemstech.com/p/gas-turbine-engine-bearings-and-seals.html

[66] Omniseal Solutions (n.d.) Omniseal Polymers. Available at: https://www.omniseal-solutions.com/components/omniseal-polymers/omniseal-spring-energized-seals

[67] Eastern Seals (2022) The Importance Of O-Rings In The Aerospace & Aeronautics Industry. Available at: https://www.easternseals.co.uk/2022/10/26/the-importance-of-o-rings-in-the-aerospace-aeronautics-industry/

[68] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.europeansealing.com/esa-position-statement-on-proposed-pfas-regulation/

[69] Omniseal Solutions (n.d.) Energy: Oil & Gas. Available at: https://www.omniseal-solutions.com/industries/energy-oil-gas

[70] Adtech (n.d.) The oil & gas industry conquers its environment with fluoropolymers. Available at: https://adtech.co.uk/about/news/oil-gas-environment-fluoropolymers

[71] Advanced EMC Technologies (n.d.) Types of Seals For Oil And Gas Industry. Available at: https://advanced-emc.com/types-seals-oil-and-gas/

[72] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.europeansealing.com/esa-position-statement-on-proposed-pfas-regulation/

Semiconductors

Fluoroelastomers are fluorocarbon-based synthetic rubbers that are a category of fluoropolymer with high elasticity and rubbery behaviour, which is achieved through chemical cross-linking[73]. They are essential to seal the ultra-clean processing chambers used to manufacture microchips and to enable thinner microchip engraving, which is crucial to driving Europe's competitiveness and resilience in semiconductor technologies and applications and help achieve both the digital and green transition[74]. The engraving process involves temperatures above 200°C in combination with fluorine plasma and highly polar chemicals[75].

Fluoroelastomers can withstand the high temperatures,aggressive etching chemicals and fluorine and oxygen plasmas, and have the necessary purity required in the production of microchips, where even trace contaminants can severely affect production yield[76][77]. For high temperature applications (up to 315°C), perfluoroelastomers (FFKM) and PTFE perform well, whereas for lower temperature applications (up to 230°C) that do not depend on resistance to certain etching chemicals, such as ketones, bases, and ethylene diamine, FKM is favoured[78].

Chemical Production

Fluoropolymers are used as seals and gaskets in a wide range of equipment for chemical processing, transport, and storage, notably in valve stem and rotary shaft sealing applications[79]. The chemicals industry uses a range of aggressive media (e.g. strong acids and bases) as feedstocks, intermediates and as final products. It is therefore crucial to contain these chemicals during processing, transport, and storage to protect workers, consumers, equipment, and the environment.

Fluoropolymers have a range of properties that make them the material of choice for these applications, such as high chemical stability, creep resistance, stress retention properties, and low friction characteristics. Because of the low leachate level of fluoropolymers, they are also used widely in the food and pharmaceutical industries[80].

Marine

The majority of ocean-going ships operate with oil-lubricated stern tubes, which accommodate the propeller shaft. The stern tube requires sealing devices to prevent the outside water entering the internal engine room and leakage of oil into the surrounding water[81]. Elsewhere on the ship, lubricating oils are used in on-deck and underwater (submerged) machinery.

For such oil-to-sea interfaces, Environmentally Acceptable Lubricants (EALs) are required to be used, which are biodegradable, non-bioaccumulative, and minimally harmful for aquatic environment[82]. Types of EAL include vegetable oils, synthetic esters, polyalkylene glycols, and water, and the sealing devices used must be compatible with all of them. FKM offers compatibility with all EAL types and is therefore the material of choice for oil lubricated stern tube seals[83].

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[73] Plastics Europe (n.d.) Glossary. Available at: https://fluoropolymers.plasticseurope.org/index.php/glossary

[74] European Commission (2022) European Chips Act: Staff Working document. Available at: https://digital-strategy.ec.europa.eu/en/library/european-chips-act-staff-working-document

[75] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.europeansealing.com/esa-position-statement-on-proposed-pfas-regulation/

[76] Plastic Europe (n.d.) Electronics Industry. Available at: https://fluoropolymers.plasticseurope.org/index.php/Applications/electronics-industry

[77] Advanced EMC Technologies (2021) Polymer Seal Options for Semiconductors. Available at: https://advanced-emc.com/polymer-seals-for-semiconductors/

[78] 3M (n.d.) Optimizing Semiconductor Equipment & Maintenance for High Performance Seals and Gaskets. Available at: https://multimedia.3m.com/mws/media/2221028O/solutions-for-optimizing-semiconductor-equipment-and-maintenance-with-3m-dyneon-perfluoroelastomers.pdf

[79] Plastics Europe (2023) The Crucial Role of Fluoropolymers in Chemical Production. Available at: https://fluoropolymers.plasticseurope.org/application/files/6116/8115/3667/Fluoropolymers_Product_Group_Newlstter_March2023.pdf

[80] Plastics Europe (2023) The Crucial Role of Fluoropolymers in Chemical Production. Available at: https://fluoropolymers.plasticseurope.org/application/files/6116/8115/3667/Fluoropolymers_Product_Group_Newlstter_March2023.pdf

[81] Marine Insight (2021) Understanding Stern Tube Arrangement on Ships. Available at: https://www.marineinsight.com/tech/understanding-stern-tube-arrangement-on-ships/

[82] US EPA (2011) Environmentally Acceptable Lubricants. Available at: https://www3.epa.gov/npdes/pubs/vgp_environmentally_acceptable_lubricants.pdf

[83] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.europeansealing.com/esa-position-statement-on-proposed-pfas-regulation/

Automotive

Fluoropolymers are used in powertrain systems within the automotive sector as internal shift seal rings, head gaskets, O_2 sensor hermetic seals, air conditioning piston rings, and valve stem seals[84,85]. Types of sealing device used are O-rings seals in fuel containment systems and fuel injectors[86], and O-rings and radial lip shaft seals in transmissions or differentials to retain fluid and prevent external contamination. Fluoropolymers, such as FKM and PTFE, are favoured because of their resistance to high temperatures, forces and pressures, and oil and water[87].

Food & Beverage

Fluoropolymer sealing devices, including O-rings and flange gaskets, are used in a variety of food processing and packaging systems. Examples are filling and portioning systems; bottling, canning, and capping machinery; grinding and forming systems, injection devices, and decorating systems[88]. Key properties of fluoropolymers that make them attractive for use in the food and beverage sectors are their low leachate rates and ability to withstand the aggressive cleaning regimes[89] required to meet the hygiene standards under Regulation (EC) No 1935/2004 on food contact materials[90]. They must also preserve flavour so must not transfer any taste or aroma[91].

Manufacture of Pharmaceutical Products and Preparations

O-rings and inflatable seals are used within the pharmaceutical industry during the manufacture of active ingredients and their conversion into products suitable for administration to prevent contamination. During the production and synthesis stage, toxic chemicals are used, as well as high pressures and both high and low temperatures[92].

The performance requirements of pharmaceutical seals are chemical compatibility, high and low temperature resistance, abrasion resistance, and the ability to withstand aggressive cleaning regimes. Fluoropolymers are among the materials used for seals, because of their superior properties. FKM and FFKM both have similarly large temperature ranges[93,94], while both can withstand demanding operating conditions and meet hygiene requirements[95]. PTFE has high chemical resistance and when expanded has an excellent degree of flexibility and purity[96]. PTFE also has a water repellent surface that can resist build-up of substances and make them easy to clean[97].

Power generation

Fluoropolymer seals and gaskets are used in a variety of green technology applications to protect solar panels and wind turbines from a range of environmental, mechanical, thermal, and chemical stresses. These technologies must be resistant to weather and UV light, have low and high working temperatures, high operating pressures, and use acids and solvents. PTFE, FEP, PFA, and PVDF are desirable materials for use in sealing devices that protect the components of solar panels and wind turbines from the aforementioned

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[84] Teflon (2023) Teflon™ Fluoropolymers in Automotive. Available at: https://www.teflon.com/en/industries-and-solutions/industries/automotive

[85] ESA (2022) European Sealing Association (ESA) position statement relative to the European proposal for PFAS regulation in relation with the Sealing Industry. Available at: https://www.europeansealing.com/esa-position-statement-on-proposed-pfas-regulation/

[86] Chemours (n.d.) Automotive Fact Sheet. Available at: https://www.chemours.com/en/-/media/files/corporate/pfas/fluoropolymers-automotive-fact-sheet.pdf

[87] SKF (2014) Automotive transmission and driveline seals. Available at: https://cdn.skfmediahub.skf.com/api/public/0901d19680357a1c/pdf_preview_medium/0901d19680357a1c_pdf_preview_medium.pdf#cid-165344

[88] FPE Seals (2023) Food & Beverage. Available at: https://www.fpeseals.com/industries/food-beverage

[89] Trelleborg (2023) Seals for Food & Beverage Applications. Available at: https://www.trelleborg.com/en/seals/your-industry/food-and-beverage/products

[90] See: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:en:PDF

[91] Freudenberg (n.d.) Hygiene and Process Reliability. Available at: https://www.fst.com/sealing/markets/process-industry/food-andbeverage/

[92] Eastern Seals (n.d.) Pharmaceutical seal integrity. Available at: https://www.easternseals.co.uk/sectors/pharmaceutical-seal-integrity

[93] Eastern Seals (n.d.) Pharmaceutical seal integrity. Available at: https://www.easternseals.co.uk/sectors/pharmaceutical-seal-integrity

[94] TRP (n.d.) The chemistry behind FFKM's temperature range. Available at: https://trp.co.uk/chemistry-behind-ffkm-temperature-range

[95] Ibid footnote 93

[96] Ibid footnote 93

[97] Teflon (n.d.) Teflon™ Fluoropolymers in Pharmaceutical and Biopharmaceutical Manufacturing. Available at: https://www.teflon.com/en/industries-and-solutions/industries/industrial-manufacturing/pharma-biopharma

stressors[98]. Fluoropolymers are also used in gaskets in fuel cells and lithium-ion batteries to provide chemical, heat, and oxidation resistance[99]. The durability of fluoropolymers is key to minimising failures and maintenance stoppages and their use has delivered significant yearly cost savings compared to renewable energy technologies made from other materials[100].

General equipment

In addition to the specific applications detailed above, fluoropolymer seals and gaskets are also used in a range of general-purpose equipment. Examples include pumps and compressors where seals and gaskets must withstand intense pressure and temperatures and resist corrosive chemicals in fluids and gases. O-rings made from FKM, FFKM, and PTFE can be used in wet seals, mechanical seals, stator seals, and shaft seals. These materials are also used in gaskets for heat exchangers and general-purpose pipes, such as those exposed to strong acids and solvents and sea water[101].

Manufacture of instruments and appliances for measuring, testing and navigation

Fluoropolymer seals and gaskets can be used in satellite applications where instruments need to be protected from the outside atmosphere and internal corrosive fluids and substances that are carried by the satellite for its other functions, such as hypergolic fuels that power its thrusters[102].

2.2.3 Current status and projected future of the sealing device market in the EEA

2.2.3.1 Sealing Device industry: trends and baseline projections

The expected growth of the sealing device industry over the next ten years, as reported by manufacturers and importers of sealing devices in the EEA, is consistent with the growth projections made by the study team based on past trends and future macroeconomic projections using Eurostat databases. On average, the industry expects its turnover to grow at a real Compound Annual Growth Rate (CAGR) of 1.9% over the period as reported in survey, which is aligned with growth projections based on historical trends identified in Prodcom data for this Study. Considering this, the external and independent projections by the study team have been used to form the future baseline scenario for the sealing device industry and the figures presented here. All monetary figures are presented in 2021 euros, controlling for the effects on inflation.

Over the coming decades, it is assumed that these key trends will continue if no further regulatory action is taken, establishing the baseline or ‘Do nothing’ scenario, i.e., a counterfactual case in which the proposed restriction of PFAS is not implemented. In addition, the projections, made solely based on the industry’s history and the macroeconomic environment, are aligned with these industry expectations. These baseline scenario projections and trends are considered for five different business indicators:

- Turnover and number of products sold
- Gross value added (GVA, contribution to GDP)
- Operating expenditure
- Capital expenditure
- Research and development
- Employment.

Current and past baseline figures for the production value of the sealing device industry are taken, for each type of sealing device, from Eurostat’s Prodcom database. Other measures for the sector, such as turnover, employment and expenditures are available in Eurostat’s Structural Business Statistics (SBS) at a higher sector level. The sector size from Prodcom in proportion to the wider sector in the SBS is used to scale down figures from the SBS. All baseline growth projections are estimated based on historical trends at the level of

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[98] Adtech (n.d.) The use of fluoropolymers in green technology. Available at: https://adtech.co.uk/about/news/use-fluoropolymers-green-technology

[99] Fluorostore (2022) Fluoropolymer Applications in the Renewable Energy industry. Available at: https://www.fluorostore.com/en-int/blogs/news/fluoropolymer-applications-in-the-renewable-energy-industry

[100] Plastics Europe (2018) The Fluoropolymer Industry in Europe – A Socio-Economic Perspective. Available at: https://fluoropolymers.plasticseurope.org/application/files/9116/1167/4026/Fluoropolymer_Brochure_A4_Final_March2018_6.pdf

[101] 3M (n.d.) Industrial machinery solutions from 3M. Available at: https://www.3m.co.uk/3M/en_GB/industrial-machinery-uk/

[102] Omniseal Solutions (2021) Case Studies: Weather Satellite Calibration Instrument. Available at: https://www.omniseal-solutions.com/case-studies/weather-satellite-calibration-instrument

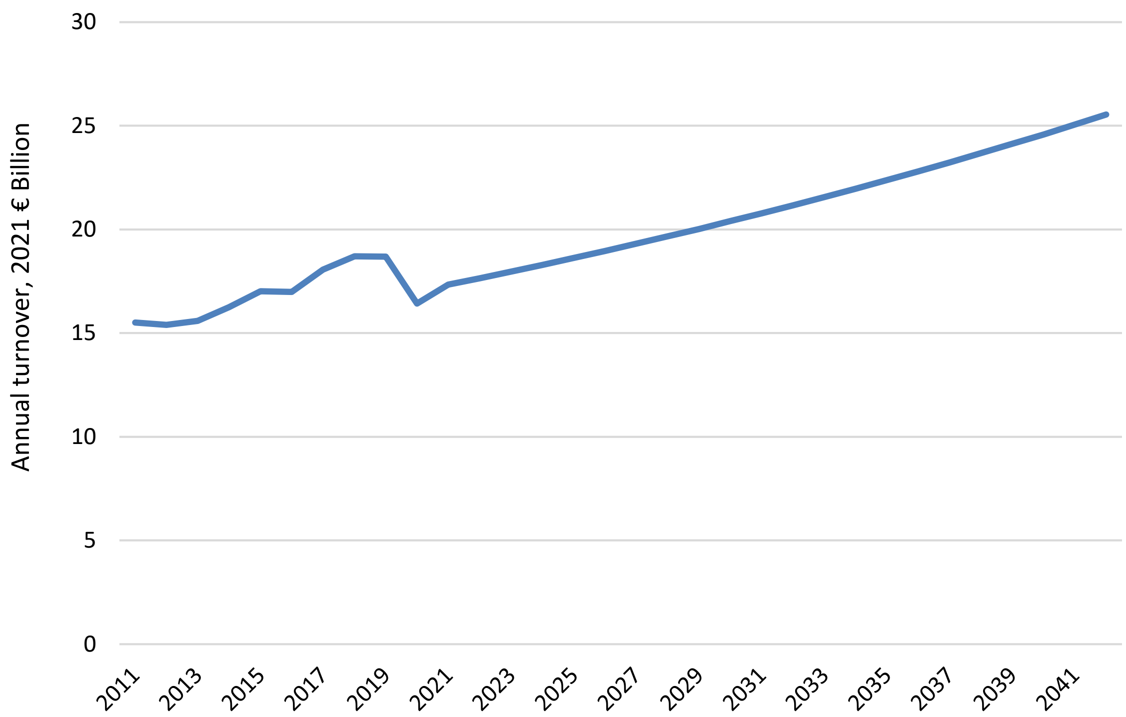
the EU sealing device industry, whereby past trends were extrapolated into the future from 2021 to 2042 (see Annex A3.1 for a detailed overview).

I. Turnover and Output of the EEA sealing device industry

The EEA sealing device industry's turnover has an estimated market value of €17.3 billion in 2021, and is projected to grow at a Compound Average Growth Rate (CAGR) of 1.9% over the next two decades in real terms (i.e. controlling for inflation), as depicted in Figure 2-1 below. This estimate is based on past trends for the sealing device industry, and on the current and expected growth for the European economy, the overall business context and the policy baseline, and is in line with stakeholders' expectations as provided in consultation. These projections amount to a cumulative growth close to 46% between 2021 and 2042.

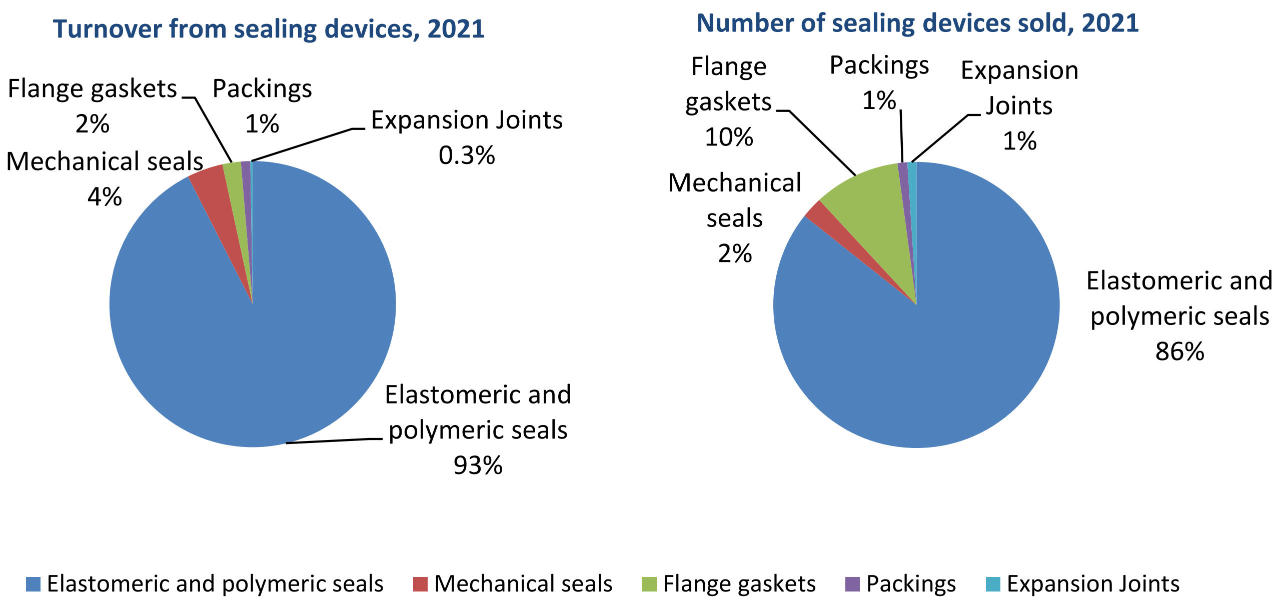
Considering turnover projections for each type of sealing device, all types show positive growth over the next two decades. The turnover from mechanical seals and expansion joints is projected to grow at real CAGRs of 3.5% and 2.1% respectively over the next two decades, exhibiting the highest growth over the period. In contrast, the turnover from elastomeric and polymeric seals and flange gaskets exhibits the lowest real CAGR at 1.2%, whereas the turnover from packings is projected to grow at a real CAGR of 1.7% between 2021 and 2042.

Figure 2-1 Turnover by type of sealing device (€ Billion, current prices), historical data and baseline projections. Source: Prodcom database (2011-2021).



By type of sealing device, Figure 2-2 shows the split of sales turnover (left) and of the number of sealing devices sold in the EEA (right) as reported by survey respondents. 93% of turnover in 2021 results from the sales of elastomeric and polymeric seals; and 7% from other categories of sealing devices: mechanical seals (4%), flange gaskets (2%), packings (1%) and expansion joints (0.3%). In terms of the number of sealing devices placed on the market, the breakdown shows a similar split, although with a higher weight of flange gaskets (10%), with elastomeric and polymeric seals representing close to 86% of the market.

Figure 2-2 Split of turnover and number of different types of sealing devices placed on the market (million units) in 2021. Source: consultation with industry stakeholders.



II. Gross Value Added (GVA, contribution to GDP)

The GVA of manufacturers and importers of sealing devices, more technically defined as the value of output or production minus intermediate consumption of goods and services (gross, i.e., before taxes), refers to its contribution to Gross Domestic Product (GDP). The stakeholder consultation, combined with statistical sources from Prodcom and SBS, allowed the estimation of GVA and baseline projections based on production value and intermediate consumption.

The GVA of the sector amounted to around €2.1 billion in 2021, equivalent to 12% of its economic output. GVA is projected to increase between 2021 and 2042 at a CAGR of 3.0%, which is higher than the sector's output growth. Based on the responses to the survey, although not directly linked by respondents, the study team considers that two trends have potentially contributed to this:

- Intermediate costs (OPEX) have and are projected to grow at a slightly slower pace than output (1.7% vs 1.8% per year) over the next two decades.
- The sector's expenditure on R&D is also expected to grow more rapidly than output (2.1% vs 1.8%). The sector's innovation will likely translate into higher value added in the sector.

In the baseline scenario, these trends are assumed to continue with the expected growth rates based on historical trends, thus producing growth for GVA at a CAGR of 3.0%, reaching € 4.0 billion in 2042.

III. Operating expenditure

The operating expenditure of EEA producers and importers of sealing devices refers to the value of costs incurred by the industry to maintain their regular operations. The stakeholder consultation provided data on operating expenditure for 2021, allowing to estimate a baseline value for 2021 of around €13.6 billion. According to data, between 2011 and 2019, OPEX increased at a real CAGR of 2.2%, later declining slightly during 2020 as a result of the Covid-19 restrictions. Growth in OPEX is projected to grow broadly in line with turnover growth, as these types of costs are generally proportional to production, with a CAGR of 1.7% and reaching € 19.2 billion in 2042.

IV. Capital expenditure

In this study, capital expenditure (CAPEX) refers to the money spent on acquiring assets. Between 2011 and 2021, CAPEX grew at a CAGR of 2.5%, and was estimated to be around € 1.2 billion in 2021. For the next two decades, in a baseline in the absence of any restrictions, capital expenditure in the EEA sealing device industry is assumed to continue to grow at the same rate as in the previous decade and higher than turnover growth, and therefore this measure of investment would reach € 2.0 billion.

V. Research and development

Expenditure on R&D by manufacturers and importers of sealing devices is expected to grow at a CAGR of 2.1% between 2021 and 2042, similarly to general capital investment. This is thought to be likely in part due to its lower magnitude in € (around € 1.0 billion in 2021), in comparison to turnover, indicating that there is room for higher growth (turnover is projected to grow at a CAGR of 1.8%), but feasible overall, due to its relatively lower amount in € million. Therefore, projections for R&D result in a total of € 1.6 billion in 2042.

VI. Employment

The sealing device industry in the EEA is estimated to employ around 43,900 persons in 2021. As the EEA sealing device sector continues to expand in the future, this is likely to be complemented by an increase in labour demand. However, this relationship between the sector's output and employment has some particularities:

- In the short run, employment is typically less volatile than sectoral output or production. For example, when output drops, employment declines with lower intensity and, usually, with a time lag. The adjustment in employment is also likely to spread over a longer period than for output. This is driven by the relative rigidity of the labour market in the EU-27 when compared to the market of goods and services, meaning that production is more easily and immediately adjusted than employment.
- In the long run, however, employment and production are assumed to follow similar trends, unless any significant technological and/or production process changes substantially affect this relationship between production and employment. As these changes are uncertain, they have not been considered in the baseline projections.

Therefore, employment is assumed to grow in line with turnover at a CAGR of 1.8% per year between 2021 and 2042, with an estimated employment of 63,500 jobs in 2042.

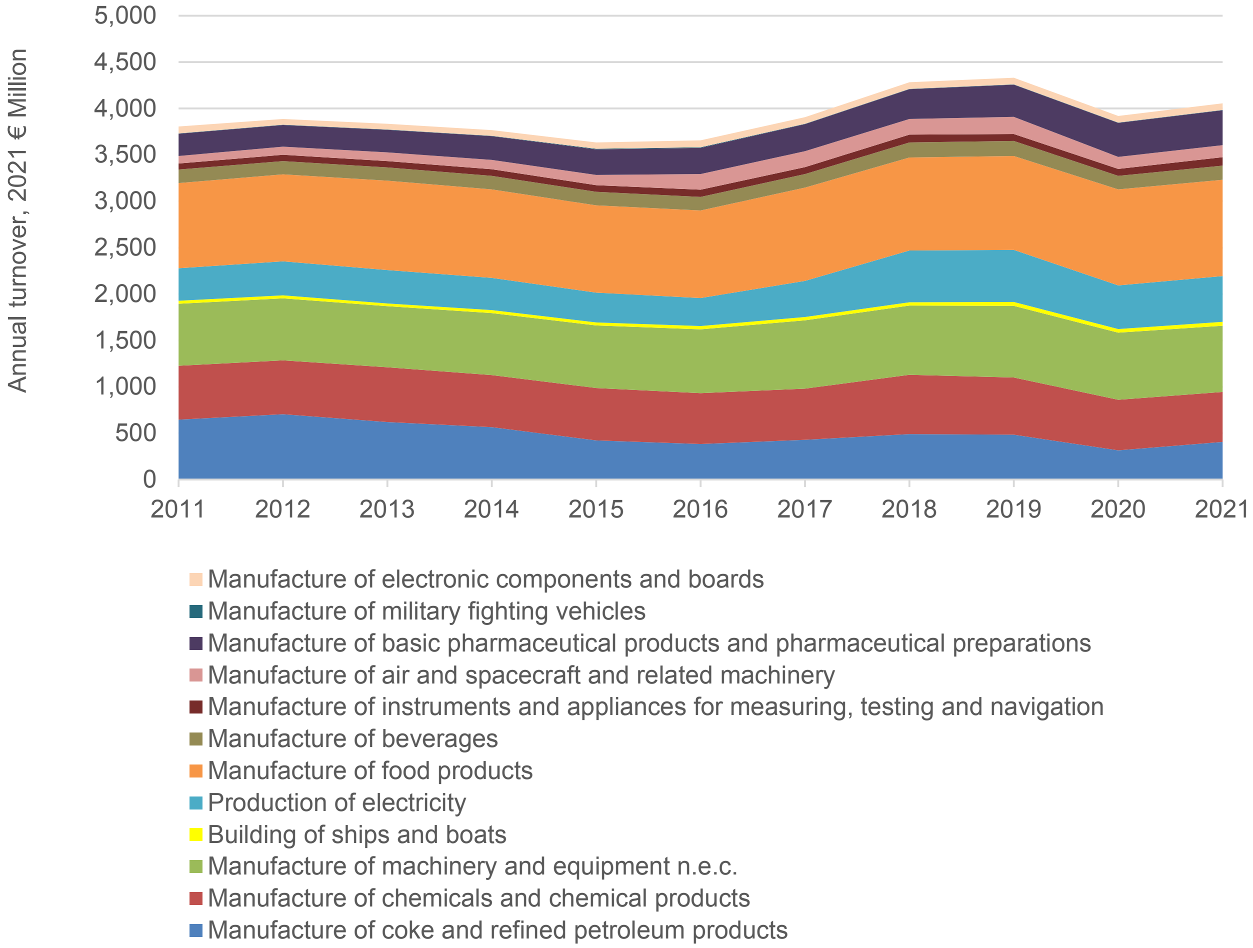
2.2.3.2 Sealing device downstream users: trends and baseline projections

Sealing devices, including fluoropolymer-based sealing devices, are used within a wide range of downstream applications, which are important for the continued functioning of society. For example, downstream applications have been identified in sectors such as the manufacture of chemicals, the food and beverage industry, the maritime sector, oil and gas, power generation, pharmaceutical products, and aerospace and defence.

Together, these downstream sectors represent thousands of billions of euros in joint sales turnover, estimated around €4,000 billion in 2021, which does not reflect their full social value. Figure 2-3 below displays the EEA aggregate turnover value of each of the downstream user applications considered for this assessment (i.e., either shortlisted or having had as participants in consultation activities) over the period 2011-2021. Overall, the turnover value in downstream user application sectors has grown at a CAGR of 1.6% between 2011 and 2019, with a slight decline in 2020 as a result of the restrictions during the Covid-19 pandemic, declining from €4.3 billion in 2019 to just under €3.9 billion in 2020 and resuming growth in 2021.

Figure 2-3 shows that the greatest turnover for sealing device applications is linked to the manufacturing of food products. The share of its turnover over the overall value of downstream user applications remains at 26% in 2021 and has grown at a CAGR of 1.2% between 2021 and 2042. Manufacture of machinery and equipment (18%) and manufacture of chemicals and chemical products (13%) are next in economic importance within the group.

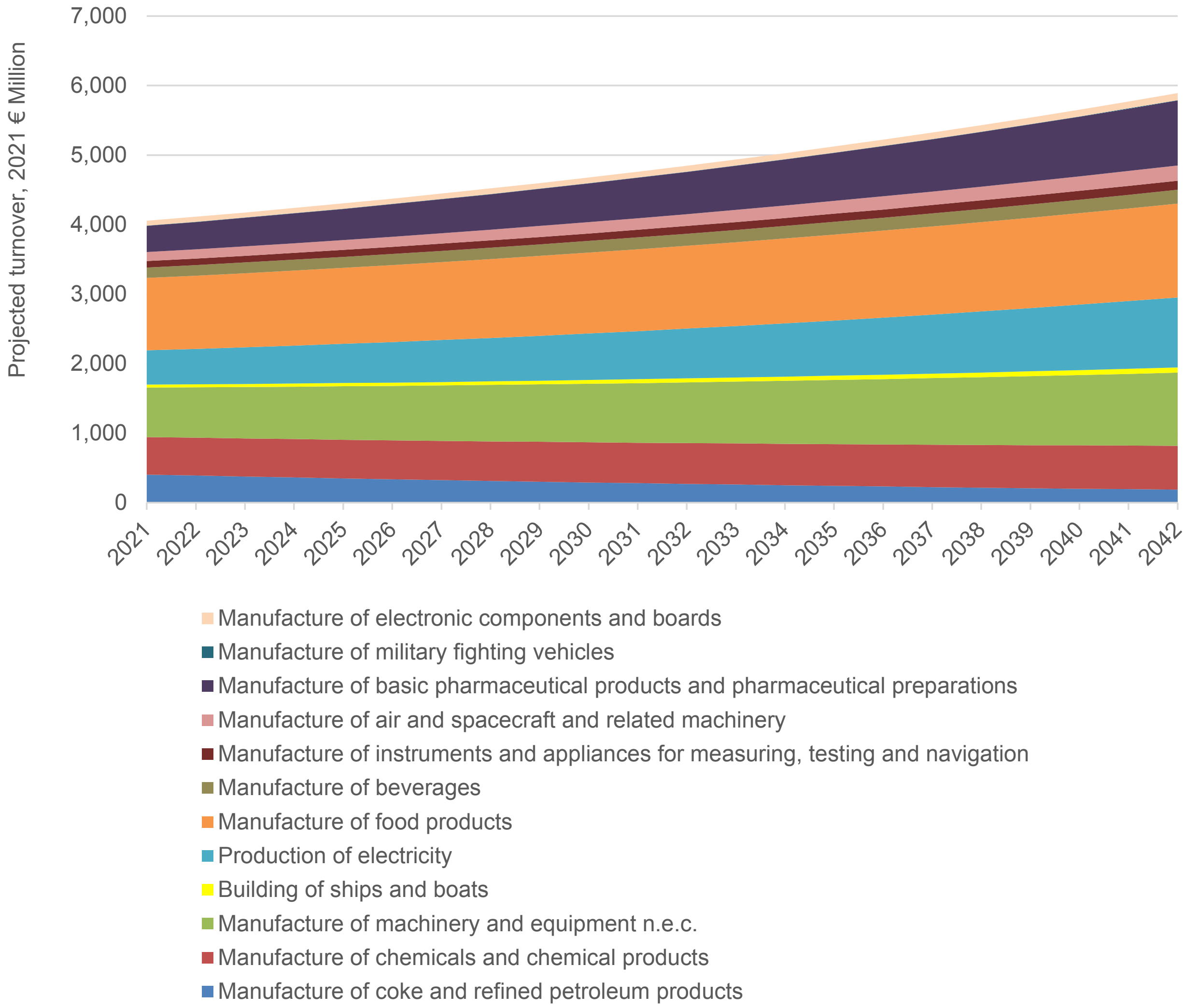
Figure 2-3 Turnover by relevant product application (€ Million, constant 2021 prices), historical data and baseline projections. Source: Structural Business Statistics (Eurostat, 2011-2021).



The historical data from SBS on the turnover of each downstream user application was projected at the sector level from 2021 to 2042 based on past trends. The resulting growth rates estimated for the period 2021-2042 are varied, but overall moderate. Figure 2-4 shows the baseline projections for each downstream user sector.

Three sectors are going to have a relatively higher growth within the group: manufacture of basic pharmaceutical products and preparations (CAGR 4.4%), production of electricity (CAGR 3.5%), and the manufacture of air and spacecraft and related machinery (CAGR 2.8%), although the latter is smaller in size.

Figure 2-4 Baseline projections of the turnover of selected downstream using sector applications (€ Million, constant 2021 prices). Own elaboration based on SBS data.



Having identified the sectors in which sealing devices play an economic role or are applied, it was not possible to identify sufficient or representative evidence as to the role these devices play. Forty-nine users across 10 different sector applications were engaged in the consultation; however, these are insufficient to draw conclusions for the sectors overall –they capture a very low percentage, below 5%, of the joint turnover sales value across the applications shown in Figure 2-4 for 2021.

Thus, only the sample estimates will be presented and assessed within this report as to the effects that are estimated for downstream users (i.e. not extrapolated to the sectoral level), noting the limitations. The overall scale of impact across downstream users will remain uncertain.

Therefore, the characterisation of the remaining economic variables of the downstream user application sectors in the rest of this Section relies on the figures provided by industry in consultation, and this baseline for downstream users will be shown at the sample level only (i.e., not extrapolated to the whole sector in general[103]). For four of these applications, the number of responses allows for values and impacts at the sectoral level while keeping anonymity and confidentiality.

Baseline scenario projections and trends are considered for the following seven business indicators (shown below in Table 2-4 along with their current, 2021, aggregate levels as reported by survey participants).

[103] Impacts from the restriction on downstream users' economic figures will also be calculated using the sample as reference, and extrapolations will be commented where possible, with the caveat that those extrapolations will be heavily impacted by the sample composition. Capturing what could happen to that many sectors on aggregate requires either oversimplifying assumptions or a much larger sample that was not possible to obtain.

Table 2-4 Current (2021) values for each of the variables of analysis, aggregated for the sample of sealing device downstream users that participated in the online survey.

Business indicators	2021 value (2021 €)
Turnover	€58,000 million
Intermediate consumption and operating expenditure	€44,100 million
Capital expenditure	€2,300 million
Research and development	€900 million
Employment	145,000 FTE jobs

In order to form the future sample baseline, all baseline growth rates are estimated based on publicly available data of the production volume at the level of the each of the application sectors in the EU (see Figure 2-3), and then applied to the figures reported by industry respondents in consultation.

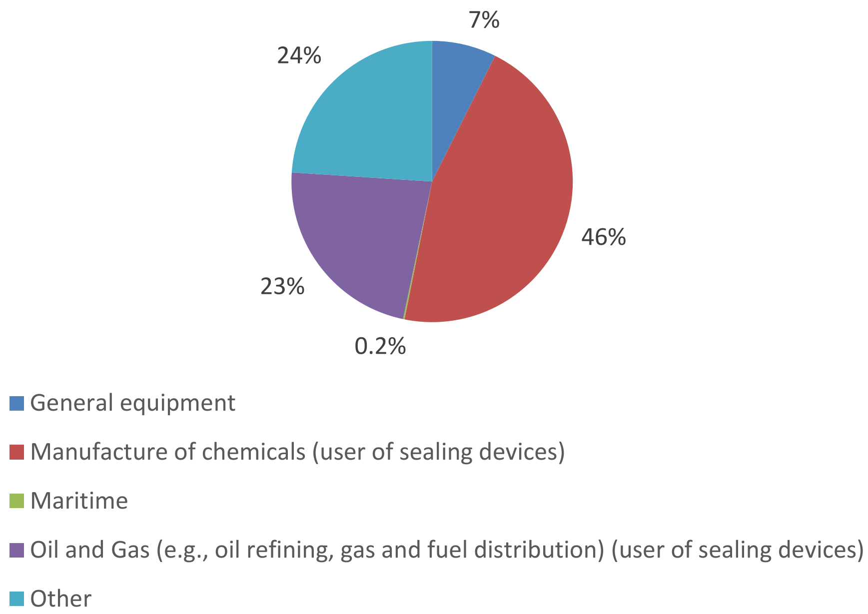
I. Turnover of the sample of EEA sealing device downstream users

Based on the projections presented in Figure 2-4, the total turnover of the sample of sealing device downstream users is expected to grow at a CAGR of 1.8% over the next two decades. This estimate is based on historical trends that allow the projections at the sectoral level for all sectors presented above within the EEA. These projections amount to a cumulative growth of approximately 45% over this period, reaching € 84.2 billion in 2021.

By downstream applications, the composition of the sample is presented below. Manufacturers of chemicals as users of sealing devices amounts to 46% of the turnover in the sample, with 23% to oil and gas (i.e., manufacture of petroleum products, refining), and 7% to general equipment. Downstream user applications with less than 5 respondents were grouped together in a separate category, ‘Other’, which amounts to 24% of the turnover from the sample. This composition by turnover means that the results from the analysis of impacts based on information from the survey to downstream users of sealing devices will be more heavily affected by impacts to chemicals manufacturers and to the oil and gas industry.

Further, sample representativeness of each of the sectors, defined as the percentage of turnover from the whole sector covered by respondents to our survey is generally low: 4.9% in the case of chemicals manufacturers, 3.2% in the case of petroleum products manufacturers, 0.6% in the case of general equipment, and 0.2% of the turnover from ship construction. Hence, the conclusions presented in this report will refer only to our sample and only represent impacts on our sample of respondents.

Figure 2-5 Split of the sample turnover by sealing device application sector. Source: consultation with sealing device downstream users.



II. Gross Value Added (GVA) of the sample of EEA sealing device downstream users

The GVA of downstream users of the sealing devices in the scope of the proposed restriction, more technically defined as the value of output or production minus intermediate consumption of goods and services (gross, i.e., before taxes), refers to its contribution to Gross Domestic Product (GDP). The stakeholder consultation returned data that allowed the calculation of current GVA and estimation of future trends, which were used to produce baseline projections.

The GVA of the sector amounted to around €8.0 billion in 2021, equivalent to 14% of its economic output. Based on the expected and projected evolution of the production value and intermediate consumption into the future, the GVA is projected to slightly grow by 0.1% per year on average between 2021 and 2042, with a cumulative increment of 2.9% during that period. Based on the responses received to the survey, although not directly linked by respondents, the study team considers the trends that contribute to this result:

- On the one hand, intermediate costs (OPEX) are expected to grow at a slightly higher pace than output (2.0% vs 1.8% per year) over the next decade, pushing the GVA downwards.
- On the other hand, the sector's expenditure on R&D is projected to grow more rapidly than output (2.3% vs 1.8%). The sector's innovation has likely translated into higher value added in the sector, mitigating the negative effect of relatively increasing operating costs on the GVA.

In the baseline scenario, these trends result in the growth for GVA at a CAGR of 0.1%, reaching €8.2 billion in 2042.

III. Intermediate consumption and operating expenditure of the sample of EEA sealing device downstream users

The operating expenditure of downstream users of sealing devices within the scope of this study refers to the value of costs incurred by the industry to maintain regular operations, and amounted to € 44.1 billion in 2021. The total operating expenditure of the sample of downstream users is expected to grow at a CAGR of approximately 2.0% over the next two decades. This estimate is based on the responses provided by downstream users of sealing devices within the EEA, covering operating costs in 2021 and expectations in baseline, and is also informed by the baseline projections at the sector level using public statistics from Eurostat's SBS. In 2042, operating expenditure of this sample of downstream users of sealing devices would be € 67.4 billion.

III. Capital expenditure of the sample of EEA sealing device downstream users

According to survey respondents, their capital expenditure was € 2.9 billion in 2021. Between 2021 and 2042, the expected growth in capital expenditure is estimated to be higher than the expected growth for turnover, with an expected annual growth in CAPEX of 2.3%. This estimate is based on historical trends that allow the projections at the sectoral level within the EEA, and is in line with the responses provided by downstream users of sealing devices. The projections to 2042 result in a capital expenditure of € 3.7 billion at the end of the period.

IV. Research and development sample of EEA sealing device downstream users

R&D expenditure in the sample of sealing device downstream users is estimated to have been € 0.9 billion in 2021. The expected future trend for expenditure in R&D over the next two decades is in line with the expected growth for capital expenditure, with a CAGR of 2.3%. This estimate results from a projection based on historical trends of capital investment, and is in line with the responses provided by downstream users of sealing devices within the EEA. R&D expenditure therefore would reach € 1.5 billion in 2042.

V. Employment of the sample of EEA sealing device downstream users

Employment in the surveyed downstream users of sealing devices is around 145,000 persons in 2021. As the production volume of sealing devices downstream users continues to expand in the future (see Figure 2-4), this is likely to be complemented by an increase in labour demand. There is typically a high correlation between economic output and employment, and this can be expected over the upcoming two decades with both economic indicators projected to increase. Employment in sealing device downstream user industries is expected to grow at a CAGR of approximately 1.9%. This estimate is based on employment in the downstream user industries of sealing devices within the EEA and historical trends at the sector level using data from Eurostat's SBS. Employment in 2042 would then reach 216,200 jobs.

2.3 DEFINITION OF THE 'RESTRICTION' SCENARIO

The proposed restriction translates into an immediate restriction of the manufacture, placing on the market (including import) and use of fluoropolymers that are not subject to derogations (see Section 2.1.1). Therefore, companies within the sealing device industry would lose their fluoropolymer-based sealing device portfolios unless they are able to manufacture alternatives, which may require the decommissioning of existing manufacturing facilities and significant capital investment to support new operations. With respect to downstream users, they would lose any production portfolio that relies on the use or content of fluoropolymer-based sealing devices, unless alternative sealing devices or alternative technologies are implemented that perform the same or sufficiently similar functions so as to allow the required levels of safety and product characteristics, and therefore, that have been tested, approved and validated.

Businesses are therefore expected to be able to mitigate at least a share of the potential product withdrawals that would result from the restriction of fluoropolymers. In order to achieve this mitigation, they would need to incur additional capital, operating and R&D expenditure. In particular, as a result of the restriction, businesses would need to increase their CAPEX and OPEX per unit of sales, and these costs are associated with substitution and/or reformulation of sealing devices. On the other hand, costs associated to any share of products that may be lost as a result of the restriction, would be lost as well.

These impacts would therefore affect the size and cost of operation of the companies within the EEA sealing device industry. The net reduction in EEA business operations, or direct impacts, would propagate through the EEA economy and have indirect and induced effects (indirect effects constitute a reduction in demand for inputs through the value chain of suppliers to the sealing device industry, while induced effects refer to the reduction in overall demand of consumer goods in the whole economy due to job losses as a result of the direct and indirect impacts) estimated in terms of potential reductions in the sector's contribution to GDP and employment over time.

The potential mitigation strategies that businesses may follow to mitigate portfolio losses could include the substitution of fluoropolymers with other substances, the substitution of sealing devices with other technologies, the abandonment of certain production lines in the EEA, etc.

There is a large amount of evidence required for the assessment of economic impacts for the sealing device industry of the restriction of fluoropolymers that fall within the scope of the proposed PFAS restriction. There are a few sealing device manufacturers in the EEA, but an indeterminate number of importers, which also generate economic activity within the EEA and would be affected by the restriction. There is also a range of downstream user sectors of sealing devices that can be classified with various degrees of detail, conditional on data availability.

The evidence available in published reports and studies, as well as economic statistics, is insufficient to quantify the potential business impacts of the restriction of the fluoropolymer sealing devices in scope without the introduction of a wide range of assumptions. Therefore, engaging business stakeholders from across the whole sealing device industry and various downstream user sectors to gather primary evidence on their operations and their value has been central to the assessment of economic impacts of the restriction proposal.

The consultation activities involved two targeted consultations with business stakeholders, one with sealing device manufacturers and importers, and the other one with downstream users for a selection of key application sectors.

2.3.1 Possible Derogations Under the Proposed Restriction

The proposed restriction includes derogations for the use and manufacture of fluoropolymers. PFAS polymerisation aids have been given a time-limited derogation of 6.5 years after entry into force for use in the production of fluoropolymers, except PTFE, PVDF, and FKM. Table 8 of the proposed restriction states that the exclusion of PTFE, PVDF, and FKM from the derogation for polymerisation aids in the production of fluoropolymers is on the basis that technically and economically feasible non-fluorinated processing aids (NFPAs) are available for these fluoropolymers, which make up around 80% of the global production of fluoropolymers[104]. Major manufacturers, such as Gujarat Fluorochemicals Ltd (GFL), Arkema, Solvay, and Chemours, offer a product range made using NFPAs. Currently, it is estimated that 50% of PTFE is manufactured using suspension polymerisation, which uses NFPAs. The suspension method produces granular polymers, with homopolymers and modified polymers. Information from manufacturers of sealing devices indicates that granular PTFE is used to produce their products, because of cost reasons and the flexibility of moulding and machining they provide[105][106].

The other 50% of PTFE is made from emulsion polymerisation, which is the method for producing fine powder and dispersion PTFE products. This technique currently uses fluorinated polymerisation aids (FPAs), but it's expected to transition to NFPAs in the future.

Around 86% of FKM currently uses NFPAs, with this expected to rise to 100%. ECTFE and PCFTE do not use NFPAs at present, but all production is expected to transition to NFPAs in the future (see table below)[107].

Table 2-5 Use of FPAs in the production of fluoropolymers[108]

Fluoropolymer	% of global production	Use of FPAs	% of global production not currently requiring FPAs	% of global production that will not require FPAs
PTFE	**53%**	**-**	**26.5%**	**53%**
PTFE Suspension	26.5%	N	26.5%	26.5%
PTFE Emulsion	26.5%	Y	0%	26.5%
PVDF	16%	N	16%	16%
FKM	**10.9%**	**-**	**9.4%**	**10.9%**
FKM Copolymer	7.8%	N	7.8%	7.8%
FKM Terpolymer	3.1%	Y/N	1.6%	3.1%

[104] Cousins, I (2023) Fluoropolymer Lifecycle Considerations: a Reason for Concern?

[105] Eclipse (n.d.) The Best Way to Process Teflon® (PTFE) for Optimal Seal Performance. Available at: http://eclipseseal.com/blog/seals/best-way-process-teflon-ptfe-optimal-seal-performance/

[106] Teflon (n.d.) Teflon™ PTFE Granular Molding Powders. Available at: https://www.teflon.com/en/products/resins/ptfe-granular

[107] Cousins, I (2023) Fluoropolymer Lifecycle Considerations: a Reason for Concern?

[108] Ibid footnote 107

Fluoropolymer	% of global production	Use of FPAs	% of global production not currently requiring FPAs	% of global production that will not require FPAs
FEP	**10%**	**Y**	**0%**	**0%**
PCTFE	**2.7%**	**N**	**2.7%**	**2.7%**
PVF	**2%**	**Y**	**0%**	**0%**
PFA	**1%**	**Y**	**0%**	**0%**
ETFE	**1%**	**Y**	**0%**	**0%**
THV	**0.3%**	**Y**	**0%**	**0%**
ECTFE	**0.3%**	**N**	**0.3%**	**0.3%**
Others	**2.5%**	**Unknown**	**-**	**-**

To note, other fluoropolymers are placed on the market for use in sealing devices, e.g. FFKM, but it has not been possible to identify the percentage of global production that requires FPAs.

Derogations have also been given for fluoropolymers used in the production of industrial and professional food and feed, and those used in the petroleum industry for 6.5 years and 13.5 years respectively. This would cover any sealing devices used within those sectors.

2.4 TIME AND GEOGRAPHICAL BOUNDARIES OF THE SEA, AND OTHER SCOPE CONSIDERATIONS

The section describes the scope of the SEA of the impacts of the proposed PFAS restriction on the fluoropolymer sealing industry. It details the geographical and temporal scope of the analysis, and the fluoropolymers and downstream users that will be of focus.

2.4.1 Geographical and temporal scope

The geographical scope of the analysis is the European Economic Area[109] (EEA), in line with the scope of the proposed PFAS restriction. The temporal scope is up to 2042, with the baseline and restriction scenario being projected to this date to allow for the restriction and its effects to fully take place.

2.4.2 Chemical scope

While all fluoropolymers are covered by the proposed PFAS restriction, the chemical scope of this study includes eight fluoropolymers (see Table 2-6).

Table 2-6 Fluoropolymers in scope of this assessment

Name	Other Identifier	CAS Number(s)
Polytetrafluoroethylene	PTFE	9002-84-0
Fluoroelastomers (Fluorine Kautschuk Material)	FKM	9011-17-0 / 25190-89-0 / 56357-87-0
Perfluoroelastomers	FFKM	26425-79-6
Fluorinated ethylene propylene	FEP	25067-11-2
Tetrafluoroethylene propylene	FEPM	27029-05-6
Polychlorotrifluoroethylene	PCTFE	9002-83-9

[109] The EEA comprises the current EU-27 and Iceland, Liechtenstein and Norway.

Name	Other Identifier	CAS Number(s)
Perfluoroalkoxy polymer	PFA	26655-00-5 / 31784-04-0
Poly(vinylidene fluoride)	PVDF	24937-79-9

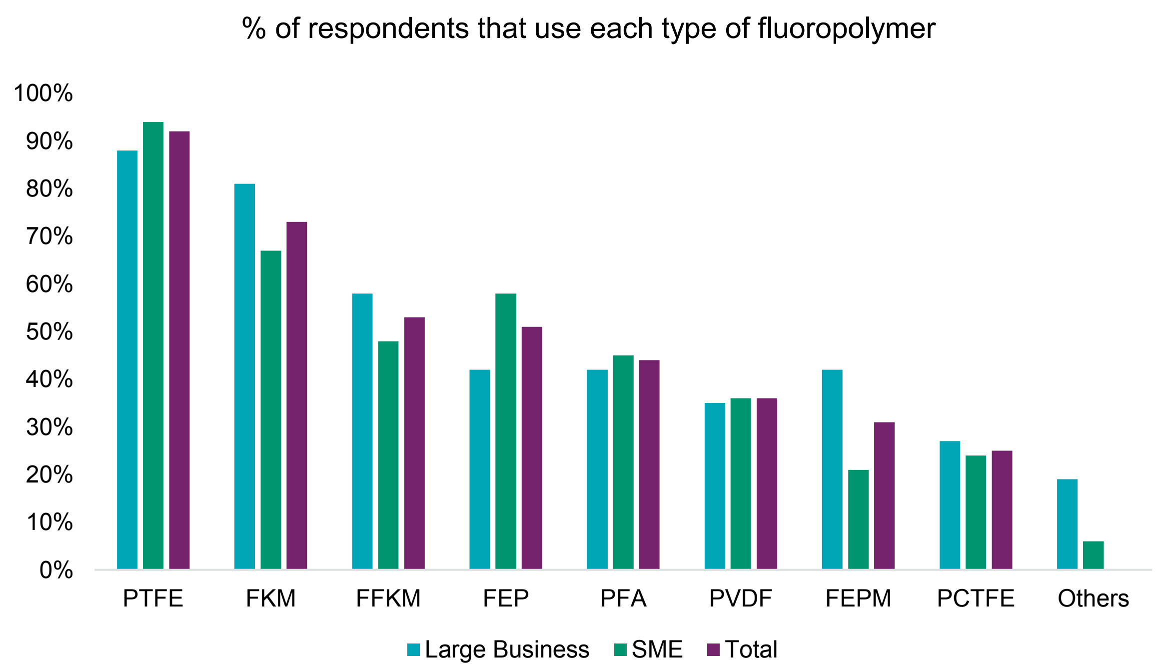
Based on information received from ESA and its members, the use of the fluoropolymers in scope has been mapped to sealing devices. These are shown in the table below.

Table 2-7: Fluoropolymers uses in different types of sealing device

Fluoropolymer	Packings	Mechanical Seals	Flange Gaskets	Expansion Joints	Elastomeric & Polymeric Seals
PTFE	✓	✓	✓	✓	✓
FKM	✓	✓	✓	✓	✓
FFKM	✓	✓	✓		✓
FEP		✓			✓
FEPM		✓			✓
PCTFE		✓	✓	✓	✓
PFA		✓		✓	✓
PVDF		✓			

Information received during the consultation to sealing device manufacturers and importers in the EEA provides a breakdown of the most commonly used fluoropolymers in sealing devices manufactured and/or placed on the market (see Figure 2-6).

Figure 2-6 Intensity of use of each type of fluoropolymers in sealing devices, as reported by consultation respondents. Percentages represent the percentage of respondents that use each type of fluoropolymers in their sealing devices.



2.4.3 Sectoral Scope

This SEA covers both the impacts on fluoropolymer sealing device manufacturers and importers, and their downstream users. Fluoropolymer-based sealing devices come in a variety of designs (see Section 2.2.2.1) and are used in a wide range of sectors (see Section 2.2.2.2), so to deliver a cost-effective socio-economic analysis, the study focused on a select number of downstream sectors, which were chosen based on:

1. Volume/value of sales of sealing devices to these downstream sectors, based on feedback from members (80:20 rule, i.e., 20% of sectors which purchase 80% of the volume/value)
2. Criticality of the sectors in our socio-economy (e.g., the power sector, etc.)
3. Level of buy-in from downstream users to engage with the consultation and ultimate participation in the survey

Based on information received from ESA, the following four sectors were selected for in-depth assessment:

- General equipment
- Manufacture of chemicals
- Maritime
- Oil & Gas

3. ANALYSIS OF THE RESTRICTION IMPACTS

3.1 ECONOMIC IMPACTS

An ex-ante assessment of the economic impacts of a PFAS restriction that includes fluoropolymers widely used in sealing devices is presented in this section. Economic impacts will consist of business impacts borne by the sealing device manufacturing and importing sector, and by a sample of manufacturers and/or importers of downstream user applications of sealing devices. Potential knock-on effects from the impacts on sealing device manufacturers and importers, throughout the whole European economy are presented. This analysis constitutes a focussed assessment of business-driven economic impacts, based on quantitative and qualitative insights provided in the two targeted consultations.

First, the assessment of potential impacts that the sealing device industry (i.e. manufacturers and/or importers) may face from the proposed restriction, accounting solely for the impacts on their sealing device portfolios, is presented. Second, the assessment of impacts of the proposed restriction on sealing device downstream users is presented. These two assessments rely on: the baseline developed in Section 2.2.3, the most recent data on the sealing device market from Prodcom and the Structural Business Statistics (SBS), evidence on expected outcomes of the restriction gathered via survey of 59 sealing device manufacturers and/or importers (estimated to be representing 91% of the whole sealing device industry's turnover value), a sample of 49 downstream users from different industries, and secondary research.

These outputs are presented separately for the sealing device industry, and for sealing device downstream users. For each of these groups, results are structured in the following way:

- The scope and potential scale of impacts as indicated by the business portfolio that would be affected by the restriction
- A consideration is made of business responses to these impacts – this includes a summary of qualitative responses to the survey on expected performance of alternatives that may be available today or in the future and their comparison with fluoropolymer-based sealing devices vis a vis their costs, properties, safety profile, and energy consumption
- Costs and benefits for the sealing device industry and on downstream user industries, including their turnover, GVA, intermediate consumption and operating costs, capital investment and R&D expenditure, the regulatory burden faced by these sectors, and employment
- Other qualitative business considerations.

3.1.1 Business impacts on manufacturers and/or importers of sealing devices

The proposed restriction translates into an immediate restriction of the manufacture, placing on the market (including import) and use of all PFAS. Companies within the sealing device industry would lose their portfolios of sealing devices using or containing PFAS unless they were able to manufacture alternatives.

Businesses expect to be able to mitigate only a small share of the potential product withdrawals that would result from the restriction of the PFAS in scope. To achieve this mitigation, they would need to incur additional capital, operating and R&D expenditure i.e., costs associated with substitution and/or reformulation. Therefore, as a result of the restriction, businesses would need to increase their CAPEX and OPEX per unit of sales. Additionally, any alternative would need to be tested and validated by its users, for each specific use.

These impacts would affect the size and cost of operation of the companies within the EEA sealing device industry. The net reduction in EEA business operations, or direct impacts, would propagate through the EEA economy and have indirect and induced effects (indirect effects constitute a reduction in demand for inputs through the value chain of suppliers to the sealing device industry, while induced effects refer to the reduction in overall demand of consumer goods in the whole economy due to job losses as a result of the direct and indirect impacts), estimated in terms of potential reductions in the sector's contribution to GDP and employment over time.

The impacts introduced above are further developed in the following sections:

- The affected portfolio (3.1.1.1)
- Expected business responses (3.1.1.2)
- Costs and benefits driven by the impacts on EEA sealing device industry (3.1.1.3)

3.1.1.1 The affected portfolio

The business scope of companies participating in the consultation[110] to sealing device manufacturers was generally limited to the production and import of sealing devices. 6% of the turnover reported by companies was dedicated to other purposes, which are interpreted to secondary but related activities of the companies, for example, sales of fixed assets. Overall, their portfolios from the sales of sealing devices in scope represented on average[111] 94% of the total turnover of sealing device market, or €15.7 billion in 2021.

Out of these sales of sealing devices, survey participants were asked to report the percentage their turnover generated from sales of devices containing or using fluoropolymers[112]. This represents around a quarter (or 24%) of all sales turnover from sealing devices, equivalent to €3.8 billion in 2021. In other words, a quarter of baseline sales of sealing devices could be **potentially affected by any type of restriction of PFAS and, more specifically, fluoropolymers**. These potentially affected sales will be referred to as the **'affected portfolio'**, and constitute a first and most conservative estimate of the potential loss in business (or market) size within the sector under the restriction scenario when compared to the baseline.

Estimates of the potentially affected portfolio differ notably by company participating in the online survey, however. For example, for over a quarter of respondents, the potentially affected portfolio represented the 90-100% of their sales, whilst for another quarter of respondents, the potentially affected portfolio did not surpass 25% of their business. The percentage of sales of devices containing fluoropolymers also vary by type of device, which is considered in the Table 3-1 below.

According to the regulatory timeline that is expected, the restriction would not be likely to enter into force before 2025, with a transition period of at least 1.5 additional years. That is, the restriction would be implemented in full around 2027. Evidence collated from the survey was thus overlayed with this potential implementation schedule to produce an estimate of sales turnover that would exclude the potentially affected portfolio of sealing devices from 2021-2042, showing an estimate of the maximum potential losses within the sector in a scenario where no alternatives are found for PFAS and/or sealing devices in the industry[113]. Figure 3-1 below presents these estimates.

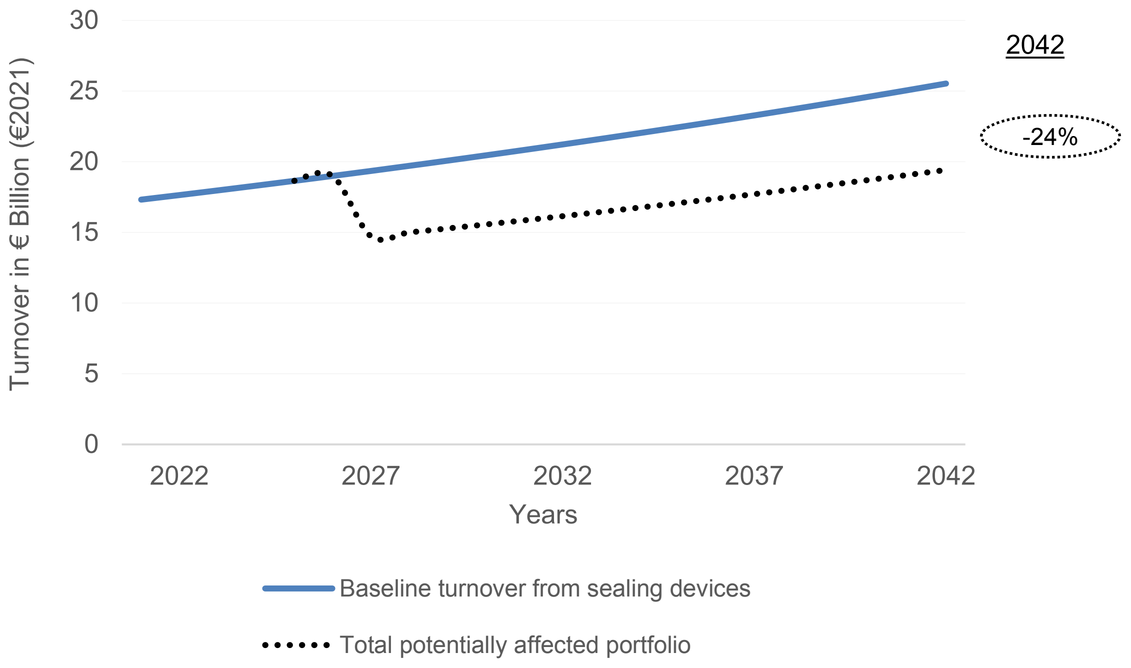
[110] The survey of sealing device downstream users was considered to be highly representative of the sector, with turnover from participants in the survey covering 91% of the estimated whole market value. See Section 2.1.3.3 for details on the consultation.

[111] 24% is the weighted average of the sealing device portfolio in turnover value € over each company's total turnover. While for a majority of survey participants this percentage varies between 50% and 100%, there are some large companies with a much larger business scope. This entails distributional effects in the event of a restriction (e.g., smaller businesses may be pushed out of the market with higher likelihood than larger ones).

[112] Fluoropolymers are the subset of PFAS that sealing devices can contain and/or use in their manufacture.

[113] Alternatives might still be found in other sectors. Results from the consultation with downstream users provide additional insights on viable alternatives to the ones provided by the sealing device industry.

Figure 3-1 Production portfolio of sealing devices (in terms of total turnover) that is in scope of being affected by the restriction of the PFAS in scope.



Source: Ricardo analysis based on Eurostat data and a bespoke survey of sealing device manufacturers and/or importers.

The estimated potentially affected portfolio or maximum potential turnover losses against the baseline can be considered an unlikely upper bound for the potential reduction of the EEA sealing device industry's business, as it assumes that the industry does not adapt, where possible, to mitigate these impacts. This projection is taken forward as the starting point for the quantification of the potential impacts on the EEA sealing device industry and knock-on effects on the broader economy.

As outlined above, on average the affected sealing device portfolio containing PFAS represents around a quarter (24%) of the entire sealing device manufacturers and/or importers' total sales turnover[114]. However, for many of the companies surveyed it represents between 90% to 100% of their business, implying that they would be forced out of business in the absence of a strategy that allows them to steer their production towards other products.

By type of sealing device, the potentially affected portfolio of devices varies between 4% (for expansion joints) and 34% (for mechanical seals) of the total sales turnover for each type of sealing device produced and/or imported by the industry. A detailed breakdown of the affected portfolio and turnover for each type of sealing device is presented in Table 3-1.

Table 3-1 Affected portfolio and total turnover for each type of sealing device produced and/or imported by the EEA sealing device industry (€ 2021).

Type of sealing device	Total turnover from each type of sealing device (€ 2021)	Potentially Affected Portfolio (% of turnover from each type of sealing device)
Elastomeric and polymeric seals	€ 5.7 billion	19% (€1.1 billion)
Mechanical seals	€2.3 billion	34% (€0.8 billion)
Flange gaskets	€2.6 billion	14% (€0.4 billion)

[114] 24% is the weighted average of the sealing device portfolio in turnover value € over each company's total turnover. While for a majority of survey participants this percentage varies between 50% and 100%, there are some large companies with a much larger business scope. This entails distributional effects in the event of a restriction (e.g., smaller businesses may be pushed out of the market with higher likelihood than larger ones).

Type of sealing device	Total turnover from each type of sealing device (€ 2021)	Potentially Affected Portfolio (% of turnover from each type of sealing device)
Packings	€2.2 billion	5% (€0.1 billion)
Expansion Joints	€4.5 billion	4% (€0.2 billion)

3.1.1.2 Expected business responses

The evidence collected suggests that, in response to the proposed restriction, businesses will substitute and/or reformulate around fifth of their affected portfolio, in sales turnover value €, to mitigate market losses and adapt to the new regulatory environment. Box 3-1 outlines the evidence collected related to the EEA sealing device industry's capacity to substitute and/or reformulate that has been considered in this analysis.

Box 3-1 Substitution and/or reformulation of products that may be affected by the proposed restriction.

59 businesses, including 33 SMEs and 26 large businesses, participated in an online survey to gather evidence of how they might respond to the adoption of a horizontal PFAS restriction, including substitution and/or reformulation, and the likely scale of these responses.

Businesses surveyed suggest that they would be able to substitute and/or reformulate around 20% of the products (in terms of total sales turnover) that may be affected by the proposed restriction, although there is some uncertainty (i.e., 20% of the potentially affected portfolio of devices in turnover terms).

Business expectations are affected not only by what might be technically and economically feasible but also how their customers may react to the substitutes and/or reformulated products.

The survey suggests that the ability of businesses to substitute or reformulate the products that may be affected could range between 13% and 25% of their affected portfolio (20% is the central estimate), on average across device types, although this is uncertain and will depend on a positive market uptake.

Moreover, the degree of expected substitution and reformulation varies widely across respondents and types of sealing devices. Ability of businesses to substitute and/or reformulate will be different across business type, size and affected products. For example, SMEs report on average a higher scope for substitution (29%), while large companies remain close to around 20%. By type of sealing device, the ability of businesses to substitute or reformulate their products varies considerably between 11% (for expansion joints) and 43% (for flange gaskets). A detailed breakdown of the possible rates of substitution and reformulation by type of sealing device is presented in Table 3-2.

Table 3-2 Substitution and Reformulation for each type of sealing device

Type of sealing device	Substitution and Reformulation (% of affected portfolio for each type of sealing device)
Elastomeric and polymeric seals	20%
Mechanical seals	20%
Flange gaskets	43%
Packings	12%
Expansion joints	11%

Businesses may also need time to adjust their operations and establish a final substitute and/or reformulated product that can be placed on the market. In some cases, businesses may already have a readily marketable alternative to place on the market upon adoption of policy changes. In others, businesses may require years of research and development and product approval before an alternative can be brought to the market. Based on survey responses, sealing device industry businesses, on average, expect a lead time of 7.6 years to bring a substitute and/or reformulated product to the market. However, the lead time varies considerably by type of sealing device, between an expected 3.1 years for flange gaskets and 7.8 years for elastomeric and polymeric seals. A summary of the lead time to bring a substitute and/or reformulated product to market is presented in Table 3-3 below.

Table 3-3 Substitution and Reformulation for each type of sealing device

Type of sealing device	Average lead time to market
Elastomeric and polymeric seals	7.8 years
Mechanical seals	5.2 years
Flange gaskets	3.1 years
Packings	5.4 years
Expansion joints	7.4 years

In conclusion, some substitution and/or reformulation is likely, and businesses will attempt to maximise this where economically viable. However, this substitution and reformulation activities would only likely mitigate around 20% of total potential market withdrawals of sealing devices that would otherwise be necessary as a result of the PFAS restriction; and they would take time to implement (and to generate a stream of income).

Source: Ricardo analysis based on a bespoke survey of sealing device manufacturers and/or importers

To substitute, reformulate and/or withdraw sealing devices affected by the PFAS proposed restriction, business will thus need adjust capital and/or R&D expenditure plans and manufacturing or operating processes. The evidence collected in consultation suggests that businesses have some capacity to pass some of this new regulatory burden through to their clients. However, the survey responses also suggest that overall sales of the EU sealing device industry are highly responsive to price changes. Therefore, the increase in regulatory burden is likely to be supported mainly by manufacturers themselves, at least within the EEA.

These potentially negative impacts might be more pronounced for the extra-EEA export market, especially when combined with strong or growing competition from players based outside of the EEA and not subject to the proposed restriction. According to public statistics from Eurostat's Prodcom, the extra-EEA export market for sealing devices is equivalent to 27% of the sales turnover of companies in the EEA sealing devices industry.

Box 3-2 outlines the evidence collected of the EEA sealing device industry's capacity to pass increased regulatory burden onto clients and the market responsiveness to potential product price changes.

Box 3-2 Pass through of regulatory burden for products that may be affected by the proposed restriction.

Businesses participating in this consultation also considered the extent to which they would be able to pass through any additional regulatory burden down their supply chain, which is estimated to be around 42%.

These businesses also explored the price elasticity of their product portfolio in the EEA. Respondents were not asked to report any information of the prices of their products, but rather their ability to pass through any increases in regulatory costs to their customers and their customers' potential responsiveness to such adjustments in prices. Overall, they considered that their products are, on average, highly price elastic, with price elasticity of demand estimated at around -2.6. This means that the quantity sold in the EEA is highly responsive to price changes, that is, a 10% increase in prices would result in a nearly 26% reduction in the quantity sold.

This means that, given current market dynamics, businesses may not be able to pass through a large part of the increased regulatory burden to their clients with limited additional impacts on the size of their operations. Instead, price increases would negatively affect their sales, leading to sales reductions higher than the turnover that would be recovered with higher prices.

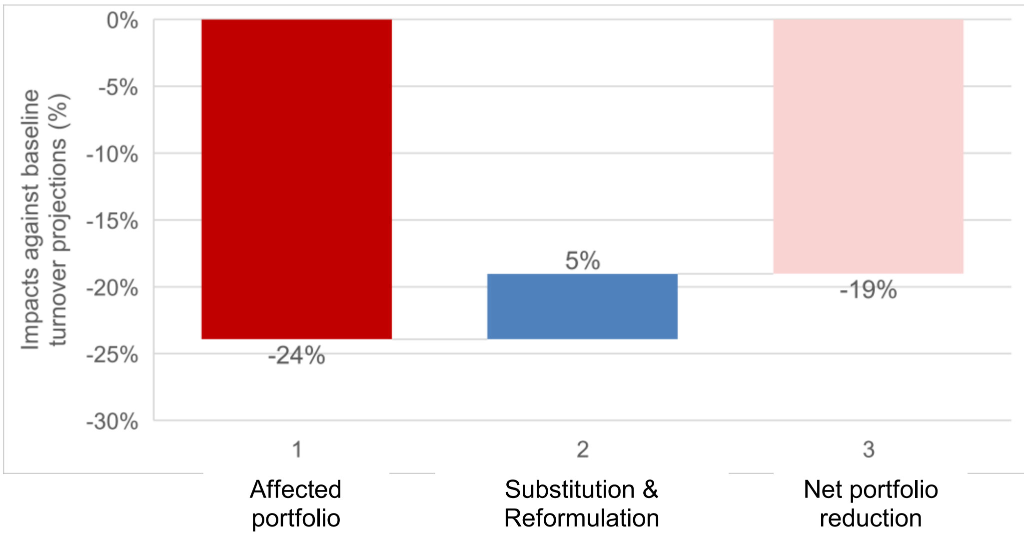
Additionally, if alternatives to be sold to downstream users require substantial alterations to existing articles or products to ensure safety due to differing hazard properties, this would require additional CAPEX and OPEX also from downstream users, thus increasing the cost burden that is transferred to them and reducing their willingness to pay for more expensive alternatives.

There are uncertainties as to how businesses and their customers will respond. However, given this evidence, there might be a low likelihood that sealing devices companies would decide to pass on any notable percentage of additional costs through prices at the cost of potentially higher market losses. Thus, these second-order impacts are excluded from the quantitative assessment of impacts on turnover and knock-on implications.

Source: Ricardo analysis based on a bespoke survey of sealing device manufacturers and/or importers

Figure 3-2 below illustrates the core steps of the impact pathway statically, from the estimation of the total potentially affected portfolio to the turnover losses that are estimated to result from the introduction of the restriction considered in this study (central estimates).

Figure 3-2 Static stepwise representation of the portfolio in scope of being affected by the proposed restriction and expected responses from businesses (only first-order impacts[115], in percent of baseline turnover)



Source: Ricardo analysis based on EEA and Eurostat data, and a bespoke survey of sealing device manufacturers and/or importers.

In sum, and as set out in Figure 3-2, the total potentially affected product portfolio of sealing devices from the PFAS restriction is equivalent to a quarter (24%) of the baseline total turnover from the sale of sealing devices in the EEA (**Step 1**).

Around 5 percentage points of this market will likely be substituted or reformulated in the next decade, assuming that the proposed restriction is implemented (**Step 2**), thus meaning that a share of the loss resulting from Step 1 can be mitigated.

This means that the proposed restriction, when accounting for potential business responses, could lead to a reduction in product portfolio and business (in turnover terms) of around 19% or equivalent to €3.0 billion of the 2021 market (**Step 3**).

Manufacturers and importers have noted through stakeholder consultation their views on the availability of viable alternatives. These views include:

- On average, 80% of manufacturers and/or importers reported that they were not aware of the existence of any alternatives to fluoropolymers and/or fluoropolymer-containing sealing devices that are currently available.
- There is a lack of consensus on the cost of alternatives, with 32% of manufacturers and importers reporting higher costs, 20% reporting equal costs and 17% reporting lower costs compared to PFAS/ PFAS-containing products. Among the possible sources of additional costs provided in consultation are: certification and testing, material changes requiring investing in new equipment, and administrative and documentation work. It was also indicated that a not too solid business case for alternatives would preclude the investment.

[115] First-order impacts exclude adjustments via prices (see Box 3-2).

- 53% of manufacturers and importers noted that the health hazards or risks of these alternatives are either equal or higher than the fluoropolymers and/or fluoropolymer-containing sealing devices whereas 54% of manufacturers and importers noted that the environmental hazards or risks of these alternatives are either equal or higher than the fluoropolymers and/or fluoropolymer-containing sealing devices.
- Around 40 to 50% of the manufacturers and respondents felt that the difference in performance of these alternatives would have a negative effect on the daily lives of industrial, professional and consumer users.

Time-limited derogations are, however, expected to positively affect the extent of potential substitution. Over time, companies may be able to further develop and implement non-fluoropolymer-based sealing device alternatives.

The information-gathering exercise via consultation took place before the restriction proposal from the 7th of February was published. Thus, the survey questions did not differentiate between obtaining shorter or longer time-limited derogations. As a way to address this, two extreme scenarios have been modelled for sealing device manufacturers: one in which 20% of the portfolio is substituted and/or reformulated and 28% of the portfolio obtains a 5-year derogation, additional to the 1.5-year transition period (Scenario 2); and another scenario in which 25% of the portfolio is substituted and/or reformulated and 28% of the portfolio obtains a 12-year derogation, also additional to the 1.5-year transition period (Scenario 3). Therefore, it is considered that the potential impacts on the market could be somewhere between the two Scenarios if time-limited derogations are granted.

Moreover, the quantitative impact estimates presented earlier have been overlaid with implementation timeline assumptions and time-limited derogation scenarios, and these are presented in the following sections. In this presentation, we have also included a Scenario 1 with a 1.5-year transition period and potentially lower levels of substitution due to lower availability of alternatives and substitutes in the shorter term (13% substitution).

Evidence on the time to market of alternatives and new products (see Table 3-3) also supports the idea that more substitution will be viable over time, while without time for innovation, substitution can be more limited.

3.1.1.3 Costs and benefits driven by the impact on the EEA sealing device industry

The consultations with sealing device manufacturers and/or importers enabled the confirmation of the scope of their production portfolio that is likely to be affected by the proposed restriction and the identification of potential business responses.

To assess the net impacts of these policy options on the EEA sealing device industry, a baseline and two policy scenarios were developed:

- The sectoral **baseline** (2021-2042) was developed by employing statistical techniques and trend analysis on publicly available evidence of the turnover from Eurostat's Prodcom Database and Structural Business Statistics[116], combined with reported data by industry stakeholders. This baseline scenario assumes that the proposed restriction is not implemented, or what would be equivalent for this sector, that fluoropolymers are exempted from the restriction.
- A first policy scenario (**Scenario 1**) considers the proposed restriction entering into force in 2025, with a 1.5-year transition period for all manufacturers and users of PFAS to implement substitutes and alternative products. The affected products would be withdrawn from the market unless they are substituted and/or reformulated, which happens instantaneously after the 1.5-year transition period ends in 2027.
- A second scenario (**Scenario 2**) considers that businesses may be granted derogations for a period of 5 years additional to the 1.5-year transition period, so they can develop and bring new substitutes and/or reformulated products to the market while continuing to use the products affected by the proposed restriction. This would lead to smaller turnover losses earlier on. Over time, turnover will converge to the levels estimated in Scenario 1.

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[116] Eurostat (2023), *Structural Business Statistics Database*. [online] Eurostat Available from: Database - Structural business statistics - Eurostat (europa.eu) [Accessed 05/2023]

- A third scenario (**Scenario 3**) considers that businesses may be granted a longer derogation period of 12 years additional to the 1.5-year transition period, so they can continue to use these products after the implementation of the proposed restriction and develop substitutes and/or reformulated products in the meantime. Thus, is expected to further delay turnover losses, and reduce them, as a larger proportion of the affected portfolio would be able to be substituted and/or reformulated with more time to innovate, converging to a higher turnover level than estimated in Scenario 1.

All the three policy Scenarios are devised as extreme situations in which a) no derogation is granted, b) 5-year derogations are granted to the use of fluoropolymers in all sealing devices where derogations are expected by survey participants, or c) 12-year derogations are granted to the use of fluoropolymers in all sealing devices where derogations are expected by survey participants. It is understood that the final impacts of a PFAS restriction on the sealing device market will be somewhere between these three options, closer to each depending on the extent of derogations that are finally conceded. Based on these policy scenarios and the available evidence from the bespoke business consultations, Eurostat and secondary research, the net impacts on the EEA sealing device industry and the knock-on effects on the European economy were assessed against the baseline scenarios. These are described against the five business measurements:

- Turnover
- Intermediate consumption and operating costs
- Capital expenditure and Research and Development
- Other opinions and insights by the sealing device industry. Although the restriction is not expected to have effects until at least 2027, results are presented in annualised terms over the period 2024-2042 for comparison.

3.1.1.3.1 Turnover

The adoption of the policy options considered is estimated to lead to a reduction in sales or size of the EEA sealing device industry in terms of turnover[117] and number of products manufactured and sold. The extent of this reduction will depend upon the scope and timetable of the legislative changes as well as the type of business responses expected.

First order effects, that is, the impacts on business operations excluding any pass through of additional regulatory costs to customers through price adjustments, are considered in Table 3-4. This potential loss of turnover stems from products and product lines which contain fluoropolymers and cannot be substituted or reformulated, and hence are restricted and would need to be withdrawn as a consequence of the restriction. Those affected product lines that can be substituted or reformulated will continue to provide a source of revenue to these businesses, and hence not all of the baseline turnover from sales of these products would be 'lost', although such business response has other implications on manufacturers and importers, such as effects on OPEX and CAPEX that are explained in subsequent sections.

Table 3-4 Annualised impacts on the size of the EEA sealing device manufacturers and importers' business against the baseline scenario in terms of total turnover (€ 2021).

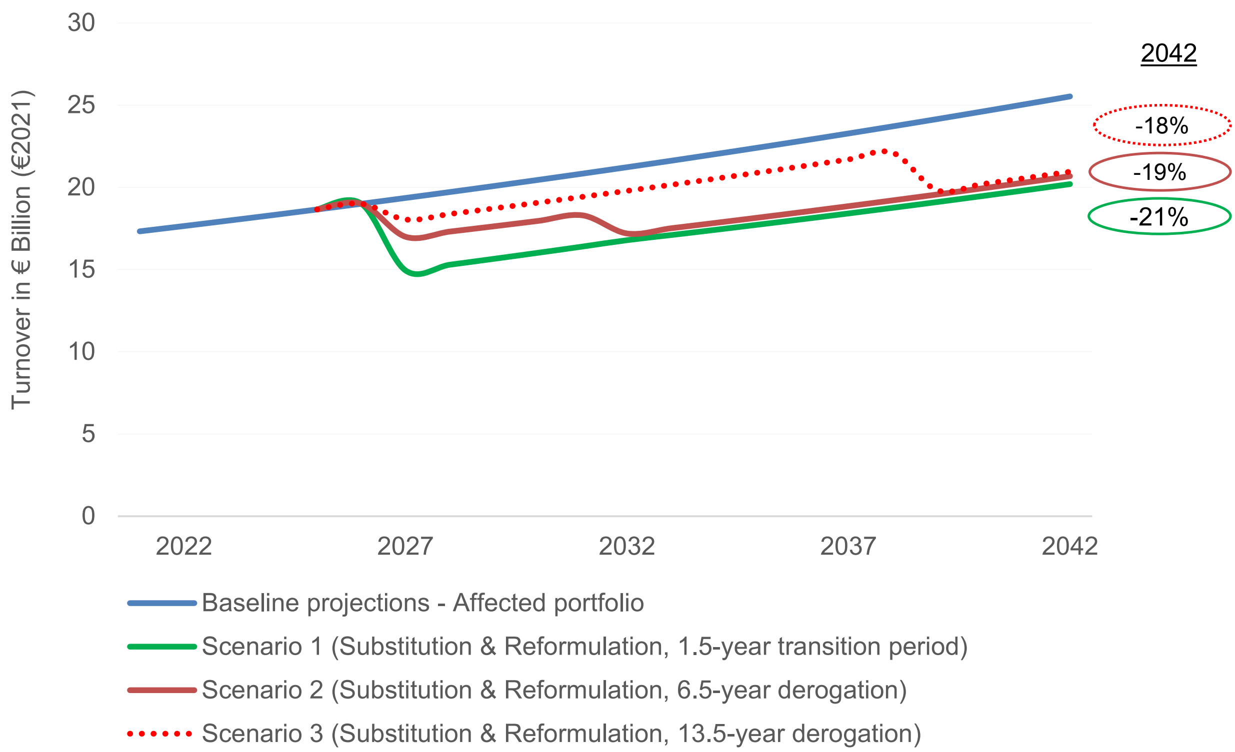
Scenario	First order effects or impacts on business sales overall
Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Manufacturers and importers in the EEA sealing device industry are estimated to **lose €3.7 billion (€ 2021) of turnover each year on average** over the period 2024-2042, when compared to the baseline scenario.

[117] Turnover refers to total sales of the EEA sealing device manufacturers and importers, thus including sales of products in the EU or abroad. There is an implicit assumption that activities targeting export markets will also be affected, on average, in a similar way to the market targeting EU customers. The effects on the exports are uncertain and could be more or less significant than the impacts that may apply to the manufacturing and/or use of substances within or for customers in the EU, depending on the attractiveness and costs of substitutes and alternative products without fluoropolymers, that may be competing in an international market with the traditional fluoropolymer-based sealing devices.

Scenario	First order effects or impacts on business sales overall
Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Manufacturers and importers in the EEA sealing device industry are estimated to **lose €2.9 billion (€ 2021) of turnover each year on average** over the period 2024-2042, when compared to the baseline scenario.
Scenario 3 (Substitution and Reformulation, 13.5-year derogation)	Manufacturers and importers in the EEA sealing device industry are estimated to **lose €1.6 billion (€ 2021) of turnover each year on average** over the period 2024-2042, when compared to the baseline scenario.

The impacts are also presented over time in Figure 3-3 below.

Figure 3-3 Estimated impacts on the total sales turnover of sealing device manufacturers and importers in the EEA against the baseline scenario (€ 2021)[118].



Source: Ricardo analysis based on Eurostat and EEA data and a bespoke survey of manufacturers and importers in the EEA sealing device industry.

These first-order effects (as shown in Figure 3-3) reflect the direct business response to the proposed legislative changes: by 2042, the EEA sealing devices manufacturers' and importers' market would be around 18% to 21% lower than the estimated baseline, depending on the scenario, which is equivalent to an annualised loss of turnover sales against the baseline of around €3.7 billion under Scenario 1 and €2.9 billion under Scenario 2, due to the different time-derogated paths and time and resource to innovate. Under Scenario 3, there would be a lower loss of turnover in the period equivalent to €1.6 billion each year (annualised), which is around 18% lower than the estimated baseline. These effects exclude whether companies might pass the additional regulatory burden through to their customers and the associated implications, which we refer to as 'second-order effects' and are discussed in Box 3-2 above.

[118] Please note that the diagrammatical illustrations in this study smooth the changes in turnover over time, thus assuming that these changes are continuous (rather than discrete reductions in business). For example, in Scenario 1, it is implicitly assumed that the impact of a policy change is felt immediately and businesses start to adjust their operations slightly in advance as a way of preparing for the year in which the legislation comes into effect. In reality, businesses may take action much earlier or have a 'grace period' during which they can adjust their operations and meet the new legal requirements.

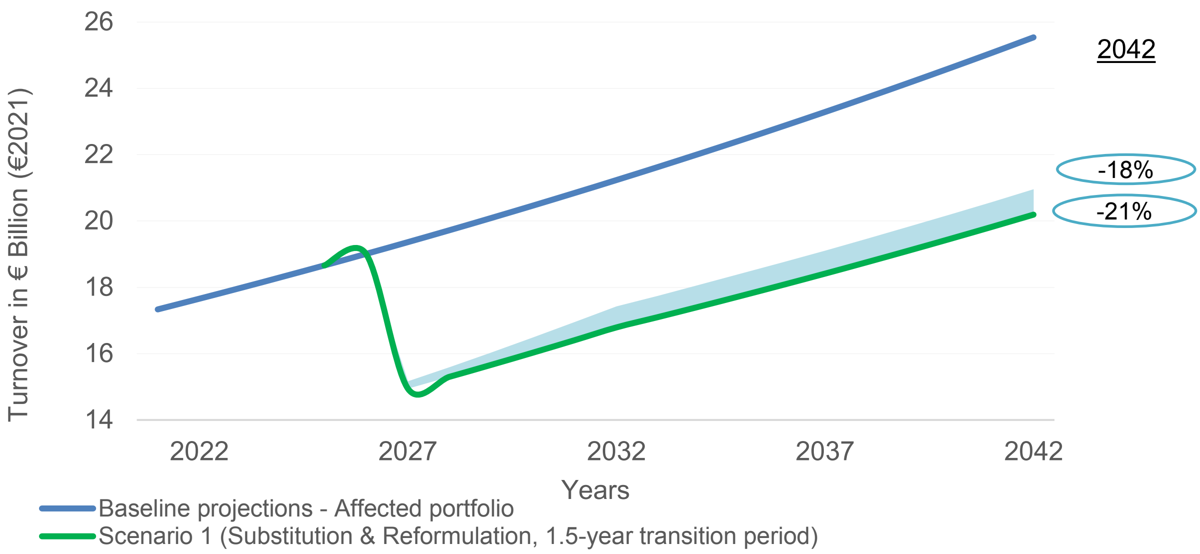
These second-order effects have been considered based on the evidence gathered through the survey of sealing device manufacturers and importers. Overall, based on the data available, it is estimated that if companies passed through some of the additional regulatory burden resulting from the proposed restriction, and, as reported by survey participants, sealing devices appear to be price elastic, this would result in a larger estimated reduction in turnover (see Box 3-2 for a discussion on the uncertainties surrounding mitigation via prices). Therefore, since this strategy would not be considered rational for companies, it is assumed that it may not be implemented.

Overall, this suggests that **even if businesses were to introduce mitigation measures whilst incurring additional operating and capital costs (first order effects), their operations and associated economic footprint would be likely to reduce significantly, with annual turnover losses against the baseline are estimated to range from €1.6 billion to €3.7 billion per year, on average[119], between 2024 and 2042.**

The scenarios established for estimating the potential policy impacts on the turnover of the EEA sealing device manufacturers and importers present the implications of key uncertainties relating to the timeframe of the proposed restriction's impacts on turnover**. Scenario 1** considers the proposed restriction happening in 2025, with a 1.5 transition period that delays impacts to 2027 and mitigating actions taking effect immediately upon restriction; **Scenarios 2 and 3** consider that businesses may need time to adapt and can apply for and/or be granted derogations, so they can bring substitutes, redesigned and/or reformulated products to the market. Within each of these scenarios there are other assumptions, and hence uncertainties, which could affect these estimations. In particular, the sensitivity of the results to the extent to which businesses may be able to substitute and/or reformulate has been explored.

Therefore, as noted earlier, if businesses do not substitute and/or reformulate at all, the EEA sealing device manufacturers and importers could lose 24% of their total turnover estimated in the baseline. The best available evidence suggests that businesses will be able to substitute, reformulate and/or redesign around 20% of their affected product portfolios (in terms of turnover). However, response dispersion around the degree of substitution in the estimates elicited from the survey to sealing device manufacturers and importers provides a range of possible substitution and reformulation that is between 13% and 25% of their affected portfolio. In any of these cases, turnover losses are not estimated to vary significantly from the central estimate. This is illustrated in Figure 3-4 below, with losses in these two more extreme cases ranging between 18 and 21% of the total turnover from sealing device manufacturers and importers' businesses.

Figure 3-4 Illustration of the sensitivity of the estimated impacts on the turnover of EU sealing device manufacturers and importers against the baseline scenario (€ 2021) to expected substitution and/or reformulation



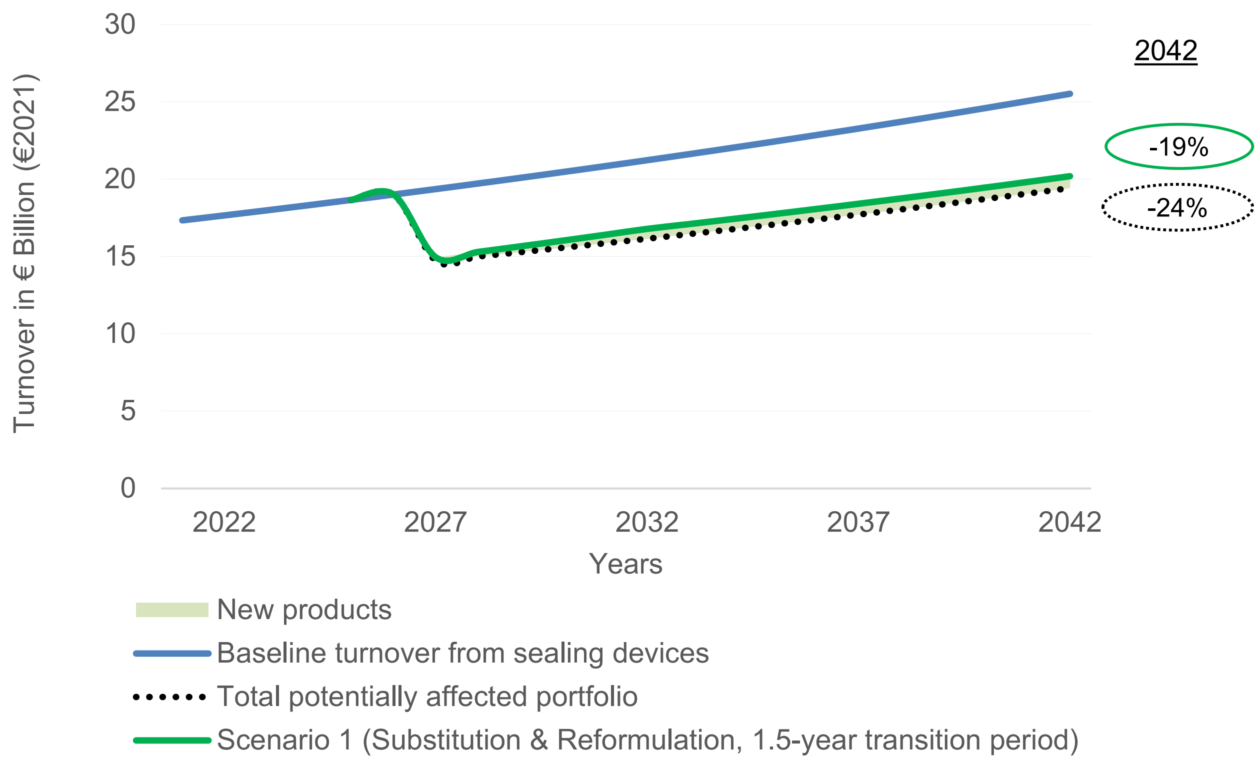
Source: Ricardo analysis based on Eurostat and EEA data and a bespoke survey of manufacturers and/or importers in the EEA sealing device industry.

Moreover, substitution and reformulation could affect the quality and attractiveness of the sealing devices sold by the manufacturers and/or importers. This could have additional indirect impacts on these businesses,

[119] A net present value of turnover losses against the baseline has been calculated, and later annualised over the period to estimate 'equivalent annual losses of turnover' as a result of the legislative changes. A real discount rate of 3.5% has been employed in line with the European Commission's Better Regulation Guidelines.

potentially limiting their ability to reduce turnover losses, especially in the face of international competition. This is highlighted in Figure 3-5 below; the shaded area represents the scope of turnover related to the sales of alternatives to the sealing devices containing fluoropolymers that, as reported, is expected to be achieved to mitigate losses resulting from the proposed restriction. If that expectation fails (supply side) or those alternatives are not well received in the market (demand side), losses would be higher and up to the full 'potentially affected portfolio' shown in Figure 3-1, 24% of sealing device manufacturers and importers' turnover. The difference between 24% (affected portfolio) and 19% (impact after substitution and reformulation), 5%, is the degree of substitution, reformulation and product redesign that sealing device manufacturers consider feasible at present.

Figure 3-5 Estimated impacts on the total turnover of sealing device manufacturers and importers in the EEA against the baseline scenario (€ 2021). The scope of new products / substitutes / alternatives is shaded in light green for reference.



Source: Ricardo analysis based on Eurostat and EEA data and a bespoke survey of manufacturers and/or importers in the EEA sealing device industry.

Sealing device manufacturers also provided their expectations on how much of their affected portfolio of products they would request and/or be granted a time-limited derogation. According to their answers, this would amount to around 28% of the total affected portfolio turnover (or 7% of total turnover from sealing devices). This share of derogation is similar to the expected level of substitution and reformulation (5% of total turnover, see Figure 3-2). It has been considered that this could be partly driven by the resopndents' expectations that they would be given the time needed to invest in developing the necessary substitutes or alternatives.

In addition, the estimated turnover losses assume that the sector's capacity to pass through the higher regulatory costs remains relatively unchanged, whereas this need not be the case in the face of growing international competition, especially in the market for alternatives to fluoropolymer-based sealing devices. If international competition of alternative substances with similar performance to these sealing devices were high, EEA sealing device manufacturers and/or importers would need to act quickly and would not be so able to share the additional costs via price increase, which would limit the ability to mitigate losses in any given scenario. It has not been possible to quantify this effect in this study.

Finally, sectoral economic output is assumed to be affected by the same proportion as turnover. GVA, however, depends on impacts not only on turnover and output, but also on intermediate consumption (or operating minus employment costs), and the analysis of impacts on the sector's and the economy's GVA can be found in Section 3.5. Intermediate consumption is considered in the next section.

By type of sealing device, Table 3-1 introduced the extent of the affected portfolio for each of them. Levels of reportedly expected substitution by sealing device and final impact as a percentage of the overall turnover from each type of sealing device are shown in Table 3-5 below.

Table 3-5 Expected substitution and reformulation by type of sealing devices and final impact as a percentage of the overall turnover from each type of sealing device

Type of Sealing Device	Total turnover from each type of sealing device in 2021 (€ 2021)	Potentially Affected Portfolio (% of total turnover from each type of sealing device) in 2021	Substitution and Reformulation (% of total turnover from each type of sealing device) in 2021	Potential Turnover Loss against baseline scenario (% of total baseline turnover from each type of sealing device) in 2042
Elastomeric and polymeric seals	€ 5.7 billion	19% (i.e., €1,100 million)	4% (i.e., €200 million)	14% - 16% (i.e. €1,000 - €1,100 million)
Mechanical seals	€2.3 billion	34% (i.e., €800 million)	7% (i.e., €200 million)	26% - 32% (i.e. €1,200 - €1,500 million)
Flange gaskets	€2.6 billion	14% (i.e., €400 million)	6% (€i.e., 200 million)	5% - 13% (i.e., €200 - €400 million)
Packings	€2.2 billion	5% (i.e., €100 million)	1% (i.e., €20 million)	4% - 5% (i.e., €100 - €150 million)
Expansion joints	€4.5 billion	4% (i.e., €200 million)	1% (i.e., €50 million)	3% - 4% (i.e., €200 - €250 million)

3.1.1.3.2 Intermediate consumption and OPEX

More than 70% of the EEA sealing device manufacturers and/or importers surveyed for this study expected their annual operating expenditure to increase during the next 10 years as a result of these policy changes.

First, the withdrawal of products from the market would necessarily imply that sealing device manufacturers and importers would reduce their operating activities and, as a result, operating expenditure will fall. This reduction is likely to be proportional to turnover losses against the baseline. Therefore, a reduction in business operations of between 18-19%, depending on the Scenario, would result in a similar reduction in operating costs over time. For example, in 2021, this would have been equivalent to a reduction in intermediate consumption of around €2.4-2.6 billion.

Secondly, companies would also take action to find alternatives and/or substitutes to alleviate the estimated reduction in their business. Thus, some of the current operations would need to be adjusted for the manufacturing and placing on the market of substitutes and/or reformulated products, and development of new ones. Further, additional administrative and compliance requirements, such as seeking derogations and associated costs would also be incurred. Estimates based on the survey of EEA sealing device manufacturers and/or importers suggest an additional annual €380 million of recurring costs could be incurred as a result of substitution, reformulation, and testing and changes to the manufacturing process, an additional operating cost equating to 2.8% of the 2021 operating expenditure.

Overall, intermediate consumption and operating costs are likely to fall, as business size reductions outweigh increased costs. These net reductions on intermediate consumption and OPEX would be driven by the losses that are estimated to the size of operations of the EEA sealing device market. It is estimated EEA sealing device manufacturers and importers OPEX would fall in annualised terms by €1.0 (Scenario 3) to 2.4 billion (Scenario 1) compared to the baseline over 2024-2040, respectively. These estimates do not suggest, however, that there will be any cost savings from the adoption of the legislative changes. In fact, **unit costs**

are estimated to increase. For example, the 'ratio of intermediate consumption to turnover' is estimated to increase by around 5% on average, over the period 2024-2042 against the baseline.

3.1.1.3.3 Capital and R&D expenditure

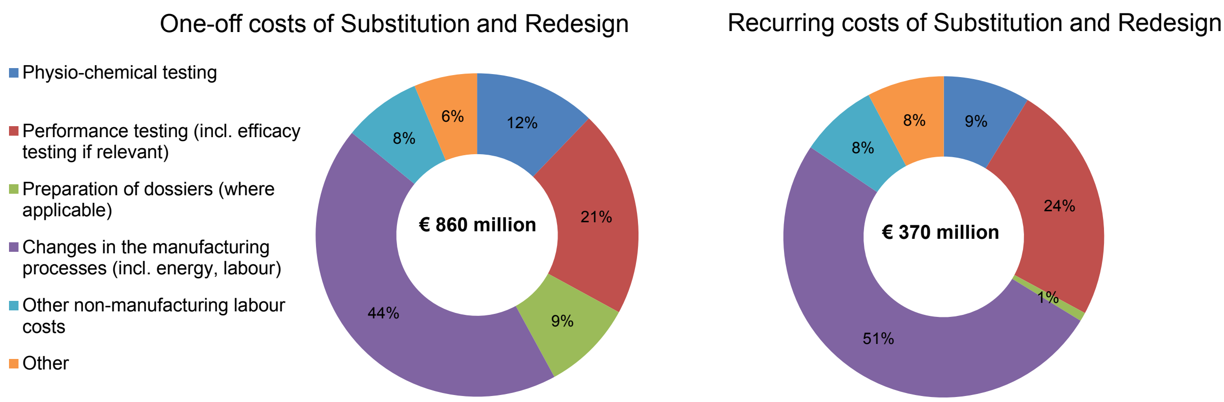
Similarly, the withdrawal of products from the market would have some implications on the capital and R&D expenditure by EEA sealing device manufacturers and importers. If the size of their business declines, it is assumed that their overall expenditure will decline as well. A 10% reduction in the size of companies manufacturing or importing sealing devices in the EEA may lead to an eventual reduction in overall investment of similar proportion, which would be equivalent to reducing investment by over €120 million each year against the baseline.

Nevertheless, these manufacturers and importers will also need to increase their investment in capital and R&D as they work to, for example, change their manufacturing processes, identify quality substitutes and alternatives and redesign products. Based on the survey of sealing device manufacturers, it is estimated that an additional €150 million (€ 2021) would need to be invested annually over 10-15 years from the adoption of the policy changes to support the changes that sealing device manufacturers would need to embark on to mitigate further operational and turnover losses.

Overall, net reductions on intermediate CAPEX and R&D expenditure are estimated in line with business size reductions. These reductions in expenditure do not mean that there will be any cost savings per unit of output from the adoption of the legislative changes. In fact, **per unit expenditure could increase, at least with regards to adjusting manufacturing processes and completing the required investments for effective substitution and reformulation. Based on the survey of sealing device manufacturers and/or importers for this study, the 'ratio of CAPEX to turnover' is estimated to increase against the baseline by around 14% on average, over the period 2024-2042.**

Overall, and according to survey respondents, additional recurring and one-off costs related to substitution, reformulation and innovation are distributed among the categories shown in Figure 3-6 below. The most relevant cost for the development of substitutes and alternative products is related to implementing necessary changes in the manufacturing process (44% of one-off costs and 51% of recurring costs), while another 21-24% of the costs relates to performance testing once new products have been conceived.

Figure 3-6 Split of one-off and recurring costs of substitution, reformulation, and product redesign. Source: Ricardo survey to sealing device manufacturers and importers.



3.1.1.3.4 Other opinions and insights by the sealing device industry

There is general **consensus within the sealing device industry that the proposed restriction would have detrimental impacts on their businesses based in the EEA**, especially considering that there are no viable alternatives for the vast majority of applications of the fluoropolymers under proposed restriction. More than 80% of manufacturers and importers from the survey reported that they expect negative impacts of varying degrees in the EEA as a result of the proposed restriction, with more than 70% reporting the likelihood of "major" (i.e., the sector would not be able to continue its activity whatsoever) or "significant" (i.e., they would drop various sealing device production lines and/or sites) negative changes.

- Many manufacturers and/or importers feel that owing to the significant role played by sealing devices in ensuring the safe operation of equipment in several industries, the technical benefits of the fluoropolymers used in their production far outweigh any associated hazards.
- The potential reduction in operational efficiency, performance and durability resulting from the move to non-PFAS sealing devices would inevitably increase the risk to safety at production sites as well as the risk of pollution, leakages and emissions into the ground, water and atmosphere.

Many manufacturers also note the scope for potential relocation of their business outside the EEA in response to the restriction, to locations where they can continue to use fluoropolymers for the manufacture of sealing devices. This would entail employment losses within the EEA as well as reduced investment and R&D expenditure.

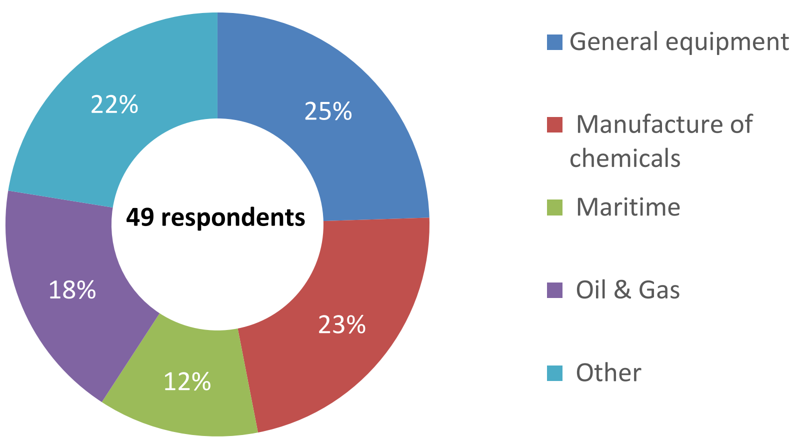
3.1.2 Business impacts on downstream users of sealing devices

The restriction of the manufacture, placing on the market and use of these sealing devices containing fluoropolymers will also affect their downstream users, who would need to adapt to remain in the market. Implementing a restriction of PFAS (i.e., including fluoropolymers) would have an indirect but relevant impact on these essential products and services: if fluoropolymers are restricted, some sealing devices may no longer be viable, or at least, not without substitution and redesign of products (impact on sealing device manufacturers, see Section 3.1.1). Downstream users of sealing devices may be provided with some alternative sealing devices not containing PFAS, or with alternative technologies to be used in the manufacture in their own products and in their products themselves; otherwise, or if alternatives do not have a similar performance to fluoropolymer-based sealing devices that is acceptable to their operations and requirements, they would lose the ability to manufacture their products. Where alternatives are not viable, downstream users may no longer be able to carry out their industrial and manufacturing activities. This would have negative social and economic impacts in EEA societies that rely on the supply of these products and services.

Sectors in which sealing devices were likely to have an important role were identified and targeted through the consultation. These sectors were selected after a careful review of sealing devices applications, leading us to select specific sectors to focus our analysis on based on the importance of sealing devices for their functioning and on the importance of the sectors, both economically (e.g., size in terms of production value) and for the functioning of society (e.g., power generation). As a result of this selection, downstream users participating in the consultation spanned a range of applications: General equipment, General instrument manufacturer, Manufacture of air and spacecraft and related machinery, and of military fighting vehicles, Manufacture of basic pharmaceutical products and pharmaceutical preparations, Manufacture of chemicals, Manufacture of food and beverages, Maritime, Oil and Gas (e.g., oil refining, gas and fuel distribution), Power generation, and Manufacture of semiconductors.

The degree to which each of the applications is represented in survey responses is shown in Figure 3-7. Any sector that received with fewer than 5 participants cannot be analysed in isolation, given the statistical rules subscribed (see Annex Section A1.1). Thus, these respondents were aggregated into the category named 'Other', in order to maintain anonymity and confidentiality.

Figure 3-7 Representation of downstream using applications in survey responses.



Source: Ricardo analysis based on the survey of sealing devices downstream users.

The sample of respondents per sector was analysed. As noted previously (see Section 2.2.3.2), it was concluded that the relatively low number and type of respondents per sector did not allow for extrapolation to the sector level.

Thus, the economic impacts on downstream users are presented **as a case study of a group of companies in each of the sectors, using the sample of respondents with a total sales turnover of €58 billion in 2021,** rather than any estimates of the sectoral impacts.

The conclusions could show how the sectors these respondents belong to may be affected, at least partially if only considering the effect on the sample of respondents. In order to draw conclusions about whole sectors from the small samples by sector that were gathered, further evidence and qualification would be needed.

The extrapolation of results to the whole industry or downstream sector will also be commented where possible. **In practice, it is likely that the estimated sample impacts as valued in € will be a lower bound to the potential effects on the sector as a whole**, that is, that the sectoral impacts will be much larger than those presented at the level of the sample.

The following sections present how the impacts from the proposed restriction are expected to be experienced by downstream users of sealing devices which contain fluoropolymers.

3.1.2.1 The affected portfolio

For downstream users, the portfolio of **products containing sealing devices** with fluoropolymers will be affected by the proposed restriction, which is thus referred to as the potentially **'affected portfolio'**. Based on survey responses, it is estimated that an average of **36% of the total sales turnover from downstream user companies** participating in the survey. This is is equivalent to €21 billion out of a total sales turnover of €58 billion generated by the survey participants in 2021.

This estimate represents an average of the size of the product portfolio that may be affected and captures a diverse set of experiences. For example, the affected portfolio represents the totality of their business for a third of the company respondents. This could be driven by having overrepresentation of companies with products that are especially dependent on sealing devices within the sample of respondents.

In addition, sealing devices also have a **role to play in the manufacturing of products that do not necessarily contain these devices**. When also taking this into account, the potentially affected portfolio could rise to **77% percent of their sales** turnover of the sample of respondents[120]. This is is equivalent to €45 billion out of a total sales turnover of €58 billion generated by the survey participants in 2021.

However, existing manufacturing equipment that uses sealing devices is not directly subject to the restriction, which means that the busineses owning this equipment would be affected when their assets or any of their parts (e.g., sealing devices) reach their end of life and/or require replacement at the next maintenance cycle. Typical useful life of manufacturing equipment could range between 15-35 years, however, sealing devices may have shorter lives, potentially around 10-15 years based on input from sealing device manufacturers.

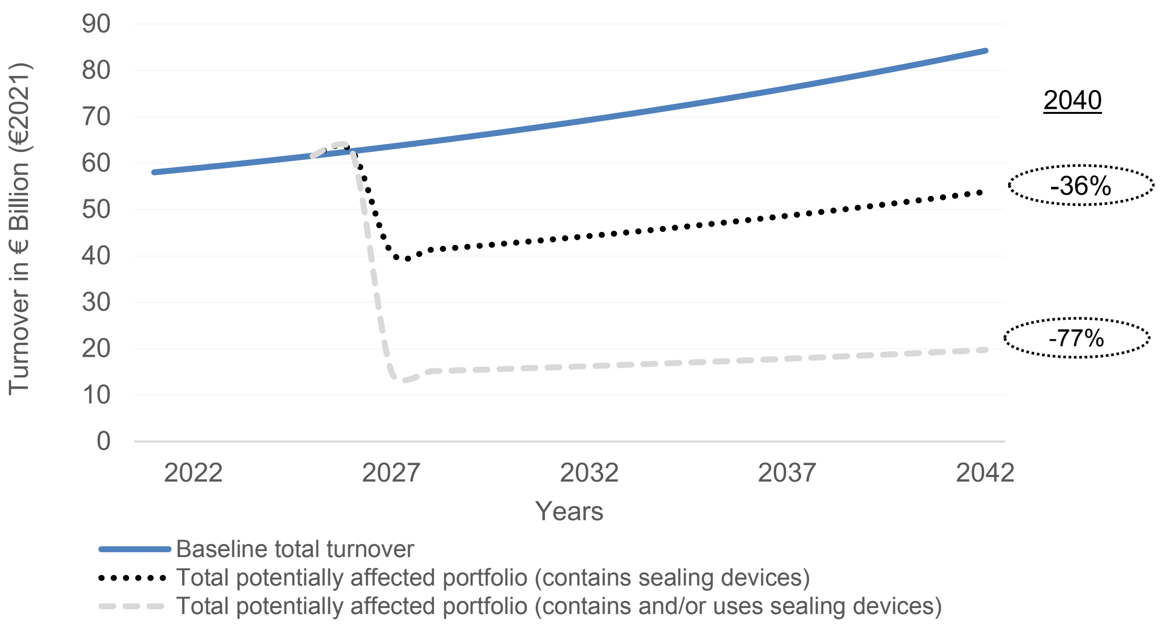
This would mean that, whilst in the shorter-term, any impacts of the proposed restriction would primarily affect manufacturers of products containing sealing devices (that is, around 36% of their sales turnover), over the medium to longer term or 10-15 years from now, the potential impact could be felt in a larger proportion of the industry, at a scale somewhere between 36%-77% of downstream user sales turnover.

According to the expected regulatory timelines, the restriction would likely enter into force in 2025, and after a 1.5-year transition period, it would be implemented in full. Evidence collated from the survey was overlayed with this expected schedule to produce the total affected portfolio series until 2042 to show the maximum potential losses if no alternatives are found for PFAS by the sealing device downstream users[121]. Figure 3-8 below presents the estimates of the size of the portfolio of products in scope of the restriction for the surveyed sample of sealing devices downstream uses against their baseline projections of turnover until 2042.

[120] This would be an upper bound as it assumes that the set of products that contain sealing devices and the set of products that use sealing devices do not overlap.

[121] Alternatives might still be found in sectors other than the ones consulted here. Results from the consultation to downstream users provide additional insights on viable alternatives to the ones provided by the sealing device manufacturers and importers.

Figure 3-8 Product portfolio (in terms of total sales turnover) that could be potentially affected by the restriction of PFAS in scope, for a sample of downstream users of sealing devices across selected sectors.



Source: Ricardo analysis based on Eurostat and EEA data and a bespoke survey of sealing devices downstream users.

In the next 10-15 years, whilst many sealing devices in machinery or other assets do not require replacement, companies will have time to innovate and/or develop alternatives so that the restriction of fluoropolymer-based sealing devices will not affect their manufacturing processes as much as it is estimated today. Thus, it is concluded that whilst the **scale of the potentially affected portfolio of downstream users of sealing devices might range from 36%-77%, it will likely be closer to 36% of total sales turnover, especially in the shorter-term.**

With a focus, therefore, on the portfolio of downstream products containing sealing devices, the scale of the potentially affected portfolio is presented by application in the Table below, next to the total annual turnover of each application in 2021. That is, based on the earlier arguments, this now excludes any considerations associated with the manufacturing process (i.e., whether products and thus their sales could be indirectly affected if the machinery or production process contains sealing devices even if the final products do not).

Table 3-6 Total turnover and potentially affected portfolio of the sample of downstream users (DU) participating in the survey (€ 2021) producing products containing sealing devices.

Downstream user sectors	Total sales turnover for the sample of DU participating in the survey (€ 2021)	Affected Portfolio (% of sales turnover comes from products containing sealing devices)
General equipment	€4,296 million	62%
Manufacture of Chemicals	€26,530 million	46%
Maritime	€103 million	35%
Oil and Gas	€13,175 million	27%
Other	€13,903 million	23%

Source: Ricardo analysis based on the survey of sealing devices downstream users.

This Table also showcases the ranges in potential scale of impacts across the selected sectors, based on the sample of respondents. The potentially affected portfolio is proportionately larger in ‘general equipment’ than ‘oil and gas’, whilst the largest potentially affected portfolio in absolute terms is identified within the ‘manufacture of chemicals’ sector.

3.1.2.2 *Expected business responses*

Upon the introduction of the proposed restriction or even before, however, businesses will consider whatever action they can take to migitate the impact on their activity. For example, they may substitute, reformulate and/or redesign their products and manufacturing processes. Companies were consulted, and their responses suggested that, on average, **22% of this affected portfolio (of products containing sealing devices with fluoropolymers) that would be affected by the restriction could be substituted and/or reformulated with alternatives not containing PFAS**.

This means that a fifth of the potentially affected portfolio would be adjusted or substituted for alternatives, and thus not withdrawn from the market; althouhg this remains uncertain and will depend on a positive market uptake and on the degree of substitutability of the new products and formulas (e.g. product performance, costs, hazard profiles, and energy consumption). Box 3-3 outlines the evidence collected related to the sample of sealing device downstream users' capacity to substitute and/or reformulate that has been considered in this analysis.

Box 3-3 Substitution, reformulation and/or redesign of products that may be affected by the proposed restriction.

49 businesses manufacturing products that use sealing devices participated in an online survey for this Study, to gather evidence of how they might respond to the adoption of a PFAS restriction and the implications through the effects on sealing device availability and performance; as well as the likely scale of this response, especially including substitution and/or reformulation.

Businesses surveyed suggest that they **would be able to substitute and/or reformulate around 22% of the products that contain sealing devices as a component (in terms of turnover) that may be immediately affected** by the proposed restriction, although there is some uncertainty, while for **products that are dependent on machinery/equipment that uses sealing devices, respondents to our survey expect at present that 30% would be able to be substituted, reformulated and/or redesigned**, which would happen at the asset's end-of-life or next maintenance cycle if necessary.

Business expectations are affected not only by what might be technically and economically feasible but also how their machinery suppliers manage to innovate (expectedly leading to higher replacement of current machinery with non-fluoropolymer-based alternatives in the future and as current machinery reaches its end-of-life, minimising the impacts through this channel) and how their customers may react to the substitutes, reformulated and/or redesigned products.

Response dispersion in the survey suggests that the ability of businesses to substitute the products that may be affected could range between 8% and 70% of their affected product portfolio, on average, although this is uncertain and will depend on maintaining key properties and requirements for downstream users, so that there is a positive market uptake by them and their end consumers.

Further, the degree of expected substitution and reformulation varies widely across respondents, with 60% of respondents reporting to be able to substitute less than 30% of their affected portfolios, and 25% of respondents reporting to be able to substitute more than 80%. The ability of businesses to substitute and/or reformulate will also be very different across business type, size and affected products. For example, the expected degree of substitution, reformulation and other changes is found to be very limited for SMEs (9% on average), who have less buffer to invest in innovation than larger companies.

The effects of the proposed restriction and business responses will thus vary across different applications as sectors such as general equipment and manufacture of chemicals are particularly affected. For an extended discussion on the viability and properties of alternatives for different applications as reported by the industry, see the end of this section and Section 3.5.4.

Businesses may also **need time to adjust their operations and establish a final substitute and/or reformulated product that can be placed in the market**. In some cases, businesses may already have a readily marketable alternative to place on the market upon adoption of policy changes. In others, businesses may require years of research and development and product approval before an alternative can be brought to the market. For downstream users, this might even involve substantial changes to their production processes.

Besides the typical substitution of the fluoropolymers-based sealing devices that they use with an alternative item (i.e., substitution), or the recalibration of their formulas or mixtures to remove fluoropolymer-based sealing devices (i.e., reformulation, which is only in the hands of sealing device manufacturers), some of the changes for downstream users upon the proposed restriction may involve complex adaptations of their whole manufacturing processes so as not to use sealing devices or to use alternative devices. For instance, adapting key components to accommodate differences in physical properties of the alternatives, which could be an issue in comparison with the sealing devices that are currently being used due to the different physical properties of the alternatives to sealing devices. Some compromises in terms of performance, energy efficiency or safety are also expected from alternatives.

Finally, end consumers, especially commercial and industrial ones, may need to adapt their systems when those reach their end of life and have to switch to non-fluoropolymer-based sealing devices or alternatives. This, in some cases, will imply the replacement of wider manufacturing equipment; instead of a simple renewal of an existing sealing system, if technology experiences substantial changes, downstream users and possibly end-consumers may need to adapt and make new investments too. The replacement of the equipment may even happen earlier if the existing one needs repairing before the end of its life, since it might not be available. These two instances would incur additional investment for equipment owners that has not been possible to quantify in this study.

In conclusion, some substitution, reformulation and/or product redesign is likely, and businesses will attempt to maximise this where economically viable: this is likely to mitigate between 8%-70% of total potential market withdrawals resulting from regulatory changes and take time to implement. **The lower estimate of 8% is interpreted to be substitution that is immediately accessible for everyone in Scenario 1 (i.e., immediate restriction with a 1.5-year transition period)**; **the central estimate of 22% is interpreted to be substitution that is expected to be accessible for everyone, although with some time to implement** (i.e., 5 years to develop, coinciding with the timeframe of shorter derogations, of 5 years additional to the 1.5-year transition period); finally, **the higher estimate of 70% is interpreted to be the substitution level that the more informed and innovative companies may expect to implement, and therefore, would reach the totality of the market over a longer timeframe**. Therefore, with a 12-year derogation as in Scenario 3, a 70% substitution is modelled.

Source: Ricardo analysis based on a bespoke survey of sealing devices downstream users.

In order to achieve this mitigation, companies would need to incur additional capital, operating and R&D expenditure. Therefore, as a result of the restriction, businesses would need to increase their CAPEX and OPEX per unit of sales, with new costs associated with substitution and/or reformulation.

The evidence collected suggests that businesses have some capacity to pass some of this regulatory burden through to their clients. Additionally, the survey responses suggest that overall sales of the sample of surveyed downstream users are very responsive to price changes. Therefore, the increase in regulatory burden is unlikely to be transferred to consumers via prices, and therefore will further affect the market of downstream users, at least within the EEA, according to the sample surveyed. This can be different for the extra-EEA export market if there is a strong or growing competition from players based outside of the EEA and not subject to the proposed restriction. According to information elicited in the survey, more than half of respondents consider that the proposed restriction will negatively or very negatively impact their competitiveness.

Box 3-4 outlines the evidence collected of the sample of sealing device downstream users' capacity to pass increased burden onto clients and the market responsiveness to potential product price changes.

Box 3-4 Pass-through of regulatory burden for products that may be affected by the proposed restriction by downstream users.

Businesses participating in this consultation also considered the extent to which they would intend to pass through any additional regulatory burden to their customers, which is estimated to be around 62%.

These businesses also explored the price elasticity of their product portfolio in the EEA. Respondents were not asked to report any information of the prices of their products, but rather their ability to pass through any increases in regulatory costs to their customers and their customers' potential responsiveness to such adjustments in prices.

Overall, they considered that their products are, on average, price elastic, with price elasticity of demand estimated at around -1.39. This means that the volumes of sealing device downstream product applications and uses sold in the EEA are quite responsive to price changes, that is, a 10% increase in product prices would result in a 13.9% reduction in the quantity sold.

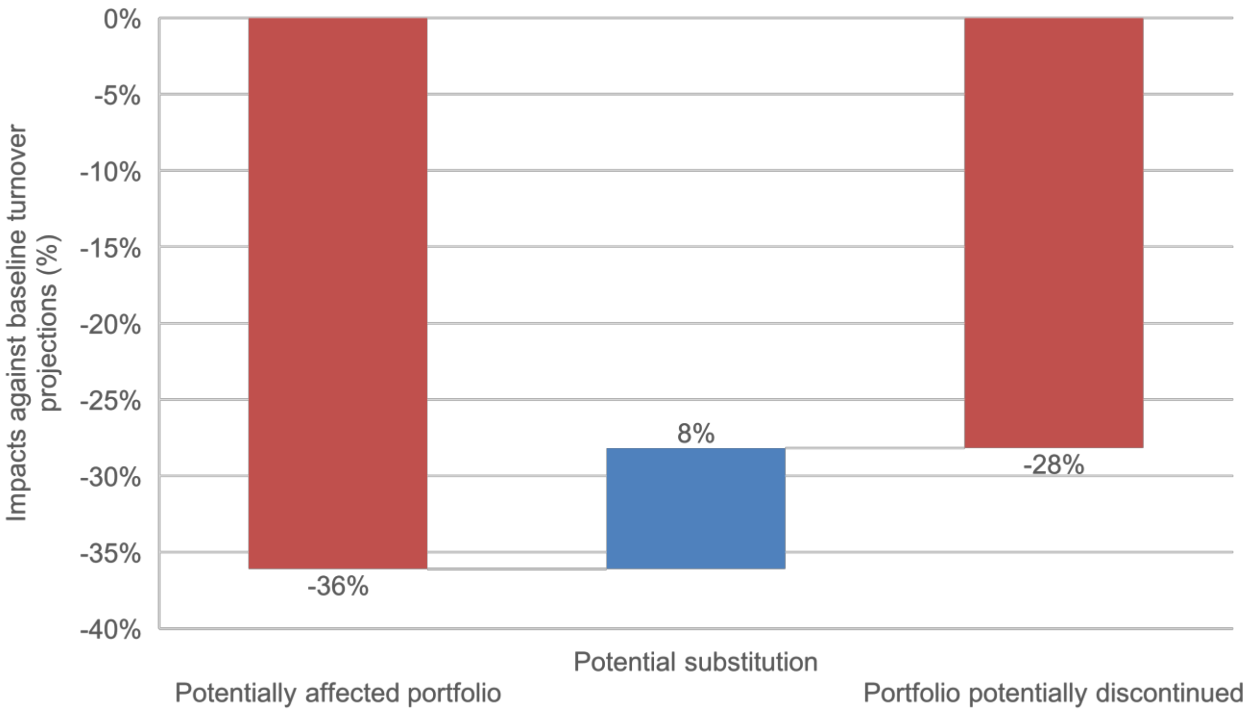
This means that, given current market dynamics, businesses may not be able to pass on the increased regulatory burden to their customers without having to experience larger additional impacts on the size of their operations. This could, however, change (i.e., improve), for example, if customers have no alternative but to accept the new products without fluoropolymers or without fluoropolymer-based sealing devices, but the effect will be stronger (i.e., worse) if the export market is a large share of the market of downstream applications of fluoropolymer-based sealing devices and there are still fluoropolymer-based solutions sold outside of the EEA, or change if preferences vary or product performance of the new alternatives is different, which will be considered qualitatively in this study.

Source: Ricardo analysis based on a bespoke survey of sealing device downstream users.

Therefore, as a result of the restriction, businesses would need to increase their CAPEX and OPEX per unit of sales, with new costs associated with substitution and/or reformulation.

Figure 3-9 below illustrates the different steps of the impact pathway statically, from the estimation of the total potentially affected portfolio to the turnover losses that are estimated to result from the introduction of the restriction considered in this study (central estimates).

Figure 3-9 Static stepwise representation of the portfolio in scope of being affected by the proposed restriction and expected responses from businesses (in percent of baseline turnover)[122]



Source: Ricardo analysis based on the survey of sealing devices downstream users.

Following Figure 3-9, the total potentially affected product portfolio from the proposed restriction is equivalent to 36% of the baseline total turnover or market of the surveyed sealing device downstream users (**Step 1**).

Around 8 percentage points of this market will likely be substituted, reformulated, or redesigned in the next decade, assuming that the proposed restriction is implemented (**Step 2**), thus meaning that a share of the loss resulting from Step 1 can be mitigated.

This means that the proposed restriction, when accounting for potential business responses, could lead to a reduction in product portfolio and business (in turnover terms) of around 28% or equivalent to €20.9 billion of the 2021 market (**Step 3**).

Surveyed sealing device downstream users have noted through stakeholder consultation their views on the availability of viable alternatives. These views include:

[122] In this graph, S&R, for brevity, stands for Substitution and Reformulation.

- Many downstream users highlight the impossibility of substituting products containing components made of fluoropolymers due to performance-related concerns. For many applications, the unique physical properties of fluoropolymer-based sealing devices are currently impossible to replicate with alternatives. In such a situation, downstream users would have to adjust their products such as decreasing the maximum temperatures their products can operate in or decrease the expected lifespan of a product. This would not be an option for all applications, as resistance in extreme conditions is a requirement as part of the process that sealing devices are used in.
- Loss of competitiveness in global markets would also occur. This could happen through two main channels. The first one would be through reduced competitiveness in global markets due to the alternatives to fluoropolymer-based sealing devices costing more in comparison to other markets which have not banned fluoropolymers and the second channel would be due to the inability of EEA-based downstream users to produce products for which there are no non-fluoropolymer based alternatives. In their opinion, companies in other geographies would benefit greatly from this as European companies would simply be forced not to produce some specific products.
- Some downstream users also voice concerns for the additional regulatory burden related to testing, recertification and requalification of non-fluoropolymer-based alternatives (e.g., fire testing, fugitive emission testing and extended cycling tests (operations, pressure and temperature).

These concerns will negatively impact downstream users of sealing devices and the European economy as a whole due to its effects throughout the supply chain. However, time-limited derogations are expected to affect positively the extent of potential substitution. Over time, companies may be able to further develop and implement alternatives to fluoropolymer-based sealing devices in their products, developed by themselves, or by others (e.g., by sealing device manufacturers and by machinery and equipment suppliers).

Overall, downstream users expect to be able to obtain derogations for 70% of their affected portfolio[123]. Since the information gathering exercise via consultation took place before the restriction proposal from the 7th February was published, survey questions did not differentiate between obtaining shorter or longer time-limited derogations. Hence, two extreme scenarios have been modelled: one I which 70% of the portfolio obtains a 5-year derogation, additional to the 1.5-year transition period (Scenario 2), and another scenario in which 70% of the portfolio obtains a 12-year derogation, also additional to the 1.5-year transition period (Scenario 3). Therefore, the final result is expected to be somewhere between the two Scenarios. In Scenario 1, only the 1.5-year transition period is granted to everyone, and some substitution takes place after the size of the market is reduced as a result of the restriction.

Results overlayed with implementation timelines and with scenarios where time-limited derogations of 5 and 12 years are granted are presented in the following sections.

3.1.2.3 Costs and benefits driven by the impact on the EEA sealing device downstream using industries

The consultations with downstream users enabled the confirmation of the scope of their production portfolio that is likely to be affected by the proposed restriction and the identification of potential business responses.

To assess the net impacts of these policy options on downstream users of sealing devices, a baseline and the same two restriction scenarios as shown for the evaluation of impacts on sealing devices manufacturers and importers (see 3.1.1).

Based on these policy scenarios and the available evidence from the bespoke business consultations, Eurostat and secondary research, the net impacts on the EEA sealing devices sector and the knock-on effects on the European economy were assessed against the baseline scenarios. These are described across four different areas:

- Turnover

[123] It is acknowledged that upstream, manufacturers and importers of sealing devices consider they might be able to secure derogations for around 28% of the sales turnover from their sealing devices. Downstream users, however, consider that they might be able to obtain derogations for a higher proportion of their business. This is not necessarily incoherent, because some sealing devices may facilitate proportionately more business downstream than others. Whilst it is possible to expect that these proportions should be closer to each other, the evidence presented in this Study reflects the validated responses of companies operating across the supply chain in scope.

- Intermediate consumption and operating costs
- Capital expenditure and Research and Development
- Other opinions and insights by sealing device downstream users

3.1.2.3.1 Turnover

The adoption of the policy options considered is estimated to lead to a reduction in sales or size of the sample of downstream users in terms of turnover[124] and tonnes manufactured and sold. The extent of this reduction will depend upon the scope and timetable of the legislative changes as well as the type of business responses expected.

First order effects, that is, the impacts on business operations excluding any pass through of additional regulatory costs to customers through price adjustments, are considered in Table 3-7.

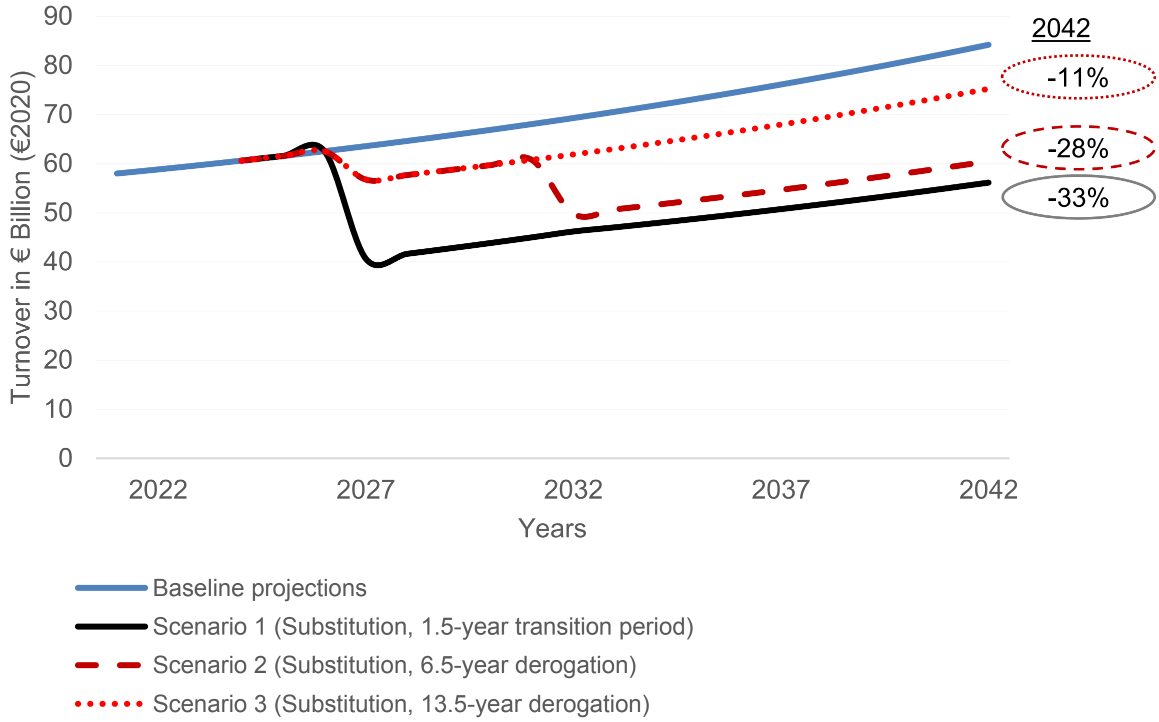
Table 3-7 Annualised impacts on the size of (sample of) downstream users' businesses against the baseline scenario in terms of turnover (€ 2021).

Scenario	First order effects or impacts on businesses overall
Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Surveyed sealing devices downstream users are estimated to **lose €19.5 billion (€ 2021) of turnover each year on average** over the period 2024-2042, when compared to the baseline scenario.
Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Surveyed sealing devices downstream users are estimated to **lose €12.8 billion (€ 2021) of turnover each year on average** over the period 2024-2042, when compared to the baseline scenario.
Scenario 3 (Substitution and Reformulation, 13.5-year derogation)	Surveyed sealing devices downstream users are estimated to **lose €6.1 billion (€ 2021) of turnover each year on average** over the period 2024-2042, when compared to the baseline scenario.

The impacts are also presented over time in the Figure below.

[124] Turnover refers to total sales, thus including sales of products in the EEA or abroad. There is an implicit assumption that activities targeting export markets will also be affected, on average, in a similar way to the market targeting EEA customers. The effects on the exports are uncertain and could be more or less significant than the impacts that may apply to the manufacturing and/or use within or for customers in the EEA.

Figure 3-10 Estimated impacts on the turnover of the sample of downstream users of sealing devices against the baseline scenario (€ 2021)[125].



Source: Ricardo analysis based on Eurostat and EEA data and a bespoke survey of sealing devices downstream users.

These first-order effects (as shown in Figure 3-10) reflect the direct business response to the proposed legislative changes: in the absence of time-limited derogations (Scenario 1), by 2042, the downstream users' market would be around 33% lower than the estimated baseline, which is equivalent to a turnover loss at the end of the period of analysis of around €28.1 billion, according to the surveyed sample.

In Scenario 2, with a time-limited derogation of 6.5 years, companies have more time and resources to adapt, attaining a somewhat higher level of substitution. As a result, by 2040 their market is 28% lower than the estimated baseline, which is equivalent to a turnover loss at the end of the period of analysis of around €23.7 billion. In Scenario 3, a notably higher scope of substitution is feasible for the sample, and losses against the baseline estimation are of €9.0 billion by 2042 (or around a 10% reduction against baseline). These effects exclude the possibility by sealing device downstream users of passing any additional regulatory burden through to their customers and the associated implications, which we refer to as 'second-order effects' and are discussed in Box 3-4.

Overall, this suggests that **although this sample of downstream users is expected to be able to introduce mitigation measures whilst incurring additional operating and capital costs (first order effects), they may not be able to pass through some of these costs to their customers (second order effects), and their operations and associated economic footprint would still be likely to negatively affected. Annual turnover losses against the baseline are estimated to range from €6.1 billion to €19.5 billion per year, on average[126], between 2024 and 2042 (noting that this only captures effects in our small sample of downstream users, not the whole EEA industry).**

The scenarios established for estimating the potential policy impacts on the turnover of the EU sealing device downstream users present the implications of key uncertainties relating to the timeframe of the proposed

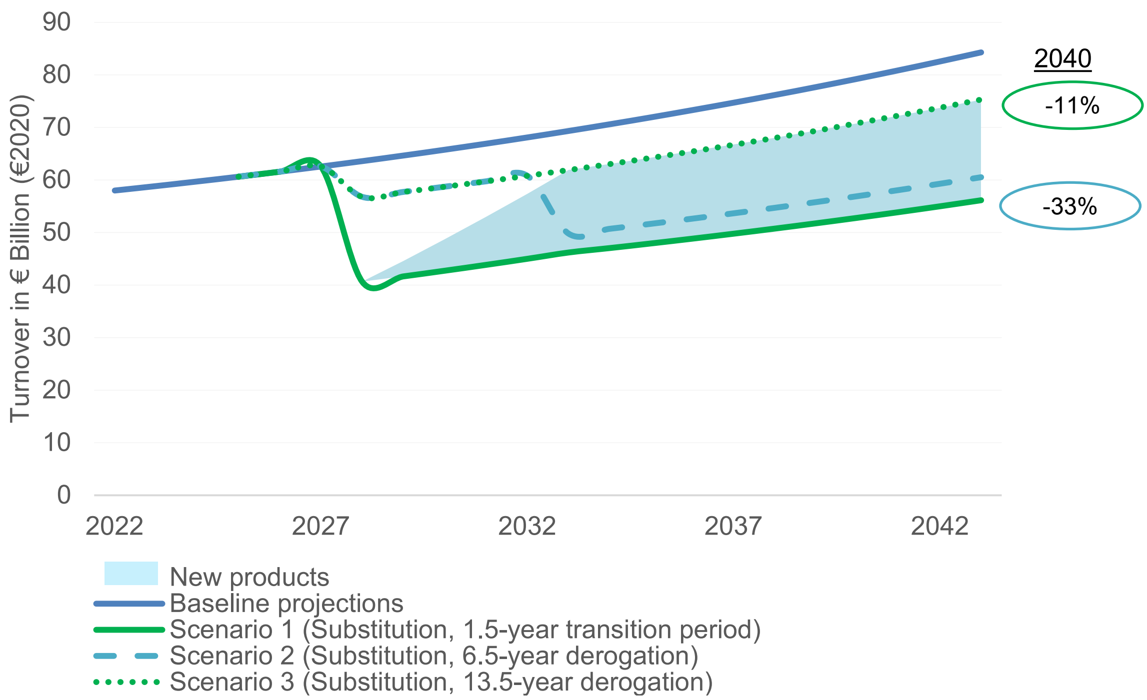
[125] Please note that the diagrammatical illustrations in this study smooth the changes in turnover over time, thus assuming that these changes are continuous (rather than discrete reductions in business). For example, in Scenario 1, it is implicitly assumed that the impact of a policy change is felt immediately, and businesses start to adjust their operations slightly in advance as a way of preparing for the year in which the legislation comes into effect. In reality, businesses may take action much earlier so that they can adjust their operations and meet the new legal requirements.

[126] A net present value of turnover losses against the baseline has been calculated, and later annualised over the period to estimate 'equivalent annual losses of turnover' as a result of the legislative changes. A real discount rate of 4% has been employed in line with the European Commission's Better Regulation Guidelines.

restriction's impacts on turnover. Scenario 1 considers the proposed restriction happening in 2025, with the restriction taking effect in 2027, after the 1.5-year transition period, and mitigation actions taking effect over 5 years; Scenario 2 considers that businesses may need that time to adapt and resources in the meantime (e.g., businesses need to delay the hit of the restriction so they can make the necessary investment) so they can bring substitutes and/or reformulated products to the market, so a 5-year derogation is granted; in Scenario 3, a longer, 12-year, derogation is granted to all sealing device downstream users in the sample, and the extra time allows an extra level of innovation, further mitigating the impact of the restriction. Within each of these scenarios there are uncertainties which could affect these estimations. In particular, the sensitivity of the results to the extent to which businesses may be able to substitute and/or reformulate has been explored.

As noted earlier in this section, if businesses do not substitute and/or reformulate at all, the EEA sealing device downstream users could lose 36% of the turnover estimated in the baseline. The best available evidence suggests that businesses will be able to substitute and/or reformulate 22% of their affected product portfolios (in terms of turnover value), on average. However, uncertainty around the degree of substitution in the estimates elicited from the survey to sealing device downstream users provides a range of possible substitution, reformulation and other changes that is between 8% and 70%. These two extreme cases would imply that turnover losses would vary within a range between 11% and 33% for sealing device downstream users. It is assumed that early implementation of the restriction implies lower levels of feasible substitution, while longer derogations allow time, resource and knowledge-sharing so that these industries can attain up to 70% substitution, and hence minimise market losses to 11%. This is illustrated in Figure 3-11 below.

Figure 3-11 Illustration of the sensitivity of the estimated impacts on the turnover of sealing device downstream users against the baseline scenario (€ 2021) to expected substitution and/or reformulation



Source: Ricardo analysis based on Eurostat data and a bespoke survey to sealing device downstream users.

Moreover, substitution and reformulation could also affect the quality and attractiveness of the products sold by EEA sealing device downstream users. This could have additional indirect impacts on EEA sealing device downstream users, potentially limiting the ability of businesses to mitigate turnover losses especially in the face of international competition. If products containing sealing devices, manufactured with fluoropolymers elsewhere, are preferred by consumers and industry outside of the EEA, then substitutes developed in the EEA would only be demanded in the EEA, thus possibly increasing the negative impact of the restriction on EEA sealing device downstream users.

In addition, the estimated turnover losses understand that the sector's capacity to pass through the higher regulatory costs remains is limited, if at all possible, as gathered from information provided by downstream users in survey, whereas this would be accentuated in the face of growing international competition, especially in the export market. If international competition increases, it would do so to the detriment of the EEA sealing device downstream users, which would lead to worse potential turnover losses (against the baseline) in any given scenario. It has not been possible to quantify this effect in this study.

The ranges for the 2042 final impact by downstream application as the percentage of turnover affected by the restrictions against the baseline scenario will be as follows:

Table 3-8 Expected impact on turnover by 2042 as a percentage of the overall turnover from each category of downstream user.

Downstream Application	2042 Turnover impacts €2021 % against the baseline scenario
General Equipment	-23% to -62%
Manufacture of Chemicals	-43% to -46%
Maritime	-31% to -35%
Oil and Gas	-26% to -27%
Other	-21% to -23%

Source: Ricardo analysis based on the survey of sealing devices downstream users.

Finally, sectoral economic output or production value (estimated to be around 90% of the sector's turnover) is assumed to be affected in the same proportion as turnover in the first-order effects. Thus, **if the estimates from the sample are applied to the production volume of all the different downstream user applications, joint losses in production volume would likely reach between 11% and 33% jointly for all sealing device downstream applications in scope between 2024 and 2042, compared to baseline projections.**

GVA, however, depends on impacts not only on turnover (and output), but also on intermediate consumption (or operating minus employment costs). Intermediate consumption is considered in the next section.

3.1.2.3.2 Intermediate consumption and OPEX

More than 90% of the sealing device downstream users surveyed for this study confirmed that they would be required to change their operations and manufacturing processes as a result of these policy changes, implying additional operating and capital expenditure. For most of those (60%), this will imply negative or very negative effects: from reducing the production capacity to dropping some lines of production, or multiple production lines and even sites. More than 30% reported that their sector would not be able to continue operations (although this was not focussed on the respondents from a particular sector). These changes carry with them cost reductions for the lost business, and new costs for the productive changes to be implemented (i.e., substitution, reformulation and product redesign, and adaptation of the manufacturing process to the new products).

First, the proposed restriction would likely force downstream users to reduce their operating activities, unless they can maintain production without the use of fluoropolymer-based sealing devices. As a result of this business reduction, operating expenditure will fall. This reduction is likely to be proportional to turnover losses against the baseline: in other words, a reduction in business operations of around 10% would result in reduction in operating costs over time. For example, in 2021, an operational contraction of 10% would have been equivalent to a reduction in intermediate consumption of around €4.4 billion.

Secondly, companies would also take action to find alternatives and/or substitutes to alleviate the estimated reduction in their business. Thus, some of the current operations would need to be adjusted for the manufacturing and placing on the market of substitutes and/or reformulated products. Further, additional administrative and compliance requirements, such as performance testing, certification and preparation of dossiers, changes to the manufacturing process, and associated costs would also be incurred.

Overall, intermediate consumption and operating costs are likely to fall. These net reductions on intermediate consumption and OPEX would be driven by the losses that are estimated to the size or operations of surveyed sealing devices downstream users. These estimates do not suggest, however, that there will be any cost savings from the adoption of the legislative changes. In fact, unit costs are estimated to increase.

Estimates based on the survey to sealing devices downstream users for the figures on additional recurring costs incurred as a result of substitution, reformulation, innovation, testing and other compliance activities support the need for additional operating expenditure. **In fact, this evidence points towards an average 0.5% increase in unit costs, as measured by the 'ratio of intermediate consumption to turnover'.**

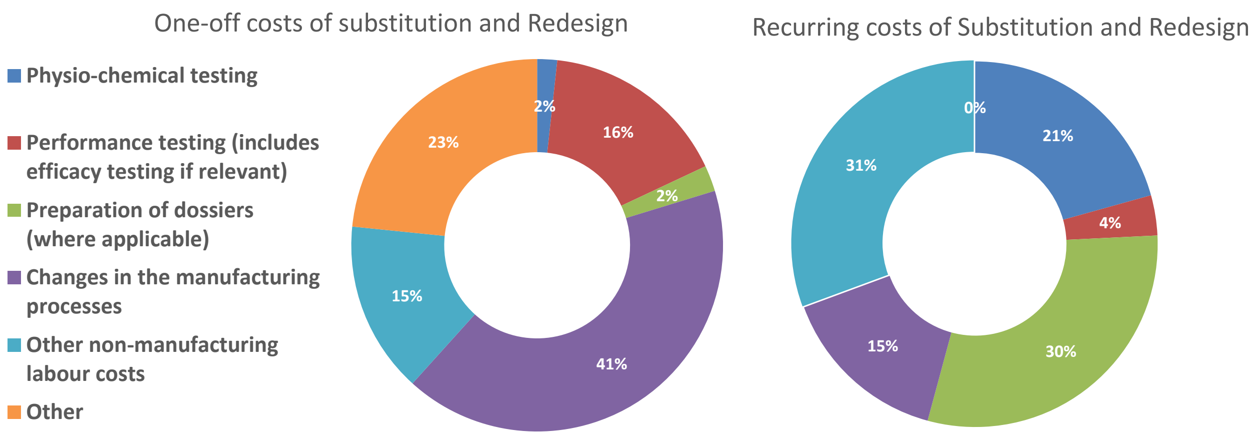
3.1.2.3.3 Capital and R&D expenditure

Similarly, the withdrawal of products from the market would have some implications on the capital and R&D expenditure of sealing devices downstream users. If the size of their business declines, it is assumed that their overall expenditure will decline as well. A 10% reduction in the size of the surveyed businesses in terms of their turnover would lead to an eventual reduction in overall investment of a similar proportion, which would have been equivalent to reducing investment by around €200 million in 2021 against the baseline.

Nevertheless, these companies will also need to increase their investment in capital and R&D as they work to, for example, change their manufacturing processes, identify quality substitutes and alternatives and reformulate their products. Based on the survey to sealing devices downstream users, it is estimated that an additional €150 million (€ 2021) would be invested annually over 10-15 years from the adoption of the policy changes to support these changes that their companies would need to embark on to mitigate further operational and turnover losses. For these companies, this implies an increase in CAPEX of around 7.8% for the retained business during that period.

Therefore, these reductions in expenditure do not mean that there will be any cost savings from the adoption of the legislative changes. In fact, unit expenditure could increase, at least with regards to adjusting manufacturing processes and completing the required investments for effective substitution and reformulation. **Based on the survey of sealing device downstream user companies conducted for this study, the 'ratio of Capex to turnover' would be expected to increase against the baseline, by almost 8% during the years of stronger investment.**

Figure 3-12 Split of one-off and recurring costs of substitution, reformulation, and product redesign. Source: Ricardo survey to sealing device downstream users.



Source: Ricardo analysis based on the bespoke survey of sealing devices downstream users.

3.1.2.3.4 Other opinions and insights by sealing device Downstream Users

Downstream users report that if fluoropolymers are banned this will have a considerable impact on their operations. Downstream users report the following about that these restrictions:

- Being unable to substitute sealing devices that contain fluoropolymers in their production lines, as the required properties of these fluoropolymers cannot be replicated by non-PFAS alterantives in many cases.
- The restriction would severely jeopardize the EU's chips initiative. The semiconductors manufacturing processes cannot be changed in the available 7-10 years which severely affects the EU's goals of becoming a global leader in semiconductors as inter-metallic dielectric processes are hard to adjust and are dependent on PFAS-based devices, such as fluoropolymer seals and gaskets. The semiconductor industry association has compiled some technical reports and case studies on the development timeline for PFAS alternatives for different sealing devices applications[127].
- Loss of competitiveness as companies using sealing devices outside the EEA won't be subjected to these requirements, making their products relatively cheaper than the alternatives in the EU, leading to a decrease in competitiveness of European companies across several sectors in global markets.

[127] Semiconductor Industry Association, 2023. Available at: https://www.semiconductors.org/technical-papers-highlight-need-to-maintain-essential-uses-of-pfas-in-semiconductor-industry/

- Trading with countries outside the EEA would become harder as restrictions on fluoropolymers will mean the prohibition of many products entering the EEA. The shipping sector for instance uses fluoropolymers frequently, meaning that a considerable chunk of the world's vessels would have trouble in sailing through European waters
- Companies consider moving R&D, production, and logistic processes to outside the EEA, where it makes more economic sense to operate in and leave the EEA altogether due to the considerable changes in market dynamics and loss of profitability in Europe.

3.2 EXPOSURE TO FLUOROPOLYMERS AND THEIR IMPACT ON THE ENVIRONMENT

This section covers the current level of exposure and emissions of fluoropolymers and the associated environmental impacts, which are key to understanding the socioeconomic impact. Environmental exposure to fluoropolymers can occur at different stages of their lifecycle, which includes their manufacture, production and use of sealing devices, and the recycling or disposal of components and sealing devices.

When assessing the impacts on the environment, the level of exposure is an important factor. Environmental exposure can occur through emissions to air, water, or landfill, depending on how fluoropolymer waste is managed. Exposure at each stage of the supply chain will be considered in this study. This includes exposure to fluoropolymers themselves, their manufacturing aids or reagents, and degradation products resulting from disposal.

3.2.1 Exposure and emissions from fluoropolymer manufacture

PFAS of low molecular weight have traditionally been used as emulsifiers in the polymerisation of several fluoropolymers. The ammonium salts of perfluorooctanoic acid (PFOA) and perfluorononanoic acid (PFNA) have historically been the primary fluoropolymer processing aids. The use of PFOA and PFNA have subsequently been phased out, partly due to the voluntary stewardship programme between the US EPA (Environmental Protection Agency) and eight major fluorochemical producers[128], and partly due to regulatory restrictions, particularly in the US and Europe[129].

Although the signatories of the US EPA PFOA Stewardship Program have transitioned to alternative polymerisation aids, there is a still a reliance on fluorinated substances[130]. However, certain fluorine atoms have been replaced by chlorine, hydrogen, and oxygen atoms on the perfluorinated chain, which are predicted to make the substances less persistent compared to PFOA and PFNA. Alternatives to PFOA that are registered under REACH as being used as polymerisation aids in the EU are summarised in the Table 3-9 below.

Table 3-9 Alternative processing aids registered under REACH

CAS Number	EC Number	Substance Name
1280222-90-3	480-310-4	ADONA [ammonium 2,2,3-trifluoro-3-(1,1,2,2,3,3-hexafluoro-3-trifluoromethoxypropoxy)propionate]
62037-80-3	700-242-3	HFPO-DA [Ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate]
37486-69-4	-	TFEE-5 [2H-tricosafluoro-5,8,11,14-tetrakis(trifluoromethyl)-3,6,9,12,15-pentaoxaoctadecane]
908020-52-0	700-323-3	EEA-NH4 {Ammonium difluoro[1,1,2,2-tetrafluoro-2-(pentafluoroethoxy)ethoxy]acetate}

HFPO-DA, its salts, and acyl halides have been identified as a substance of very high concern (SVHC) and added to the Candidate List because of scientific evidence of probable serious effects to the environment that meets the SVHC criteria for an equivalent level of concern[131]. HFPO-DA was also found to be very persistent

[128] EPA (2022) 2010/2015 PFOA Stewardship Program. Available at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program

[129] Bock, A. R., & Laird, B. E. (2022). PFAS Regulations: Past and Present and Their Impact on Fluoropolymers. Available at: https://doi.org/10.1039/9781839167591-00001

[130] Lohmann, R., Cousins, I. T., DeWitt, J. C., Gluge, J., Goldenman, G., Herzke, D., ... & Wang, Z. (2020). Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[131] ECHA (2019) Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. Available at: https://echa.europa.eu/documents/10162/fc76aefc-fc86-a5fc-b5c4-e358467ca832

and mobile in the environment[132]. The other three polymerisation aids registered under REACH are currently undergoing a PBT/vPvB assessment.

Whilst not registered under REACH, perfluorobutanesulfonic acid (PFBS) and undecafluorohexanoic acid (PFHxA) have also been used in the production of fluoropolymers. PFBS has been identified as an SVHC and was added to the Candidate List in 2020 based on its very high persistence and mobility and high potential for long-range transport[133]. Other concerns included probable serious effects for the environment[134].

PFHxA, its salts and related substances have previously been proposed for restriction under REACH, due to their combination of hazardous properties[135]. This includes extreme persistence, mobility in the aquatic environment, and the potential for long-range transport.

HFPO-DA and PFBS are being phased out and polymerisation aids that are fluorine free or have reduced fluorine content have been developed[136,137]. This includes emulsion polymerisation processes with much reduced PFAS use, or without the use of PFAS, as processing aids[138]. There are no studies on the suitability of these alternatives for individual applications, the number of manufacturing sites likely to use them, or emissions during manufacture, so the impact on the environment from their use is unknown.

Industrial wastewater in Europe is monitored and documented in the European Pollutant Release and Transfer Register (E-PRTR). The E-PRTR Regulation (EC No. 166/2006) requires chemical manufacturers, including fluoropolymer manufacturers, to report their emissions of specific pollutants to air, water, and land if they exceed certain thresholds. Currently, individual PFAS are not included in the list of pollutants, although certain substances like PFCs can be considered as total PFAS but are limited to specific Sealing devicees. The assessment of E-PRTR data indicates that academic studies are the primary source of information regarding emissions from fluoropolymer production.

Research conducted in Europe on PFAS emissions from fluorochemical plants has identified the presence of processing aids such as HFPO-DA in downstream river water, with peak concentrations of 812 ng/L[139]. Globally, studies conducted on industrial sites specialising in fluoropolymer manufacturing have detected elevated concentrations (over 100 ng/L) of HFPO-DA in the surrounding surface water, as well as the presence of PFOA contamination (1000 ng/L) resulting from past activities[140]. Other alternative substances have also been detected in the water near fluoropolymer manufacturing sites[141,142]. These initial findings emphasize the significance of the manufacturing stage in the life cycle of products containing fluoropolymers.

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[132] ECHA (2019) Annex XV Report – Proposal for Identification of a Substance of Very High Concern on the Basis of the Criteria set out in REACH Article 57. Available at: https://echa.europa.eu/documents/10162/d7f49f83-272f-5688-6c9f-2b88bd64277a

[133] ECHA (2020) Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. Available at: https://echa.europa.eu/documents/10162/079c04a0-2464-4168-f132-a22ffb04d910

[134] European Commission (2020) SWD: Poly- and perfluoroalkyl substances (PFAS). Available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf

[135] ECHA (2019) Annex XV Restriction Report - Undecafluorohexanoic acid (PFHxA), its salts and related substances. Available at: https://echa.europa.eu/documents/10162/c4e04484-c989-733d-33ed-0f023e2a200e

[136] Solvay (2022) Producing new fluoropolymers without fluorosurfactants. Available at: https://www.solvay.com/en/article/eliminating-pfas

[137] Business Wire (2023) Techmer PM Successfully Launched its First Fluorine Free Polymer Processing Aid (PPA). Available at: https://www.businesswire.com/news/home/20230130005017/en/Techmer-PM-Successfully-Launched-its-First-Fluorine-Free-Polymer-Processing-Aid-PPA

[138] Lohmann, R., Cousins, I. T., DeWitt, J. C., Gluge, J., Goldenman, G., Herzke, D., ... & Wang, Z. (2020). Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[139] Gebbink, et al. (2017) Presence of emerging per-and polyfluoroalkyl substances (PFASs) in river and drinking water near a fluorochemical production plant in the Netherlands. Environmental science & technology, 51(19), 11057-11065.

[140] Galloway, et al. (2020). Evidence of air dispersion: HFPO–DA and PFOA in Ohio and West Virginia surface water and soil near a fluoropolymer production facility. Environmental science & technology, 54(12), 7175-7184.

[141] Munoz et al. (2019) Analysis of F-53B, Gen-X, ADONA, and emerging fluoroalkylether substances in environmental and biomonitoring samples: A review. Trends in Environmental Analytical Chemistry, 23, e00066.

[142] Brandsma S.H., Koekkoek J.C., van Velzen M.J.M., de Boer J. (2019). The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. Chemosphere, 220, pp. 493-500. Doi: 10.1016/j.chemosphere.2018.12.135

Table 3-10 A summary of specific studies on detected processing aids near industrial sites globally.

Location	Proposed source	Substance	Maximum concentration detected	Year of study
Netherlands	Fluorochemical plant	HFPO–DA/GenX	812 ng/L[143]	2016
Germany – Rhine river	Not disclosed	HFPO–DA/GenX HFPO–TA ADONA	1.98 ng/L[144] 1.55 ng/L	2016
Germany - Alz River	Fluorochemical plant	ADONA	6 200 ng/L[145]	2009
Ohio and West Virginia, USA	Fluoropolymer production Facility	HFPO–DA/GenX	>100ng/L[146]	2016
North Carolina, USA	Fluorochemical Manufacturing plant	Perfluoroalkyl ether sulfonic acids	Not disclosed[147]	2014

It's worth noting that all these studies are over five years old, and since then, HFPO-DA has been added to the Candidate List and is being phased out, along with other PFAS processing aids. As mentioned above, regulatory pressures have driven recent advancements in fluoropolymer synthesis, leading to the development of processing aids with reduced fluorine content or that are entirely fluorine-free. Gujarat Fluorochemicals Limited (GFL) have developed a non-fluorinated polymerisation aid (NFPA) for producing PTFE via emulsion, which does not fulfil the criteria for PBT or vPvB and is registered under REACH[148]. Chemours and Solvay are also both developing NFPAs[149,150] and have implemented abatement strategies for minimising emissions of fluorinated polymerisation aids where an alternative aid has not found[151].

The adoption of these alternative processing aids is expected to decrease the emission of fluorinated substances during fluoropolymer production, but not eliminate them entirely. However, no studies have examined the emissions resulting from the implementation of these fluorine-free alternatives in an industrial setting, and the number of active fluoropolymer manufacturing sites adopting this technology remains unknown. Consequently, the impact of these new alternatives cannot be quantified in this study.

143 Ibid footnote 139

144 Pan, et al. (2018) Worldwide distribution of novel perfluoroether carboxylic and sulfonic acids in surface water. Environmental science & technology, 52(14), 7621-7629.

145 Bayerisches landesamt für umwelt. PFOA und ADONA measurements at the sample site Alz/Hohenwarth (in German); Bayerisches landesamt für umwelt: 2010. Available at: https://www.lfu.bayern.de/altlasten/pfoa_gendorf/adona/index.htm
Heydebreck, et al. (2015). Alternative and legacy perfluoroalkyl substances: differences between European and Chinese river/estuary systems. Environmental science & technology, 49(14), 8386-8395.

146 Ibid footnote 140

147 Sun, et al. (2016) Legacy and emerging perfluoroalkyl substances are important drinking water contaminants in the Cape Fear River Watershed of North Carolina. Environmental science & technology letters, 3(12), 415-419.

148 GFL (2022) Company Announcement. Available at: https://gfl.co.in/assets/pdf/Announcement-9th-March-2022.pdf

149 Chemours (2022) Chemours Announces Process Innovation with New Viton™ Fluoroelastomers Advanced Polymer Architecture (APA) Offering. Available at: https://investors.chemours.com/news-releases/news-releases-details/2022/Chemours-Announces-Process-Innovation-with-New-Viton-Fluoroelastomers-Advanced-Polymer-Architecture-APA-Offering/default.aspx

150 Solvay, 2022, Producing new fluoropolymers without fluorosurfactants | Solvay

151 C&EN (2023) How fluoropolymer makers are trying to hold on to their business. Available at: https://cen.acs.org/materials/polymers/fluoropolymer-makers-trying-hold-business/101/i8

Furthermore, abatement technology has been developed to remove and recover processing aids from industrial wastewater, enabling the recovery of up to 99% of the substance. This technological advancement significantly reduces emissions from fluoropolymer manufacture[152,153,154].

3.2.2 Exposure from production and use of sealing devices

There is no evidence specifically focusing on emissions of PFAS from the production and use of fluoropolymer sealing devices, so the properties of fluoropolymers have been considered to estimate exposure. Because of the excellent chemical and temperature resistance properties, high wear resistance, and low friction properties of fluoropolymers, it can be expected that emissions during the use of sealing devices are to be minimal. Sealing devices are also designed to be fully enclosed in equipment so any exposure would only be likely to occur during the preparation, cleaning, installation, and assembly of sealing devices. The volume of fluorinated processing aids used by industry in the manufacture of fluoropolymers is reported to have decreased in Europe[155]. Efforts are also underway to limit leachable content in fluoropolymers and side chain–fluorinated polymers, which consists of unbound monomers (such as fluorotelomer alcohols (FTOHs)), oligomers, and other nonpolymeric PFAS used during the polymer manufacturing process (such as surfactants and chain transfer reagents)[156]. As a result of this, combined with the durability of fluoropolymers, emissions during the use of sealing devices are not considered to be significant.

As an example, the US EPA states that when PFAS molecules are polymerised into large molecules to create resins for parts such as sealing gaskets and O-rings, typically used in food processing equipment, the process removes nearly all the smaller, migratable PFAS molecules, resulting in a negligible amount of PFAS capable of migrating to food[157].

3.2.3 Exposure from end-of-life (EOL)

Once fluoropolymer sealing devices have been used, they will either be recycled, if they are free from contamination, or disposed of in accordance with hazardous waste legislation if they contain hazardous substances. Annex I of the Waste Framework Directive (2008/98/EC) provides a non-exhaustive list of disposal options for hazardous waste, which includes, amongst others, treatment to remove the hazardous substances, incineration, or disposal to an authorised landfill.

A recent report[158] on fluoropolymer waste in Europe concluded that almost 84% of all fluoropolymer applications were incinerated at the end of their life in energy recovery, 13% of the collected fluoropolymer waste was landfilled and around 3% was recycled.

Incineration exposes fluoropolymers to extreme heat, with temperatures from 800°C–1200°C.[159] Many studies have been conducted on the products of the thermolysis of PTFE in laboratory conditions, a short selection of these can be seen in Table 3-11.

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[152] Xiaofeng Hang et al. (2015) Removal and recovery of perfluorooctanoate from wastewater by nanofiltration, Separation and Purification Technology, Volume 145 Available from: https://doi.org/10.1016/j.seppur.2015.03.013.

[153] Hoang Nhat Phong Vo, et al. (2020) Poly-and perfluoroalkyl substances in water and wastewater: A comprehensive review from sources to remediation, Journal of Water Process Engineering, Volume 36, Available from: https://doi.org/10.1016/j.jwpe.2020.101393

[154] Cousins (2022) Fluoropolymer Lifecycle Considerations: a Reason for Concern? Presentation from EEB, Available from: Europe's PFAS problem: situation briefings by independent experts - 9 - 15 - 29 September - Webinar (eeb.org)

[155] Song, et al. (2018) Emissions, transport, and fate of emerging per-and polyfluoroalkyl substances from one of the major fluoropolymer manufacturing facilities in China. Environmental science & technology, 52(17), 9694-9703.

[156] De Silva, A. O., Armitage, J. M., Bruton, T. A., Dassuncao, C., Heiger-Bernays, W., Hu, X. C., ... & Sunderland, E. M. (2021). PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. *Environmental toxicology and chemistry*, *40*(3), 631-657.

[157] US EPA (2022) Authorized Uses of PFAS in Food Contact Applications. Available at: https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications

[158] Conversio (2022) Fluoropolymer waste in Europe 2020 – End-of-life (EOL) analysis of fluoropolymer applications, products and associated waste streams. Available at: https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf

[159] Jadhao, et al. (2022) Advancement in the Field of Electronic Waste Recycling: Critical Assessment of Chemical Route for Generation of Energy and Valuable Products Coupled with Metal Recovery. Separation and Purification Technology, 120773..

Table 3-11 Summary of thermolysis products of PTFE at various temperatures.[160,161,162]

Temperature	Thermolysis products	
400°C	COF_2 produced which reacts with traces of water to yield HF.	
500°C	Tetrafuoroethene (TFE) hexafuoropropene (HFP) Trifluoroacetic acid (TFA) Cyclooctafuorobutane (c-OFB)	(c-OFB)CF3(CF2)nCOOH CF3O(CF2)mCOOH 2-fluoroacetic acid
600°C	TFE HFP	c-OFB
850°C	TFE (~ 70%) Hexafluoropropylene (around 7%)	c-OFB (4–12%) fluoride (F^-) (in the range 3–16%)

Trifluoroacetic acid (TFA) poses a hazard to both human and environmental health as it is classified for skin corrosion category 1A, acute toxicity category 4, and aquatic chronic category 3[163]. A proven source of TFA is thermolysis of fluoropolymers and is predicted to be a major contributor to the total TFA wet deposition in Europe. Thermolysis of PTFE has been calculated as producing a 1.2% yield of TFA[164]. Waste incineration and thermal recovery treatment of fluoropolymers can therefore be a significant source of PFAS emissions to the environment.

However, evidence contrary to this comes from a recent study performed by the Karlsruher Institut für Technologie (KIT)[165] investigating the presence of 31 PFAS substances (including TFA) following municipal incineration of PTFE operating at tempeatures of 870°C - 1020°C. Only 11 were detected following incineration and none were significantly different from the baseline levels, leading the study to conclude that municipal incineration of PTFE using best available techniques (BAT) was not a significant source of studied PFAS, including TFA.

Regarding waste incineration, a study conducted in 2014 for the US EPA found that a thermal reactor system operating at 1000°C effectively destroyed fluorotelomer-based polymers without detectable levels of PFOA forming[166].

However, it should be noted that EU legislation for municipal waste incineration[167] specify a temperature requirement of 850°C. Studies investigating the persistence of fluoropolymers at these temperatures indicate that certain fluorine products remain after combustion, as indicated in Table 3.9[168].

The findings on fluoropolymer waste streams also suggest that a significant proportion of sealing devices will end up in landfills. While there is little evidence on the breakdown of fluoropolymers at landfill sites, weathering and physical stress is expected to lead to some disintegration into microplastics, despite their high chemical

[160] Ellis, et al. (2001) Thermolysis of fluoropolymers as a potential source of halogenated organic acids in the environment. Nature, 412(6844), 321-324.

[161] Simon, et al. (1998). Chemical recycling of polytetrafluoroethylene by pyrolysis. Polymer Degradation and Stability, 62(1), 1-7.

[162] García, et al (2007). Products obtained in the fuel-rich combustion of PTFE at high temperature. Journal of Analytical and Applied Pyrolysis, 80(1), 85-91.

[163] ECHA (2023) Substance Infocard – Trifluoroacetic acid. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.000.846

[164] Guo, J., Zhai, Z., & Zhang, J. (2019). The contribution of fluoropolymer thermolysis to trifluoroacetic acid (TFA) in environmental media. Chemosphere, 222, 637-644.

[165] Aleksandrov, K., Gehrmann, H. J., Hauser, M., Mätzing, H., Pigeon, D., Stapf, D., & Wexler, M. (2019). Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per-and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere, 226, 898-906.

[166] Taylor P S et al. (2014). Investigation of waste incineration of fluor4otelomer-based polymers as a potential source of PFOA in the environment. Chemosphere 110: 17–22.

[167] Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste. See: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0076

[168] Huber S et al. (Norwegian Institute for Air Research) (2009). Emissions from incineration of fluoropolymer materials. Report number: OR112/2009.

and thermal stability. Microplastics, including of PTFE, have been detected in landfill leachate which leads to increase bioavailability and environmental exposure.

3.2.4 Summary of literature findings

The table below summarises the main life cycle stages for fluoropolymer related emissions during the full sealing device lifecycle. The table states our conclusions on the significance of each stage to the total emissions throughout the lifecycle and if this contribution is quantifiable for the SEA based on the literature findings alone.

Table 3-12 Summary of environmental emission sources and significance based on literature.

Product lifecycle stage	Significance to total emissions	Reasoning for significance	Can the emissions be quantified?
Fluoropolymer manufacture	Low / Medium	Emissions from manufacturing site are well reported however the use of non-fluorinated processing aids and improved abatement technology is expected to reduce the total emissions significantly.	Predicted to be negligible. The emissions from the fluoropolymer manufacturing sites in Europe have not been reported therefore exact measurements on the emissions currently are unknown, however these would be expected to decrease dramatically with developing technology over the coming years.
Production and use of fluoropolymer sealing devices	Low	Fluoropolymers are designed to be durable or are contained within the product, therefore few emissions are expected during use.	Predicted to be negligible. Not enough evidence on emissions of leachable processing aids in fluoropolymers to quantify emissions.
EOL	High	All EOL options are expected to result in some form of fluoropolymer or fluoropolymer degradation product emissions.	Not possible – unknown how many fluoropolymer sealing devices are disposed of each year in the EU and the average weight of each device. Evidence on the percentage of waste that is incinerated or treated thermally for recycling or disposed of via landfill and the emissions from landfill are unclear.

3.2.5 Exposure and links to the environment

3.2.5.1 Exposure Pathways

Fluoropolymers exhibit very high persistence under environmental conditions, which can give rise to a wide range of challenges, particularly concerning the disposal of waste and products containing fluoropolymers[169]..

Landfills serve as significant sources of PFAS release into the environment. In particular, older unlined landfills have the potential to leach non-polymeric PFAS into the soil, air, and groundwater, leading to the contamination

[169] Lohmann, et al. (2020) Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

of rivers and eventually reaching the ocean[170,171,172]. However, in the case of modern landfills, the leachate is managed through containment and PFAS treatment measures[173].

According to studies, fluoropolymers are considered insoluble in water, immobile, not readily available to living organisms, and incapable of crossing cell membranes, largely due to their high molecular weight (>10,000 Da)[174,175]. Nevertheless, the assertion that fluoropolymers cannot enter cells and thus are not bioavailable is contested because it can be misleading. Fluoropolymer particles can undergo weathering and physical stress, resulting in their breakdown into microplastics, which enhances their dispersal and increases their bioavailability after being released from landfills into the environment. Consequently, they may ultimately enter cells in their particle form[176].

Wastewater treatment plants serve as a significant pathway for PFAS release into the environment. These plants may discharge effluents containing PFAS, which can eventually find their way into rivers, lakes, and agricultural fields[177]. Standard wastewater treatment processes that rely on biodegradation or sorption to sewage sludge often struggle to remove PFAS effectively from wastewater. Consequently, PFAS easily enter the environment and persist there for extended periods[178]. Moreover, biosolids produced during wastewater treatment processes are frequently utilised as soil amendments in agricultural fields, where PFAS can be taken up by plants, animals, and soil organisms, or re-enter the water cycle[179].

3.2.5.2 Effects of this exposure on the environment

The existing knowledge regarding the environmental fate, behaviour, and impacts of PFAS primarily revolves around two to five legacy substances[180], namely PFOA and PFOS. While data on other PFAS compounds is available to some extent, there is limited environmental data on fluorinated polymeric PFAS, so there is a lack of understanding of their environmental fate, behaviour, and toxicity[181]. Some evidence exists that shows the low toxicity of fluoropolymers to rodents[182] and that they are not bioaccumulative[183,184], meaning they would

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[170] Benskin, et al. (2012). Per- and polyfluoroalkyl substances in landfill leachate: patterns, time trends, and sources. *Environmental Science Technology*. 46, pp.11532–11540.

[171] Clara, et al. (2008) Emissions of perfluorinated alkylated substances (PFAS) from point sources—identification of relevant branches, *Water Science Technology*. 58, pp.59–66.

[172] Garg, et al. (2020) A review on the sources, occurrence and health risks of per-/poly-fluoroalkyl substances (PFAS) arising from the manufacture and disposal of electric and electronic products. Journal of Water Process Engineering 38, 101683.

[173] Robey, et al. (2020) Concentrating per-and polyfluoroalkyl substances (PFAS) in municipal solid waste landfill leachate using foam separation. Environmental Science & Technology, 54(19), 12550-12559.

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

[175]Korzeniowski, S. H., (2022) A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. Integrated Environmental Assessment and Management. 00, pp.1-30. Available at: https://setac.onlinelibrary.wiley.com/doi/pdfdirect/10.1002/ieam.4646

[176] Lohmann, et al. (2020) Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[177] Environment Agency (2021) Poly- and perfluoroalkyl substances (PFAS): sources, pathways and environmental data. Chief Scientist's Group report. Bristol. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012230/Poly-_and_perfluoroalkyl_substances_-sources_pathways_and_environmental_data_-_report.pdf

[178] Environment Agency (2021) Poly- and perfluoroalkyl substances (PFAS): sources, pathways and environmental data. Chief Scientist's Group report. Bristol. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012230/Poly-_and_perfluoroalkyl_substances_-sources_pathways_and_environmental_data_-_report.pdf

[179] Fuertes, et al. (2017) Perfluorinated alkyl substances (PFASs) in northern Spain municipal solid waste landfill leachates. *Chemosphere*. 168, pp.399–407.

[180] Lohmann, R., & Letcher, R. J. (2023). The universe of fluorinated polymers and polymeric substances and potential environmental impacts and concerns. Current Opinion in Green and Sustainable Chemistry, 100795.

[181] Environment Agency (2021) Poly- and perfluoroalkyl substances (PFAS): sources, pathways and environmental data. Chief Scientist's Group report. Bristol. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012230/Poly-_and_perfluoroalkyl_substances_-sources_pathways_and_environmental_data_-_report.pdf

[182] Naftalovich, R., Naftalovich, D., & Greenway, F. L. (2016). Polytetrafluoroethylene Ingestion as a Way to Increase Food Volume and Hence Satiety Without Increasing Calorie Content. Journal of Diabetes Science and Technology, 10(4), 971–976. https://doi.org/10.1177/1932296815626726

[183] Bour, A., Avio, C. G., Gorbi, S., Regoli, F., & Hylland, K. (2018). Presence of microplastics in benthic and epibenthic organisms: Influence of habitat, feeding mode and trophic level. Environmental Pollution, 243, 1217–1225. https://doi.org/10.1016/j.envpol.2018.09.115

[184] Sfriso, A. A., Tomio, Y., Rosso, B., Gambaro, A., Sfriso, A., Corami, F., Rastelli, E., Corinaldesi, C., Mistri, M., & Munari, C. (2020). Microplastic accumulation in benthic invertebrates in Terra Nova Bay (Ross Sea, Antarctica). Environment International, 137, 105587. https://doi.org/10.1016/j.envint.2020.105587

not fulfil the criteria for being classed as PBT or vPvB substances. **However, because of the limited data, it is not possible to draw any conclusions on the expected environmental impacts from fluoropolymer use in sealing devices.**

3.2.6 Conclusion

The environmental impacts of fluoropolymer use in sealing devices remain uncertain due to limited available data. The persistence of fluoropolymers, potential for leaching, and the formation of microplastics are causes for concern. However, the environmental fate, behaviour, and toxicity of the majority of PFAS, including fluoropolymers, is unknown. It is therefore not possible to draw any conclusions on the expected direct environmental impacts from fluoropolymer use in sealing devices.

However, there are indirect impacts to consider. The use of fluoropolymer-containing sealing devices in the chemical industry not only improves worker safety from preventing chemical spills, but also helps to prevent contamination of the environment with hazardous chemicals.

As examples, in the automotive sector, fluoropolymer-containing sealing devices are used to prevent fuel and fluid leaks, thereby minimising the release of pollutants into the environment. This helps to reduce air and water pollution and promote cleaner and more sustainable transportation. The use of fluoropolymer-containing sealing devices in renewable energy technologies, such as solar panels and wind turbines also contribute to reducing environmental impacts by facilitating sustainable energy production. The failure of a seal in a chemical plant or oil and gas platform would likely lead to widespread environmental contamination with a severe impact on environmental health.

In summary, fluoropolymer-containing sealing devices bring environmental benefits from several of their applications. It is not known with certainty whether there are available alternatives that could replace fluoropolymers in these applications, as a full analysis of alternatives was outside the scope of this study. It is noted that, should an alternative have the same chemical and mechanical resistance properties as fluoropolymers, the same persistence concern may exist. However, business responses to the consultation indicated that only 20% of fluoropolymer-containing sealing devices could be substituted and/or reformulated. On this basis, **a full restriction on the use of fluoropolymers may have significant adverse effects on environmental health due to less effective sealing of systems using or containing hazardous substances.**

3.3 EXPOSURE TO FLUOROPOLYMERS AND THEIR IMPACT ON HUMAN HEALTH

This section covers the current level of exposure and emissions of fluoropolymers and the associated human health impacts, which are key to understanding the socioeconomic impact. When assessing the impacts on human health, the level of exposure is an important factor. Human exposure to PFAS can occur through several pathways: dietary ingestion, water ingestion, inhalation of air and dust particles, hand-to-mouth contact and dermal absorption[185]. Occupational exposure to PFAS occurs mainly through inhalation and dermal contact[186], but the relative importance of occupational PFAS exposure for different populations is unclear[187]

Exposure at each stage of the supply chain will be considered in this study. This includes exposure to fluoropolymers themselves, their manufacturing aids or reagents, and degradation products resulting from disposal.

[185] De Silva, A. O., Armitage, J. M., Bruton, T. A., Dassuncao, C., Heiger-Bernays, W., Hu, X. C., ... & Sunderland, E. M. (2021). PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. Environmental toxicology and chemistry, 40(3), 631-657.

[186] Franko J, Meade BJ, Frasch HF, Barbero AM, Anderson SE. 2012. Dermal pentration potential of perfluorooctanoic acid (PFOA) in human and mouse skin. J Toxicol Environ Health A 75:50–62.

[187] De Silva, A. O., Armitage, J. M., Bruton, T. A., Dassuncao, C., Heiger-Bernays, W., Hu, X. C., ... & Sunderland, E. M. (2021). PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. Environmental toxicology and chemistry, 40(3), 631-657.

3.3.1 Exposure and emissions from fluoropolymer manufacture

As mentioned in Section 3.2.1, PFOA and PFNA have traditionally been the main fluoropolymer processing aids, and long-term exposure of production workers and neighbouring populations to these salts, and the associated adverse health effects, has been extensively documented[188]. The production of fluoropolymers is cited as one of the main sources of exposure to PFAS of humans[189] and it was the major source of legacy emissions of PFOA[190].

Of the alternative processing aids listed in Table 3-9 (see Section 3.2.1), HFPO-DA poses a risk to human health and is listed on the Candidate List because of scientific evidence of probable serious effects to human health that meets the SVHC criteria for an equivalent level of concern[191]. Testing on rodents has found HFPO-DA to have similar toxicity to PFOA[192], although there is some uncertainty regarding its pharmacokinetics in humans[193].

As mentioned in Section 3.2.1, PFBS and PFHxA have also been used in the production of fluoropolymers. PFBS was identified as an SVHC and was added to the Candidate List, partly because of its moderate bioaccumulation in humans[194]. Other concerns included probable serious effects for human health. There is also evidence that PFHxA causes adverse effects in developmental toxicity studies, leading to the conclusion that long term exposure may lead to irreversible adverse effects on human health[195].

HFPO-DA and PFBS are being phased out and polymerisation aids that are fluorine free or have reduced fluorine content have been developed (see Section 3.2.1), but the impact this will have on human health is unknown.

The available evidence on the toxicity of ADONA, TFEE-5, and EEA-NH4 (Table 3-9) indicate that they pose a low risk to human health. Gordon (2011) concludes that the toxicity profile for ADONA is acceptable based on data from animal testing, with oral toxicity and eye irritation being the primary endpoints of concern[196]. These findings are also supported by the substance's REACH registration dossier[197]. EFSA concluded TFEE-5 and EEA-NH4 to be safe for consumers when used as a polymerisation aid in the manufacture of fluoropolymers[198,199].

There have been several studies on emissions and exposure to PFAS from fluoropolymer manufacturing facilities. Fu et al (2016) found concentrations of PFHxS, PFOA, and PFOS in serum and urine samples of

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188 Lohmann, R., Cousins, I. T., DeWitt, J. C., Gluge, J., Goldenman, G., Herzke, D., ... & Wang, Z. (2020). Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

189 European Commission (2020) SWD: Poly- and perfluoroalkyl substances (PFAS).
Available at: https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf

190 Prevedouros K, Cousins I, Buck R, Korzeniowski S. 2006. Sources, fate and transport of perfluorocarboxylates. Environ Sci Technol 40:32–44.

191 ECHA (2019) Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. Available at: https://echa.europa.eu/documents/10162/fc76aefc-fc86-a5fc-b5c4-e358467ca832

192 Gomis, M. I., Vestergren, R., Borg, D., & Cousins, I. T. (2018). Comparing the toxic potency in vivo of long-chain perfluoroalkyl acids and fluorinated alternatives. Environment international, 113, 1-9.

193 US EPA. Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252−13−6 and CASRN 62037−80−3) - Also Known as "GenX Chemicals". Public Comment Draft, 2018

194 ECHA (2020) Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. Available at: https://echa.europa.eu/documents/10162/079c04a0-2464-4168-f132-a22ffb04d910

195 ECHA (2021) Final opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances. Available at: https://echa.europa.eu/documents/10162/97eb5263-90be-ede5-0dd9-7d8c50865c7e

196 Gordon, S. C. (2011). Toxicological evaluation of ammonium 4, 8-dioxa-3H-perfluorononanoate, a new emulsifier to replace ammonium perfluorooctanoate in fluoropolymer manufacturing. Regulatory Toxicology and Pharmacology, 59(1), 64-80.

197 ECHA (n.d.) Ammonium 2,2,3-trifluor-3-(1,1,2,2,3,3-hexafluoro-3-trifluormethoxypropoxy), propionate.
https://echa.europa.eu/registration-dossier/-/registered-dossier/2602/1

198 EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). (2012). Scientific Opinion on the safety evaluation of the substance, 2H-perfluoro-[(5, 8, 11, 14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] CAS No 37486-69-4 for use in food contact materials. EFSA Journal, 10(12), 2978.

199 EFSA Panel on food contact materials, enzymes, flavourings and processing aids (CEF). (2011). Scientific Opinion on the safety evaluation of the substance, Perfluoro [(2-ethyloxy-ethoxy) acetic acid], ammonium salt, CAS No. 908020-52-0, for use in food contact materials. EFSA Journal, 9(6), 2183.

workers to be several times higher than those typically found in the general population, while Girardi & Merler (2019) also found very high levels of PFOA in employee blood serum. Whilst these studies focused on legacy PFAS that are no longer used in fluoropolymer manufacture in Europe, they suggest a higher risk of exposure among workers to emerging PFAS. Detectable levels of HFPO-TA have also been found in the sera of populations residing near a fluoropolymer production plant[200]. There is evidence that the risk of exposure is not only high amongst workers, but also nearby populations, as high airborne concentrations of PFAS and deposition rates in water and soil compartments have been found near manufacturing facilities[201,202,203].

As discussed in Section 3.2.1, all these studies are over five years old, and since then, HFPO-DA has been added to the Candidate List and is being phased out, along with other PFAS processing aids. The adoption of these alternative processing aids is expected to decrease the emission of fluorinated substances during fluoropolymer production, but not eliminate them entirely.

3.3.2 Exposure from production and use of sealing devices

As discussed in Section 3.2.2, due to the properties of fluoropolymers and the enclosed nature of sealing devices, human exposure to PFAS is expected to be minimal during the use of fluoropolymer-containing sealing devices.

3.3.3 Exposure from end-of-life (EOL)

As discussed in Section 3.2.3, the majority of fluoropolymer-containing sealing devices are expected to be incinerated, and there is contradictory evidence on the thermal breakdown products of fluoropolymers. Therefore, it is not possible to draw concrete conclusions on the possible exposure and human health impacts resulting from incineration of fluoropolymers.

A significant proportion of fluoropolymer-containing sealing devices are also expected to end up in landfills. Some breakdown into microplastics is expected, although not fully evidenced, which could increase bioavailability and increase the long-term potential for human exposure.

3.3.4 Summary of literature findings

The table below summarises the main life cycle stages for fluoropolymer related emissions during the full sealing device lifecycle. The table states our conclusions on the significance of each stage to the total emissions throughout the lifecycle and if this contribution is quantifiable for the SEA based on the literature findings alone.

Table 3-13 Summary of human exposure sources and significance based on literature.

Product lifecycle stage	Significance to total emissions	Reasoning for significance	Can the emissions be quantified?
Fluoropolymer manufacture	Low	Emissions from manufacturing site are well reported however the use of non-fluorinated processing aids and improved	Predicted to be negligible. The emissions from the fluoropolymer manufacturing sites in Europe have not been reported therefore exact measurements on the emissions

[200] Pan, Y., Zhang, H., Cui, Q., Sheng, N., Yeung, L. W., Guo, Y., ... & Dai, J. (2017). First report on the occurrence and bioaccumulation of hexafluoropropylene oxide trimer acid: an emerging concern. Environmental science & technology, 51(17), 9553-9560.

[201] Zhou, J., Baumann, K., Surratt, J. D., & Turpin, B. J. (2022). Legacy and emerging airborne per-and polyfluoroalkyl substances (PFAS) collected on PM 2.5 filters in close proximity to a fluoropolymer manufacturing facility. Environmental Science: Processes & Impacts, 24(12), 2272-2283.

[202] D'Ambro, E. L., Pye, H. O., Bash, J. O., Bowyer, J., Allen, C., Efstathiou, C., ... & Murphy, B. N. (2021). Characterizing the air emissions, transport, and deposition of per-and polyfluoroalkyl substances from a fluoropolymer manufacturing facility. *Environmental Science & Technology*, *55*(2), 862-870.

[203] Bach, C., Dauchy, X., Boiteux, V., Colin, A., Hemard, J., Sagres, V., ... & Munoz, J. F. (2017). The impact of two fluoropolymer manufacturing facilities on downstream contamination of a river and drinking water resources with per-and polyfluoroalkyl substances. *Environmental Science and Pollution Research*, *24*, 4916-4925.

Product lifecycle stage	Significance to total emissions	Reasoning for significance	Can the emissions be quantified?
		abatement technology is expected to reduce the total emissions significantly.	currently are unknown, however these would be expected to decrease dramatically with developing technology over the coming years.
Production and use of fluoropolymer sealing devices	Low	Fluoropolymers are designed to be durable or are contained within the product, therefore few emissions are expected during use.	Predicted to be negligible. Not enough evidence on emissions of leachable processing aids in fluoropolymers to quantify emissions.
EOL	Low	All EOL options are expected to result in some form of fluoropolymer or fluoropolymer degradation product emissions but due to the proximity of humans to landfills and waste treatment plants, exposure is expected to be low.	Predicted to be negligible. Difficult to determine environmental pathways of microplastics from landfill and breakdown products from incineration plants.

3.3.5 Exposed Populations

Due to the unique properties of fluoropolymers, the primary use of sealing devices is in workplace and industrial settings where specific conditions demand their exceptional performance. For sealing device applications, these conditions typically involve high operating temperatures, elevated pressures, or the presence of harsh chemicals. Fluoropolymers possess outstanding resistance to heat, corrosion, and chemical attack, making them ideal for applications such as industrial equipment, chemical processing plants, and specialized manufacturing processes. Consequently, the exposure to fluoropolymers is predominantly limited to workers in these specific environments, as they are the individuals directly involved in operating, maintaining, or interacting with the equipment and materials incorporating fluoropolymer sealing devices.

Worker exposure to fluoropolymers used in sealing devices is expected to predominately occur during maintenance of equipment incorporating the sealing devices. This is because they are typically fully enclosed within the equipment, minimizing the possibility of direct contact or exposure during regular operation. However, during maintenance or repair tasks that involve disassembly or inspection of the equipment, workers may come into contact with these sealing devices, potentially leading to exposure to fluoropolymers. The likelihood of an effect from this exposure is not possible to quantify as there is no evidence specific to leachate rates in fluoropolymer sealing devices.

3.3.6 Exposure and links to human health and/or safety

The human health effects from exposure to PFAS has been well documented in scientific literature, but research has been heavily focused on a select few substances that have been phased out in the EU. Thus, little is known about the toxicology of the majority of PFAS, including fluoropolymers. This section draws upon peer-reviewed and academic studies and aims to provide application specific context as to the potential perceived risks to humans, including professionals and consumers. To do this, inferences have had to be made from literature on fluoropolymers in other applications, as there is an absence of available literature on PFAS that is specific to sealing devices.

3.3.6.1 Exposure Pathways

Typical exposure routes of PFAS include oral (e.g. food, water, dust ingestion) and inhalation of air and dust particles. Hand-to-mouth contact and dermal absorption are also other possible pathways[204]. Release of bioavailable fluoropolymer particles is plausible and supported by the scientific literature related to the bioavailability of similarly sized micro and nano plastics of fluorine-free polymers[205].

PTFE is used in many sealing applications. PFTE has been subject to multiple safety evaluations by authorities in the EU and the US. For example, the US EPA has concluded that PTFE is not hazardous, nor should be considered a priority pollutant. ECHA has also assessed PTFE and found it not to be a persistent organic pollutant (POP).

One of the main health effects associated with PTFE is polymer fume fever (PFF), which results from exposure to compounds during thermal decomposition. This occurs when PTFE exceeds temperatures of 450°C, producing carbonyl fluoride, hydrogen fluoride (through hydrolysis of carbonyl fluoride and air moisture), carbon monoxide, and low molecular weight fluoropolymers. Heating PTFE to a similar temperature can also release fumes containing ultrafine particles (approximately 20nm diameter) which has been found to be highly toxic to rats, resulting in extensive pulmonary oedema and haemorrhagic inflammation[206] [207]. Professional and industrial workers may have a higher risk of exposure to these fumes but thermal decomposition is unlikely to occur as fluoropolymer sealings are not expected to be exposed to temperatures that exceed 450°C in their intended applications.

3.3.6.2 Effects of this exposure on human health and safety

Exposure to certain PFAS has been linked to various health concerns including obesity, liver or kidney disease, irregular gene expression, spontaneous mutations, and an elevated risk of cancer. Moreover, PFAS exposure has been shown to cause reproductive problems in adults and neurodevelopmental and autoimmune disorders in children, as they can cross both the blood-placental and blood-brain barriers[208]. While scientific research on the health effects of fluoropolymers is limited compared to non-polymeric PFAS, Lohmann et al. [209] suggests that fluoropolymers may be of concern depending on the stage of their lifecycle, based on concentrations of leachates in fluoropolymer products, although there is no evidence specific to leachate rates in fluoropolymer sealing devices. However, processing aids used during their manufacture have been detected leaching out during product use, namely chromatographic instrumentation[209]. Although legacy PFAS processing aids have been replaced with non-fluorinated alternatives due to health concerns, some of these alternatives are of similar or higher toxicity and require further examination[210].

A review performed by Henry et al[211], which reviewed fluoropolymer toxicity data, human clinical data, and physical, chemical, thermal, and biological data concluded that they meet widely accepted criteria for being considered as “polymers of low concern” (PLC), and thus pose an insignificant risk to environmental and human health. This position was also supported by ECETOC’s Conceptual Framework for Polymer Risk

[204] De Silva, et al. (2021). PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. Environmental toxicology and chemistry, 40(3), 631-657.

[205] Lohmann, et al. (2020) Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[206] Oberdörster, et al. (1995). Association of particulate air pollution and acute mortality: involvement of ultrafine particles?. Inhalation toxicology, 7(1), 111-124.

[207] Johnston, et al. (1996) Characterization of the early pulmonary inflammatory response associated with PTFE fume exposure. *Toxicol Appl Pharmacol*. 140(1), pp.154-63. Available at: https://pubmed.ncbi.nlm.nih.gov/8806881/

[208] Garg, S. et al. (2020) A review on the sources, occurrence and health risks of per-/poly-fluoroalkyl substances (PFAS) arising from the manufacture and disposal of electric and electronic products. Journal of Water Process Engineering 38, 101683.

[209] Lohmann, et al. (2020) Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[210] Gomis, et al. (2018) Comparing the toxic potency in vivo of long-chain perfluoroalkyl acids and fluorinated alternatives. Environment international, 113, 1-9.

[211] Henry, B. J., Carlin, J. P., Hammerschmidt, J. A., Buck, R. C., Buxton, L. W., Fiedler, H., ... & Hernandez, O. (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 14(3), 316-334.

Assessment ("CF4Polymers")[212], and the European Commission contracted study proposing criteria for the identification of polymers requiring registration (PRR) under REACH[213].

In general, determining the impact of fluoropolymer-based sealing devices on human health is difficult as there is an overall lack of evidence on the levels of leachates (e.g., processing aids, synthesis by-products and oligomers) in individual fluoropolymer substances and products[214].

3.3.6.3 Benefits to Safety

Fluoropolymers are known for their ability to resist chemical corrosion from acids, bases, and solvents, making them a crucial component in chemical process equipment, piping, gaskets and hoses, pumps, gears, and other mechanical parts[215]. By preventing corrosion and leakage, they ensure safe handling of hazardous chemicals and prevent equipment failure[216], which could lead to significant adverse consequences on human health. Additionally, fluoropolymers have high flame retardancy, thermal stability, and are capable of self-extinguishing, which greatly enhances their fire safety profile[217]. These properties make the use of fluoropolymers crucial in applications where high levels of safety are required.

Within the chemical industry, fluoropolymer-containing sealing devices are used as gaskets in equipment for chemical processing, transport, and storage, typically to seal valve stem and rotary shaft equipment. Their high chemical resistance to a range of aggressive substances, such as acids, bases, and solvents ensures the integrity of the equipment and prevents leakage, minimizing the potential for chemical spills and worker exposure to hazardous substances, thereby contributing to worker safety.

Within the pharmaceutical and food industries, fluoropolymers are chosen for sealing devices because of their high purity and ability to withstand aggressive cleaning regimes necessary to maintain high hygiene standards. This reduces the risk of contamination and helps ensure the safety and efficacy of pharmaceuticals and food products.

In the aviation industry, the high thermal stability and flame retardancy of fluoropolymers are used in gas turbine engines to stop oil leakages, which is key to preventing equipment failure and incidents that would pose a significant risk to human safety.

Within the marine industry, fluoropolymers are used in shaft propellor bearings because of their resistance to continuous high temperatures, chemical and saltwater resistance, mechanical strength, and low friction coefficient. They must also be durable enough to last a minimum of five years, which is a typical interval between dry-docking. If alternative substances are used that cannot meet these requirements, leakage of oil into seawater may occur. Information submitted as part of the public consultation on the proposed REACH restriction of PFAS indicates that there are no alternatives available that can meet the required performance standards[218,219].

Fluoropolymer-containing sealing devices are used in automotive powertrain systems because of their chemical resistance to oils, hydrocarbon fuels, and automotive fluids. These properties ensure the integrity of engine components, fuel systems, and hydraulic systems, which improves the overall safety and reliability of vehicles.

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[212] Cummings, I. (2019). The ECETOC Conceptual Framework for Polymer Risk Assessment (CF4Polymers)-Technical Report No. 133-1.

[213] Wood (2020) Scientific and Technical Support for the Development of Criteria to Identify and Group Polymers for Registration/ Evaluation under REACH and Their Impact Assessment. Final Report. Available at: http://publications.europa.eu/resource/cellar/1cc811ff-d5fc-11ea-adf7-01aa75ed71a1.0001.01/DOC_1

[214] Lohmann, et al. (2020) Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[215] Lohmann, et al. (2020) Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

[216] Wood (2020) Socio-economic Assessment (SEA) of the US Fluoropolymer Industry Executive Summary. Available at: https://fluoropolymerpartnership.com/wp-content/uploads/2020/03/Socio-Economic-Assessment-of-the-US-Fluoropolymer-Industry-Executive-Summary.pdf

[217] Fluoropolymer Products Group of Plastics Europe (2021). Risk Management Options Analysis (RMOA). Available at: https://fluoropolymers.plasticseurope.org/application/files/9916/3671/0265/Fluoropolymers_Product_Group_-_RMOA_September_2021.pdf

[218] AEGIR Marine (2023) Submission Public Consultation ECHA PFASs restriction proposal 22 March 2023.

[219] Noordermeer and Masen (2023) Material Selection Criteria for Elastomeric Rotary Propeller Seals for Marine Applications

3.3.7 Conclusion

There is limited scientific evidence specifically investigating the health effects of fluoropolymers in sealing device applications. Existing academic studies have focused on the health effects of a select number of PFAS, which have now been phased-out in the EU. Therefore, there is limited understanding of the toxicology of the majority of PFAS. While there is evidence that fluoropolymers meet the definition of polymers of low concern (PLC)[220], when looking at the whole lifecycle of fluoropolymers (production, use, and disposal), their persistence and potential for exposure to PFAS may be a cause for concern[221].

Exposure to PFAS can occur through various pathways such as ingestion, inhalation, dermal absorption, and hand-to-mouth contact. For the PFAS that have been studied, there is significant evidence linking their exposure to various health impacts, such as obesity, liver or kidney disease, irregular gene expression, spontaneous mutations, an elevated risk of cancer, reproductive problems, neurodevelopmental disorders in children, and autoimmune disorders. However, the extent to which fluoropolymer sealing devices contribute to PFAS exposure and subsequent health risks requires further investigation and specific data on leachates and exposure levels.

PTFE is the most commonly used material in fluoropolymer-containing sealing devices, which has undergone safety evaluations by regulatory authorities. While these evaluations have concluded PFTE to be non-hazardous, it should be noted that PFTE can release toxic fumes when exposed to very high temperatures. However, under normal use, fluoropolymer-containing sealing devices are not expected to be subjected to such extreme temperatures.

Because of the lack of available evidence on fluoropolymer use in sealing devices, it is not possible to draw conclusions on the potential direct health implications from their application. Nevertheless, the health effects from fluoropolymer use in sealing devices is not limited to those associated with direct exposure to PFAS. Fluoropolymer-containing sealing devices play a key role in ensuring protection of human health across several applications and provide numerous benefits to improving safety (see Section 3.3.6.3).

As mentioned previously, a full analysis of alternatives was outside the scope of this study, so it is not known whether there are available alternatives that could meet the performance necessary to guarantee the same level of protection afforded by fluoropolymers. If alternatives with lower performance are used the level of protection of human health would decrease. If businesses are forced to shut down because of the lack of acceptable alternatives, this too would have an adverse effect on human health. For example, a lack of acceptable alternatives in the pharmaceutical and food industries may threaten food security and the availability of pharmaceuticals, as their supply would be dependent on imports from outside the EU.

Based on the 20% substitution/reformulation rate indicated by the businesses surveyed in this study, it is concluded that **a full restriction on the use of fluoropolymers may have a significant adverse effect of human health from exposure to hazardous substances.**

3.4 SOCIAL IMPACTS

Social impacts from the restriction of fluoropolymers used in sealing devices are presented in this section, based on evidence collected via survey, both quantitative and qualitative. The focus will be on the social impacts of the proposed restriction to the wider community, especially employment over the 2024-2040 period. The section will cover:

- Impact on employment of sealing device manufacturers and importers, and its knock-on effects to the overall EEA employment.
- Impact on employment of sealing device downstream users and knock-on effects to the overall EEA employment.

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[220] Henry, B. J., Carlin, J. P., Hammerschmidt, J. A., Buck, R. C., Buxton, L. W., Fiedler, H., ... & Hernandez, O. (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management, 14(3), 316-334.

[221] Lohmann, R., Cousins, I. T., DeWitt, J. C., Gluge, J., Goldenman, G., Herzke, D., ... & Wang, Z. (2020). Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS?. Environmental science & technology, 54(20), 12820-12828.

- The performance of relevant applications identified and how this will affect consumers and the wider society (e.g., risks associated, availability of alternatives, performance, costs associated, and fitness in the wider EEA environmental policy agenda).

3.4.1 Employment impacts on the sealing device Industry

The adoption of the restriction scenario considered in this study is estimated to lead to a direct net reduction in the jobs supported by sealing device manufacturers and importers in the EEA. This reduction is primarily driven by the potential reduction in size of the sealing device industry that is estimated to result from the proposed restriction.

The scale of impact on employment is estimated to be slightly lower than the impact on turnover. This has been established by reviewing historical trends and confirmed by businesses participating in consultation activities for this study. This is partly driven by the need to retain employees to meet the need to develop new alternative products with innovation, potentially improving their skills, training and/or retraining costs, and the rigidity of the labour market, among others.

In this context, it is estimated that, by the end of 2042, between 10,700 and 12,500 jobs would be lost against the baseline scenario in the sealing device industry, which is equivalent to approximately 17% to 20% of the overall employment in EEA sealing device producing and importing businesses. These direct job losses would be even larger if the sealing device industry were unable to substitute and/or reformulate as noted in their survey responses, which will inevitably depend on a positive market response to the substituted and/or reformulated products. Table 3-14 below describes the estimated average impacts on the sector's employment in the three scenarios.

Table 3-14 Estimated average impacts on the employment of EEA sealing device manufacturers and importers against the baseline scenario (jobs).

Scenario	Estimated average impacts on employment in the sector
Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	In any given year over the period 2027-2042, EEA sealing device manufacturers and importers are estimated to employ around 11,200 fewer workers on average, when compared to the baseline scenario.
Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	In any given year over the period 2027-2042, EEA sealing device manufacturers and importers are estimated to employ around 9,000 fewer workers on average, when compared to the baseline scenario.
Scenario 3 (Substitution and Reformulation, 13.5-year derogation)	In any given year over the period 2027-2042, EEA sealing device manufacturers and importers are estimated to employ around 5,200 fewer workers on average, when compared to the baseline scenario.

As noted, the analysis suggests the under Scenario 1, EEA sealing device manufacturers' and importers' overall employment would likely be 20% lower against the baseline by 2042, equivalent to losing around 12,500 jobs; in Scenario 2, their employment would be 18% lower against the baseline from 2042 (11,400 jobs), whereas under Scenario 3, overall employment would be 17% lower against the baseline by 2042, equivalent to a loss of 10,700 jobs. These effects are considered direct, in that they reflect the impact on the EU sealing device industry only. Such effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to employment.

Box 3-5 Knock-on effects on employment of the EEA.

Total impacts on employment: The direct, indirect and induced effects

The decrease in employment in the EEA sealing device manufacturers and importers is likely to have knock-on effects across the supply chain (indirect or Type I effects). These direct and indirect effects are also expected to translate into changes on overall compensation and, thus, disposable income, which would in turn further reduce consumption and have broader implications in the economy (induced or Type II effects).

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the policy options on the EEA sealing device manufacturers and importers have been estimated using an Input-Output methodology. The cumulative Type I and Type II multipliers have been assumed at around 1.3 and 1.8 respectively, based on evidence from Eurostat Input-Output tables and JRC, statistical databases from Europe and expert judgment.

Based on this, **the adoption of changes to the manufacture of sealing devices and their knock-on effects through the EU economy could lead to a reduction of between 13,800 and 16,100 jobs by 2042 when compared against the baseline**.

Source: Ricardo analysis based on Eurostat data and a bespoke survey of EEA sealing device manufacturers.

3.4.2 Employment impacts on sealing device downstream users

The adoption of the proposed restriction considered in this study is estimated to lead to a direct net reduction in the jobs supported by the surveyed sealing device downstream users. This reduction is primarily driven by the potential reduction in size of their businesses that is estimated to result from the adoption of the restriction.

The scale of impacts on employment is estimated to be lower than the impact on turnover, just like in the case of sealing devices manufacturers and importers, although the difference in intensity of this impact is larger in this case.

It is estimated that, by the end of 2042, 9,100 to 28,400 jobs would be lost against the baseline scenario, which is equivalent to 4% to 13% of the surveyed companies' current workforce. These direct job losses would be even larger if the downstream users were unable to substitute, reformulate or redesign their products containing sealing devices as noted in their survey responses, which will depend on the performance of the new products and of potential substitutes to sealing devices or to fluoropolymers therein. Table 3-15 below describes the estimated average impacts on the sector's employment in three scenarios.

Table 3-15 Estimated average impacts on the employment of the surveyed sealing devices downstream users against the baseline scenario (jobs)

Scenario	Estimated average impacts on employment in the sector
Scenario 1 (Substitution and Reformulation)	In any given year over the period 2027-2042, surveyed downstream users are estimated to employ 25,100 fewer workers on average, when compared to the baseline scenario.
Scenario 2 (Substitution and Reformulation (with delay))	In any given year over the period 2027-2042, surveyed downstream users are estimated to employ 17,300 fewer workers on average, when compared to the baseline scenario.
Scenario 3 (Faster policy implementation with delay on substitution)	In any given year over the period 2027-2042, surveyed downstream users are estimated to employ 7,900 fewer workers on average, when compared to the baseline scenario.

As noted, the analysis suggests that sealing device downstream users' employment would likely be 13% lower by 2042 in Scenario 1, equivalent to losing over 28,400 jobs against the baseline scenario; in Scenario 2, employment would be 11% lower than in the baseline by 2042, equivalent to losing 24,000, while in Scenario 3, the final impact on employment by 2042 is 4% and 9,100 jobs would be lost against the baseline in that year. These effects are considered direct, in that they reflect the impact on their businesses only. Such effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to employment.

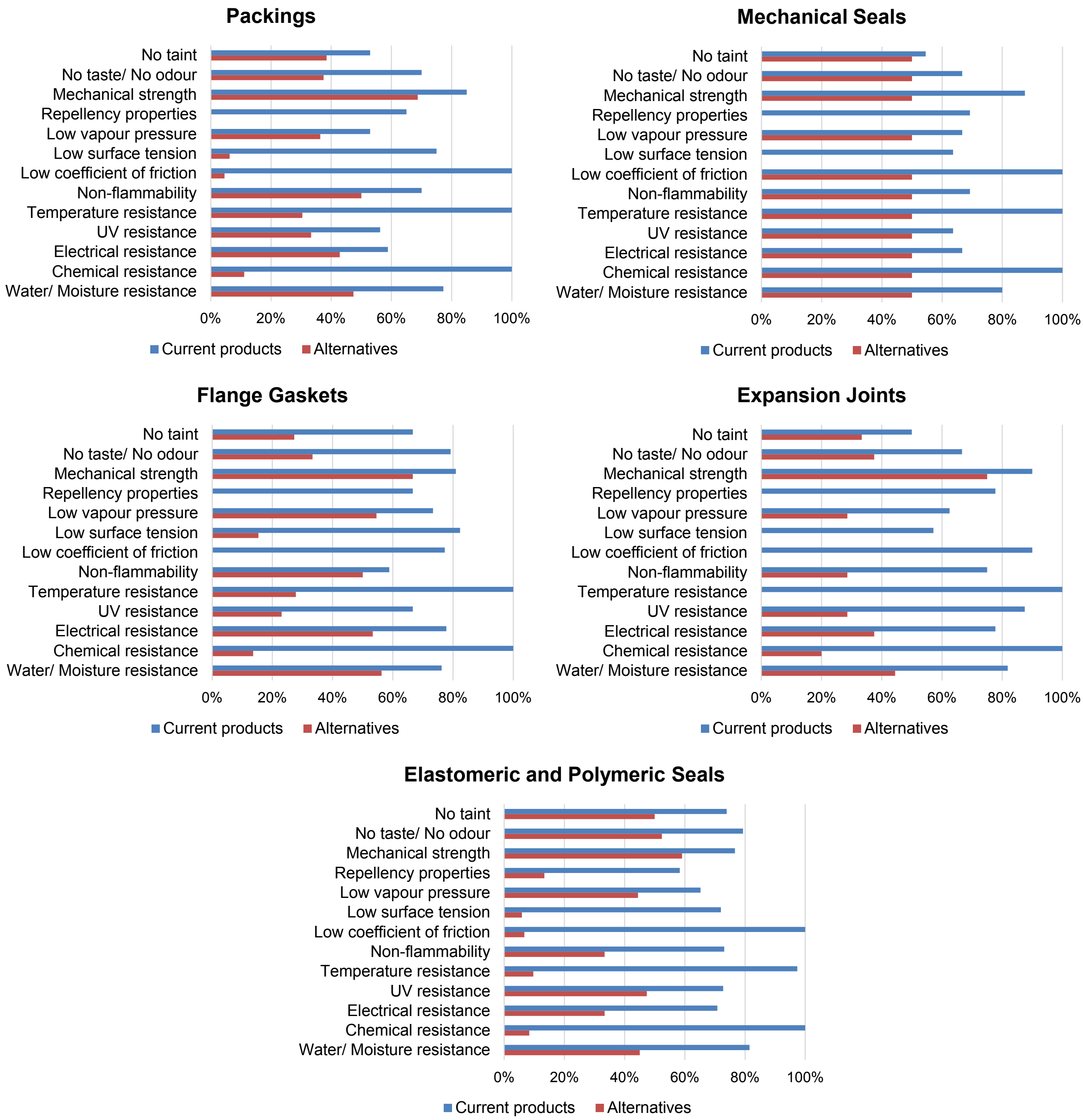
3.4.3 Other social impacts of the PFAS restriction on sealing devices

While some alternatives exist for all types of sealing device, there is considerable variation in the ability to derive key properties of fluoropolymer-based sealing devices from non-fluoropolymer-based alternatives.

Figure 3-13 shows the percentage of sealing device manufacturers and importers that consider there to be alternatives that could possess the same key properties (such as water resistance, chemical resistance, electrical resistance, UV resistance, mechanical strength, etc.) that fluoropolymers provide to the sealing devices they manufacture.

According to their responses, none of the existing alternatives can provide these key properties to the same extent as fluoropolymer-based sealing devices and there is a clear gap in terms of substitutability. In terms of key properties, alternatives seem to perform particularly poorly on chemical resistance, temperature resistance, repellence, low surface tension and low coefficient of friction. By type of sealing device, on average, mechanical seals appear to have a much smaller gap in substitutability between the fluoropolymer-based sealing devices and existing alternatives than any other type of sealing device. Manufacturers also commented openly that alternatives do not provide the same combination of properties and durability, resulting in leakages and process contamination risks and as a result, fail to meet performance, customer or industry specifications.

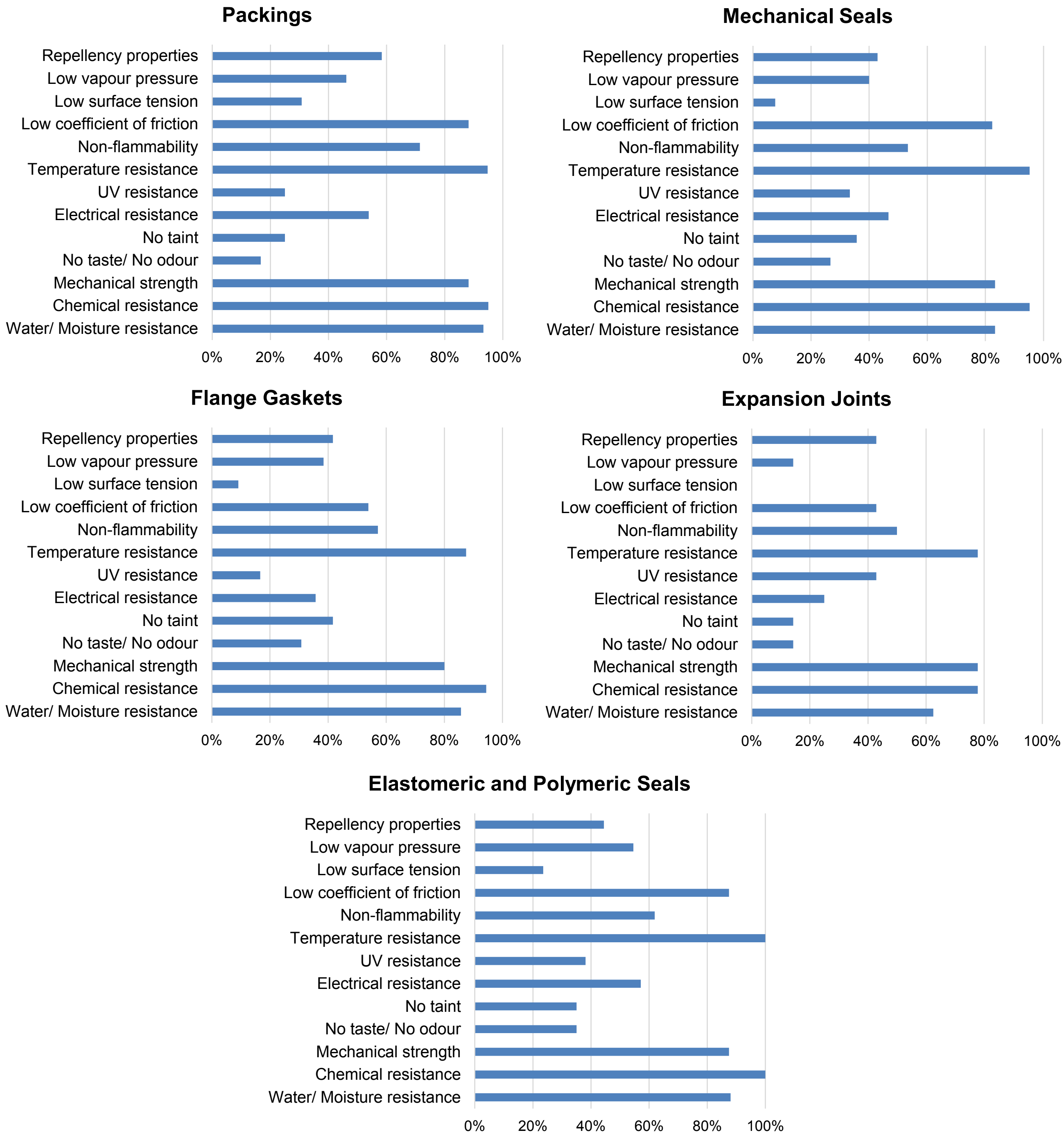
Figure 3-13 Percentage of sealing device manufacturers that report their sealing devices having each key property and proportion that report each key property being possible with non-fluoropolymer known alternatives.



Source: Ricardo analysis based on a bespoke survey of sealing device manufacturers and/or importers.

Figure 3-14 shows the percentage of sealing device downstream users that report each of the key properties of sealing devices as essential to their operations. Comparing across Figure 3-13 and Figure 3-14, both manufacturers and downstream users are mostly aligned in terms of the desired properties they wish to provide and obtain from each type of sealing device.

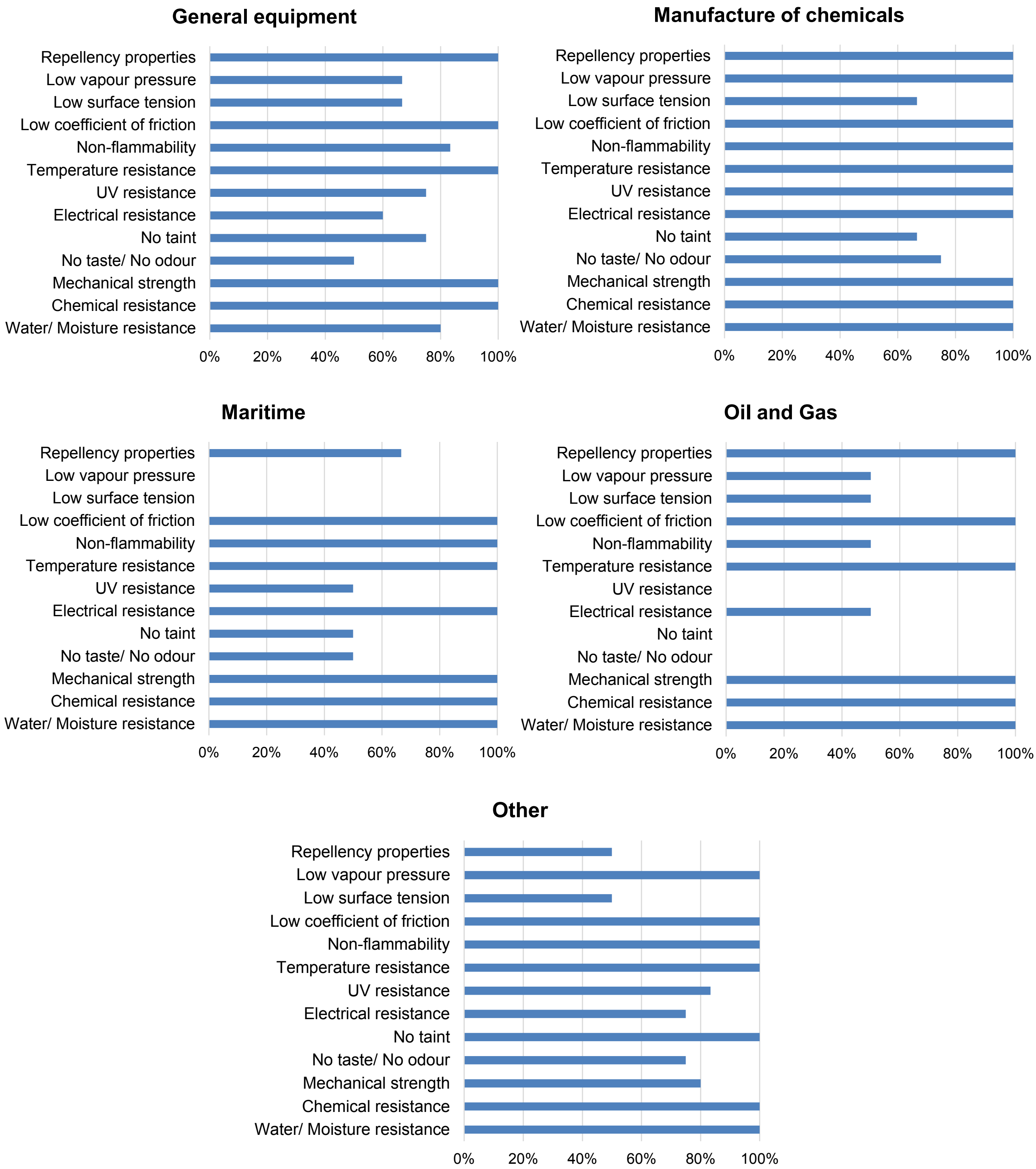
Figure 3-14 Percentage of sealing device downstream users that report fluoropolymer-based sealing device types as having each key property.



Source: Ricardo analysis based on a bespoke survey of sealing device downstream users.

Similarly, Figure 3-15 shows the percentage of sealing device downstream users by downstream user sector that report each of the key properties of sealing devices as essential to their operations. Based on their responses, the Chemicals, General Equipment, and Other sectors appear to require a much wider selection of the key properties than the Maritime and Oil and gas sectors, which are more limited in their desired selection of key properties.

Figure 3-15 Percentage of sealing device downstream users by downstream user sector that report fluoropolymer-based sealing devices having each key property.



Source: Ricardo analysis based on a bespoke survey of sealing device downstream users.

In addition, according to the survey responses from downstream users, the substitutability of the existing alternatives varies between 10% to 30%, with gaps in the substitutability of certain types of sealing devices being smaller than others. For example, the existing alternatives to expansion joints and packings are more likely to provide the desired mix of properties than the alternatives to elastomeric and polymeric seals and mechanical seals. However, given the extensive safety and performance requirements associated with the applications of sealing devices, most of these existing alternatives cannot reliably replace the fluoropolymer-based sealing devices.

As noted, where alternatives are not viable, downstream users may no longer be able to carry out their industrial and manufacturing activities. This would have negative social and economic impacts in EEA societies that rely on the supply of these products and services. These impacts could range from the knock-on implications through the value change in the form of reduced demand for inputs from the most directly affected sectors (e.g., chemicals, semiconductors) to their supplying sectors, and from them in turn to their own supplying sectors, to having to heavily rely on imported goods: food, pharmaceuticals and technology, among others (see Section 3.5). This wide range of impacts affects the strategic autonomy of Europe, and also the security of the EEA population for basic-need products. The affected sectors and industries potentially impact all key industries including those which facilitate the Green Deal aims, such as renewable energy and semiconductors.

3.5 WIDER ECONOMIC IMPACTS

The assessment of the wider economic impacts builds on the previous results on economic and social impacts. It focusses on the wider economic impacts that result from the restriction of fluoropolymers used in sealing devices stemming from the direct impacts on manufacturers, importers and downstream users of sealing devices over the 2024-2042 period.

This section includes:

- Assessment of the input-output impacts across the value chain from impacts on sealing device manufacturers and importers.
- Assessment of the input-output impacts across the value chain from impacts on sealing device downstream users.
- Understanding how the restrictions will impact trade, competition and development within the EEA market and its external market with the rest of the world, including the expected impact upon illegal trade.
- A review of arguments for derogation as reported by sealing device industry and downstream users.

3.5.1 Impacts on Gross Value Added (GVA) through impacts on sealing device manufacturers and importers

The adoption of the proposed restriction will lead to reductions in sectoral GVA[222]. These reductions will, however, be lower in magnitude to that of turnover or output, as costs increase per unit of output. However, this would depend on the ability of the EEA sealing device industry to pass on to their customers some of the increases in regulatory burden. Survey responses indicate that it would be difficult to mitigate turnover impacts via prices without further turnover losses due to demand elasticity. Therefore, results presented here abstract from price changes due to the low likelihood of their feasibility (see Section 3.1.1).

Table 3-16 below outlines the estimated impacts on GVA of the EEA sealing device production and import.

Table 3-16 Estimated impacts on the GVA of the EEA sealing device manufacturers and importers against the baseline scenario (€ 2021).

Scenario	Direct impacts on sectoral GVA
Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	The EEA sealing device manufacturers and importers are estimated to **lose €0.8 billion (€ 2021) of Gross Value Added each year on average** over the period 2024-2042, when compared to the baseline scenario.

[222] GVA is defined as production value minus the value of raw materials that are used as inputs to the sector's own production. It is therefore a sector's contribution to Gross Domestic Product (GDP).

Scenario	Direct impacts on sectoral GVA
Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	The EEA sealing device manufacturers and importers are estimated to **lose €0.7 billion (€ 2021) of Gross Value Added each year on average** over the period 2024-2042, when compared to the baseline scenario.
Scenario 3 (Substitution and Reformulation, 13.5-year derogation)	The EEA sealing device manufacturers and importers are estimated to **lose €0.5 billion (€ 2021) of Gross Value Added each year on average** over the period 2024-2042, when compared to the baseline scenario.

The analysis suggests that the sector's GVA would lose between €0.5 billion and €0.8 million each year on average over the period 2024 and 2042, when compared to the baseline scenario. These effects are considered direct, in that they reflect the impact on the EEA sealing device manufacturers and importers only. Such effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EEA economy (induced effects), leading to even larger reductions in the sector's contribution to GDP.

Box 3-6 Knock-on effects of the impacts to sealing device manufacturers and importers on the European economy[223].

Total impacts on the economy: The direct, indirect and induced effects

The decrease in the GVA of EEA sealing device manufacturers and importers is likely to have knock-on effects on the sector's supply chain (indirect or Type I effects). The direct and indirect effects are also expected to translate into a reduction in employment and thus overall compensation, which would in turn further reduce consumption and have broader implications across the economy (induced or Type II effects).

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the policy options on EEA sealing device manufacturers and importers have been estimated using an Input-Output methodology. The cumulative Type I and Type II multipliers have been assumed at around 1.9 and 2.2 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

Based on this, total reductions in GVA driven by the effects of the policies considered on the EEA overall economy could range between €1.0 billion and €1.7 billion every year on average between 2024 and 2042, which would be equivalent to shaving between 0.007 to 0.013 percentage points off the EU-27 GDP.

Source: Ricardo analysis based on EEA data and a bespoke survey of sealing device manufacturers and importers.

3.5.2 Impacts on Gross Value Added (GVA) through impacts on sealing device downstream users

These impacts would affect the size and cost of operation of the sealing device downstream users in the EEA. The net reduction in EEA business operations, or direct impacts, would propagate through the EEA economy and have indirect and induced effects, estimated in terms of potential reductions in the different sectors' contribution to GDP and employment over time.

The restriction on PFAS including fluoropolymers used in sealing devices considered will also lead to reductions in GVA for downstream users. These reductions will, however, be lower in magnitude to that of turnover or output and depend on how much costs of developing new products increase relative to how much business size is reduced as a result of the restriction.

GVA is affected by changes in output, or turnover, and intermediate consumption. The policy options are likely to result in decreases in turnover and increases in intermediate consumption, both drivers leading to reductions in GVA. This impact in GVA would represent first order effects. If sealing device downstream user companies

[223] The analysis of indirect and induced impacts relies on Input-Output tables, which are at the level of the EU-27 at most. Thus, this analysis is limited to indirect and induced impacts in the EU-27.

were able to pass through some of the cost increases to their customers via price increases, they would partially alleviate this impact in GVA, although as analysed in Section 3.1.2, based on survey responses, this is considered unlikely.

Table 3-17 below outlines the estimated impacts on GVA of the sample of downstream users in each of the three scenarios.

Table 3-17 Estimated impacts on the GVA of the surveyed downstream users against the baseline scenario (€ 2021).

Scenario	Direct impacts on sectoral GVA
Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Surveyed sealing device downstream users are estimated to **lose €2.3 billion (€ 2021) of Gross Value Added each year on average** over the period 2025-2040, when compared to the baseline scenario.
Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Surveyed sealing device downstream users are estimated to **lose €1.5 billion (€ 2021) of Gross Value Added each year on average** over the period 2025-2040, when compared to the baseline scenario
Scenario 3 (Substitution and Reformulation, 13.5-year derogation)	Surveyed sealing device downstream users are estimated to **lose €0.8 billion (€ 2021) of Gross Value Added each year on average** over the period 2025-2040, when compared to the baseline scenario

That is, the analysis suggests that downstream users' GVA would lose between €0.8 billion and €2.3 billion each year on average over the period 2024 and 2042, when compared to the baseline scenario. These effects are considered direct, in that they reflect the impact on their businesses only. Such effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to GDP.

Due to the multiplicity of sectors involving downstream user applications of sealing devices and the inability to disentangle how each of them is impacted in isolation by the proposed restriction with precision at the level of whole sectors, the analysis of knock-on effects to the overall economy has not been possible to develop with precision. However, based on the sectors involved, the Type I multiplier has been estimated to range between 1.1 and 3.3, with an average central estimate of 2.4, while the Type II multiplier is estimated to range between 1.4 and 3.9, with an average central estimate of 2.9. The implications of these multipliers are presented in the Box below.

Box 3-7 Knock-on effects of the PFAS restriction from direct impacts on the sealing device industry to the European[224] economy: direct, indirect and induced effects.

The decrease in the GVA of sealing device downstream users is likely to have knock-on effects on each of their sector's supply chain (indirect or Type I effects). The direct and indirect effects are also expected to translate into a reduction in employment and thus total compensation, which would in turn further reduce consumption and have broader implications across the economy (induced or Type II effects).

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the policy options on the EEA downstream users have been estimated using an Input-Output methodology. The cumulative Type I and Type II multipliers have been assumed at around 2.4 and 2.9 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

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224 The analysis of indirect and induced impacts relies on Input-Output tables, which are at the level of the EU-27 at most. Thus, this analysis is limited to indirect and induced impacts in the EU-27.

Based on this, **total reductions in GVA driven by the effects of the policies considered on just the sample of EEA downstream users of sealing devices could range between €2.4 billion (Scenario 3) and €6.8 billion (Scenario 1) every year on average between 2024 and 2042, which would equate from 0.02 and 0.05 percentage points of the EU-27 GDP in all cases.**

If the downstream user sectors indeed were represented by the surveyed sample, the impacts on the European GVA driven by the restriction could reach 1.0-3.3 percentage points of the EU-27 GDP.

3.5.3 Impacts on trade and competition

In a Scenario with a full restriction of PFAS, the manufacture and trade of sealing devices containing fluoropolymers would be restricted, as the ban on the manufacture and placing on the market of PFAS *de facto* restricts the import and export of sealing devices containing them. For sealing device manufacturers, the extra-EEA export market is an important part of all the economic value created by sealing devices in the EEA, representing up to 48% of that value, according to Prodcom data.

Downstream users will not be able to import, or sell whatsoever, equipment or products containing fluoropolymer-based sealing devices, which is estimated to represent around 36% of their total sales. Further, as the existing equipment used for the manufacture of their products, which also contains sealing devices, reaches the end of its useful life, the absence of alternatives to the sealing devices in this equipment could impede their manufacturing operation with the required safety and efficiency. This represents 41% of the sales of sealing device downstream users surveyed. In such a situation, products free of sealing devices that rely on fluoropolymer-based sealing devices for their manufacturing process will likely have its manufacturing activity closed down in the EEA and be relocated elsewhere, or just have the products imported.

Given the large number and production volume of industrial sectors, of which only a relevant subset was analysed here as a sample, and how reductions in sector output can be transferred through the value chain as reduced demand for production inputs and multiplied through the rest of the economy, a broad-reaching application like sealing devices can affect the overall external competitiveness of the EU and the EEA. The development of safe and competitive alternatives to fluoropolymer-based sealing devices will be key to maintain industrial manufacturing operations in the EEA and external trade.

3.5.4 Arguments for derogation by sealing device manufacturers, importers downstream users

Sealing device manufacturers, importers, and downstream users were asked to comment how the introduction of the PFAS restriction would affect their organisations. Their comments can be considered a qualitative summary of the industry's views of the potential impacts of the restriction on society as a whole.

Many respondents highlighted the competitive disadvantage they would be in if the PFAS restriction went through. Companies in the EEA would now need alternative products that would cost more or simply be impossible to produce due to the inexistence of fluoropolymers-free alternatives. This would severely impact the global competitiveness of these companies as their global competitors not subjected to these restrictions would be able to sell their products in global markets at more competitive rates while increasing prices for European consumers at home.

As discussed in Section 3.4.3, business responses received during the consultation indicate that there may not be alternative materials which can deliver the same performance as fluoropolymers. To draw reliable conclusions on the availability of acceptable alternatives, a full analysis of alternatives is required, which was outside of the scope of this study. However, a literature review indicates that alternative materials are available that could potentially replace fluoropolymers in some applications. Appendix A3 provides a non-exhaustive list of potential alternative materials for use in sealing devices.

In many cases alternative products not containing PFAS do not exist, and downstream users of sealing devices will be forced to shut down or produce products with lower performance. Due to the physical properties of PFAS previously stated, these are of extreme importance to produce some specific products which would have to change if the restriction was put in place as the exact benefits provided by the physical properties of PFAS are for some products simply impossible to replicate with alternatives. Downstream users would have to adapt their products to new physical constraints through for example lower permissible maximum temperature or rotating speed.

Due to the specific applications of sealing devices containing fluoropolymers in very specialised products, the impacts of this ban would negatively impact key strategic sectors that are currently supporting the EEA Green Deal, the common ambition on net-zero carbon emission and energy transition efforts. All these would be harmed with the proposed restriction on fluoropolymers and the EU's green goals would be severely affected as well as some key sectors the EU is currently trying to become a global leader in, namely the semiconductors sector. A semiconductor industry association report on the impact of a potential PFAS restriction on the semiconductor sector highlights the issues the sector would face if these restrictions were put into place. For many of the applications PFAS have in this sector there are currently no alternative PFAS-free applications with the industry estimating that in many cases more than 10 years are needed to develop alternatives that maintain the physical properties of current PFAS-based sealing devices. Given the EU's objective of becoming a key global player in semiconductors these restrictions would be a major blow to those ambitions.

PFAS-based sealing devices have a key role in many sectors due to their unique physical properties and the proposed restriction would have very adverse effects on European companies dependent on sealing devices as substitution costs are considerable and, in many cases, not even possible. The arguments for the derogation are therefore strong and linked to a considerable loss of competitiveness of companies operating in the EEA and the threat to the EU's ambition of becoming a green powerhouse and global leader in innovation.

4. CONCLUSIONS AND RECOMMENDATIONS

A targeted consultation with sealing device manufacturers and importers, and with sealing device downstream users from various application sectors, allowed the socio-economic analysis of impacts of a REACH restriction of PFAS. As outlined in Section 2.1.1, the restriction proposal includes fluoropolymers, which are a key component in many widely used sealing devices. Fluoropolymer-based sealing devices provide properties to sealing devices that are considered critical in some uses, such as temperature resistance, chemical resistance, low coefficient of friction, water or moisture resistance, and mechanical strength.

The economic analysis reveals that the proposed restriction is likely to have significant impacts on the EEA sealing device manufacturers and importers, on their downstream users, and the wider economy. In particular, **EEA sealing device manufacturers and importers are estimated to experience an annualised loss of between €1.6 billion and €3.7 billion per year on average between 2024 and 2042, compared to baseline projections, as a result of the proposed restriction**. For sealing device manufacturers, there is limited scope to substitute fluoropolymers in their sealing devices with alternatives, as these are application-specific materials, selected on the basis of their ability to maintain a consistently tight seal, often in extreme conditions. Derogations will allow for more time and resources to innovate. However, even then, in 2042, sectoral turnover has been estimated to range between 18% and 21% lower than in the baseline projections, depending on the derogation scenario for sealing devices.

For EEA sealing device downstream users, their loss would result from the inability to continue their manufacturing activities without the properties that fluoropolymer-based sealing devices confer to their products and/or manufacturing processes**. These downstream users are estimated to lose between 11%-33% of their baseline sales turnover, ultimately depending on the extent and duration of time-limited derogations** and the ability of these companies to develop, test and introduce alternative manufacturing processes and/or products that no longer have fluoropolymer-containing sealing devices. This estimated loss, is estimated to range between €6.1 billion to €19.5 billion in annualised terms between 2024 and 2042 , compared to the baseline projections[225], for a sample of surveyed sealing device downstream users. Whilst the sample represents a small percentage of sales turnover within the selected sectors, it is not possible to conclude whether it is representative and, thus, sectoral extrapolations cannot be concluded.

These estimated losses of business activity against the baseline are significant despite already accounting for actions that businesses would take to mitigate the effects of the legislative changes, such as substitution, reformulation and other innovation. For example, sealing device manufacturers and importers have reported that they might be able to substitute and/or reformulate around 20% of the portfolio of products that could be affected by the proposed policy changes and, a similar scale of substitution, reformulation and/or redesign would be expected from downstream users, around 22%.

These estimates are uncertain. For example, baseline product characteristics and performance are not guaranteed by these strategies, nor is customer demand. The approval process for sealing device manufacturers takes varying amounts of time (7.6 years on average, for survey participants), in order to fully understand the capability of the material before recommending it for an application, and this process would need validation to thousands of applications individually, with a non-zero risk of failure. The outcomes of innovation might constitute the placing on the market of entirely new products that may be more costly, with uncertainty in how this translates further down the value chain and the rest of the economy.

The proposed restriction would also affect the jobs supported by the sealing device manufacturers and downstream users. It is estimated that, **by 2042, between 10,700 and 12,500 jobs would be lost against the baseline scenario in the sealing device industry,** which is equivalent to approximately 17% to 20% of the overall employment in EEA sealing device producing and importing businesses. Based on the multiplier effects of this economic effect, it is estimated that the cumulative employment reduction could reach between 13,800 and 16,100 jobs by 2042 against the baseline.

For the set of downstream users surveyed, potential job losses could range between 4% and 13% of the baseline workforce of downstream users in 2042[226]. Based on the sample of respondents, these losses

[225] The sample of downstream users surveyed consisted of 49 companies pertaining to 5 different sectors, and represented overall less than 5% of their joint sales value. Therefore, extrapolations from the sample to the level of the sector have been avoided, and results will only refer to the sample.

[226] It should be noted that this is an extrapolation based on the known production value of sealing device downstream using sectors and the production value reported only by the surveyed sample, which has a limited representativeness of the whole sectors assessed.

could range between 9,100 and 28,400 by 2042, against the baseline. These cannot be extrapolated because the sample of respondents may not necessarily represent the average effects across the selected sectors.

These effects would also have knock-on impacts on the supply chain (indirect effects) and the wider EU economy (induced effects), leading to even larger reductions in the sector's contribution to employment. Given that the sample of sealing device downstream users was not representative of large sector volumes, knock-on implications at the sector level have not been quantitatively assessed in this case.

The direct contribution of sealing device manufacture and import to GVA would be between €0.5 and €0.8 billion lower per year over the period 2024-2042, on average and when compared to the baseline. When adding indirect and induced effects, **the total contribution of the EU sealing device manufacture and import to GVA would be between €1.0 and €1.7 billion lower per year over this period, on average.**

Moreover, the sample of downstream users participating in a survey for this Study would also be negatively. Their contribution to the EU economy would be €0.8 billion to €2.3 billion lower, in GVA terms, than in the baseline per year on average over this period. When we include potential indirect and induced effects, it is estimated that the GDP in the EEA would be €2.4 to €6.8 billion lower on average per year against the baseline. The scale of this impacts is likely to be larger, especially if additional companies within the selected downstream sectors would experience similar impacts. However, the extent to which that might be the case is unknown.

Table 4-1 summarises some of these impacts on key business and economic indicators of the **sealing device manufacturing and import** against the baseline and across the three scenarios considered.

Table 4-1 Annualised impacts on selected business and economic indicators of the EEA sealing device manufacturing and importing sector, against the baseline scenario.

Themes (business or economic indicators)	Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Scenario 3 (Substitution and Reformulation, 13.5-year derogation)
Turnover (first order effects)	A loss of €3.7 billion per year between 2024 and 2042 on average against the baseline	A loss of €2.9 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.6 billion per year between 2024 and 2042 on average against the baseline
Total GVA contribution (*direct, indirect, induced*)	A loss of €1.7 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.5 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.0 billion per year between 2024 and 2042 on average against the baseline
Regulatory burden	An additional annualised burden of €100 million each year between 2024 and 2042	An additional annualised burden of €150 million each year between 2024 and 2042	An additional annualised burden of €200 million each year between 2024 and 2042
Total employment contribution (*direct, indirect, induced*)	16,700 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	14,500 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	10,500 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042

Table 4-2 below summarises some of these impacts on key business and economic indicators of the sample of sealing device **downstream users** against the baseline and across the three scenarios considered.

Table 4-2 Annualised impacts on selected business and economic indicators of the sample of EEA sealing device downstream users, against the baseline scenario.

Themes (business or economic indicators)	Scenario 1 (Substitution and Reformulation, 1.5-year transition period)	Scenario 2 (Substitution and Reformulation, 6.5-year derogation)	Scenario 3 (Substitution and Reformulation, 13.5-year derogation)
Turnover (first order effects)	A loss of €19.5 billion per year between 2024 and 2042 on average against the baseline	A loss of €12.8 billion per year between 2024 and 2042 on average against the baseline	A loss of €6.1 billion per year between 2024 and 2042 on average against the baseline
Total GVA contribution (*direct only*)	A loss of €2.3 billion per year between 2024 and 2042 on average against the baseline	A loss of €1.5 billion per year between 2024 and 2042 on average against the baseline	A loss of €0.8 billion per year between 2024 and 2042 on average against the baseline
Regulatory burden	An additional annualised burden of €200 million each year between 2024 and 2042	An additional annualised burden of €300 million each year between 2024 and 2042	An additional annualised burden of €350 million each year between 2024 and 2042
Total employment contribution (*direct only*)	25,100 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	17,300 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042	7,900 fewer jobs, on average, when compared to the baseline in any given year between 2024 and 2042

There is also the need to consider the impact of these restrictions on consumers. Sealing devices are key inputs to many industrial applications that produce and manufacture a wide range of products of everyday use. Without the use of fluoropolymer-based sealing devices there could be a significant impact on the functioning of society, with e.g. food, water and power supplies, transport and safety being impacted. Without fluoropolymer-based sealing devices, such products would either not be able to be made or operate safely, increasing the risk of accidents, or would not be able to be manufactured at all, due to the operating conditions that, at present, can only be facilitated by fluorpolymer-based sealing devices.

Because of the lack of available evidence on more qualitative and quantitative aspects of the fluoropolymer use in sealing devices, it is not possible to draw conclusions on the potential direct health implications from their application. Nevertheless, the health effects from fluoropolymer use in sealing devices is not limited to those associated with direct exposure to PFAS. Fluoropolymer-containing sealing devices play a key role in ensuring the protection of human health across several applications and provide numerous benefits, including safety in the manufacturing process of chemicals, among others.

A full analysis of alternatives was outside the scope of this study, so it is not known whether there are available alternatives that could meet the performance necessary to guarantee the same level of protection afforded by fluoropolymers. If alternatives with lower performance are used, the level of protection of human safety would decrease. If businesses in certain sectors are forced to shut down because of the lack of acceptable alternatives, this too may have an adverse effect on human health. For example, a lack of acceptable alternatives in the pharmaceutical and food industries may threaten food security and the availability of pharmaceuticals, as their supply would be dependent on imports from outside the EU, reducing Europe's strategic autonomy.

Based on the 20% substitution/reformulation rate indicated by the businesses surveyed in this study, it is concluded that **a full restriction on the use of fluoropolymers could have a significant adverse effect of human health as a result of exposure to hazardous chemicals and indirect effects on the availability of products which serve basic needs such as food and healthcare.**

The environmental impacts of fluoropolymer use in sealing devices remain uncertain due to limited available data. The persistence of fluoropolymers, and the formation of microplastics are causes for concern. However, the environmental fate, behaviour, and toxicity of the majority of PFAS, including fluoropolymers, is unknown or supported by little evidence. It is therefore not possible to draw any conclusions on the expected direct environmental impacts from fluoropolymer use in sealing devices.

However, there are indirect impacts to consider. The use of fluoropolymer-containing sealing devices in the chemical industry not only improves worker safety from preventing chemical spills, but also helps to prevent contamination of the environment with hazardous chemicals.

Examples include: the automotive sector, where fluoropolymer-containing sealing devices are used to prevent fuel and fluid leaks, thereby minimizing the release of pollutants into the environment; and the use of fluoropolymer-based sealing devices in renewable energy technologies, such as solar panels and wind turbines also contribute to reducing environmental impacts by facilitating sustainable energy production.

In summary, fluoropolymer-based sealing devices bring environmental benefits from several of their applications. It is not known with certainty whether there are available alternatives that could replace fluoropolymers in these applications, as a full analysis of alternatives was outside the scope of this study. However, business responses to the consultation indicated that 80% of fluoropolymer-containing sealing devices could not be substituted and/or reformulated. On this basis, **a full restriction on the use of fluoropolymers may have an adverse effect on environmental health from emissions as a result of less effective sealing of systems using or containing hazardous substances.**

The results of this assessment highlight that the proposed restriction of PFAS, as it was conceived including all fluoropolymers that are used in the sealing devices in scope of this study, may lead to the reduction in manufacturing and/or use of downstream user applications and increase in costs thereof. Sectors that use sealing devices in their products or in their manufacturing processes need time and resource to make the necessary investment and innovate in non-fluoropolymer-based sealing device alternatives. Without further data on the impact of exposure to fluoropolymers to human health and the environment, a balance of costs and benefits cannot be determined.

4.1 OVERVIEW OF HUMAN HEALTH, ENVIRONMENTAL, SOCIAL, AND ECONOMIC IMPACTS

This section presents an overview of the assessment of the proposed restriction of PFAS carried forward in this Study. Four impact categories are assessed: environmental, human health, economic, and social impacts. Each of these categories are scored against the baseline scenario of no restriction.

A qualitative scoring framework has been used to provide a methodology for comparison of the proposed restrition with respect to the baseline scenario (outcome of the assessment of the 4 impact categories above). The qualitive framework is provided in Table 4-3.

Table 4-3 Qualitative scoring framework for assessment of the proposed restriction through its impact on sealing devices.

Score	Description of impact direction and magnitude
-3	High negative impact on the factor is expected from the implementation of the proposed restriction
-2	Medium negative impact on the factor is expected from the implementation of the proposed restriction
-1	Low negative impact on the factor is expected from the implementation of the proposed restriction
0	Neutral or unknown impact on the factor is expected from the implementation of the proposed restriction
1	Low positive impact on the factor is expected from the implementation of the proposed restriction

Score	Description of impact direction and magnitude
2	Medium positive impact on the factor is expected from the implementation of the proposed restriction
3	High positive impact on the factor is expected from the implementation of the proposed restriction

The table below provides a summary of the direction and magnitude of impacts that are expected following a restriction of the use of fluoropolymers in sealing devices. Following the scoring framework, impacts are scored on a scale from 3 (strong positive impact) to -3 (strong negative impact), with 0 representing a neutral impact, or where lack of data does not allow for conclusions to be drawn.

Table 4-4 Summary of impacts expected from restriction of fluoropolymers in sealing devices under REACH

Impact Category	Score	Level of Uncertainty	Explanation
Economic	-2	High	Impacts on various critical applications of fluoropolymer-based sealing devices such as the chemicals industry, aerospace and defence, oil and gas, and the food and drink industry, among others, could be large and preclude their continued production. However, there is large uncertainty in whether there can be suitable alternatives and there is a wide range of opinions among downstream users on whether this could be possible. There is also the risk of relocalisation of economic activities elsewhere.
Environmental health	0	High	There is insufficient data available to draw conclusions on the impact on environmental health from the breakdown of fluoropolymers and emissions of PFAS throughout. Fluoropolymer sealing devices provide a high level of environment protection against chemical spills and contamination, which would be reduced following restriction of fluoropolymers due to the lower levels of ability to substitute cited by industry. The lower performance of alternatives is expected to lead to more frequent replacement of sealing devices and equipment using sealing devices. It is assumed that if the performance of an alternative is too low or too risky, it will not be used and the activity will cease.
Human health	-1	High	There is evidence to suggest that fluoropolymers themselves are of low concern. However, there is insufficient understanding of direct PFAS exposure throughout the lifecycle of fluoropolymer sealing devices to draw conclusion on their direct impact on human health. Fluoropolymer sealing devices also provide a high level of human health protection against chemical spills and leakage, which would be reduced following restriction of fluoropolymers due to the lower levels of substitution cited by industry. The lack of alternatives is expected to lead to more frequent workplace accidents involving hazardous chemicals and food security incidents because of the important role of sealing devices in food production.
Social	-1	Medium	In terms of key properties, alternatives seem to perform particularly poorly on chemical resistance, temperature resistance, repellence, low surface tension and low coefficient of friction. Alternatives do not seem to be able provide the same combination of properties and durability, resulting in leakages

Impact Category	Score	Level of Uncertainty	Explanation
			and process contamination risks and as a result, fail to meet performance, customer or industry specifications. Some jobs would be lost following the economic loss for various downstream industries.

Below are the weights assigned to each impact category. Economic impacts have been assigned double weight due to the fact that impacts on downstream users have only been captured at the level of a sample, and not as a whole. Therefore, estimated numbers are expected to be larger, although with uncertainty on whether the sample accurately represents the extent of impacts for each downstream using sector assessed. Additionally, it is understood that more sectors than those assessed in this study would be affected by a restriction of PFAS that bans the manufacture and placing on the market of fluoropolymer-based sealing devices.

Table 4-5 Weightings by impact category.

Impact category	Weight
Human Health	1
Environmental	1
Economic	2
Social	1

The final score is the weighted average across impact categories: -1.5. This score positions the restriction of fluoropolymers in sealing devices in a low-to-medium negative score range.

4.2 RECOMMENDATIONS

As a result of the need for additional data to assess the human health and environmental impacts of fluoropolymers, and the need to mitigate impacts on the EEA economy and wider society through the identification of alternatives, the following recommendations have been drawn from this assessment:

As an exemption does not appear feasibile under RO2, it may be appropriate to introduce a derogation for fluoropolymer-based sealing devices to the REACH restriction, which takes into account the proposed derogation for polymerisation aids (RO2 derogation 5a). In light of the absence of alternatives for the large majority (78%) of the fluoropolymer sealing applications, the derogation should include a review period (e.g. 12 years) that allow for reconsideration of the availability and suitability of alternatives in order to prevent significant impacts on the competitiveness of the EU and the ability to meet the objectives of the EU Green Deal. Finally, said derogation and review period should also consider the average useful life of manufacturing equipment containing fluoropolymer seals and gaskets (typically 15-35 years) and the fact that those components must be replaced over the life of the equipment, thereby requiring the availability of fluoropolymers.

APPENDICES

A1 DATA COLLECTION APPROACH

A1.1 Stakeholder consultation

A1.1.1 Economic impact surveys to sealing device manufacturers and downstream users

The aim of both surveys was to collect evidence that would form the basis for an assessment of the extent to which a restriction of fluoropolymers would impact the operations of EEA sealing device manufacturers, importers and downstream users. The assessment also took into account how all these businesses would expect to respond to the restriction (e.g. by moving to alternatives – other fluoropolymers or to non-fluoropolymer sealing devices-, both as manufacturers, importers and as consumers of fluoropolymer-based sealing devices, considering potential derogations, etc.). The intention was for this to allow the quantification of knock-on effects through the value chain, based on the evidence collected directly from businesses.

Generally, both surveys consisted of the following four parts:

- Part 1, gathering data about the respondents in terms of their size, activities, area of operation, etc.
- Part 2, seeking to form a baseline for the sector's turnover, costs and expenditures, employment, regulatory burden, based on current information provided by companies and their expectations of growth over the next decade in a 'No restriction' Scenario.
- Part 3, assessing businesses' expected responses or reactions to the restriction proposal (e.g. substitution of fluoropolymers with other substances, or of sealing devices with other technologies, abandonment of certain production lines, application for derogations, etc.) and their costs and benefits over the next decade.
- Part 4, collecting a direct assessment by participants of the overall expected impacts of the proposed restriction, to be used as complementary to the previously provided information on reactions to the restriction and as a sense check (e.g. turnover, employment, overall investment, and costs).

The survey covered all of the key business and economic impacts that were screened as potentially most significant (see Section 2.1.3.2). The types of questions covered across these key business impacts and/or proxies are outlined in Table A 1 below:

Table A 1 Types of questions covered by both economic impact surveys.

Policy, key business impacts or proxies	Information sought by the survey for evidence on operations in the EEA (not an exhaustive list)
Policy	Establishing the relevance of the restriction proposal for each respondent
Turnover / business size	• 2021 turnover and tonnes of sealing devices in scope sold (or of downstream applications thereof), number of products; annual growth expected in the absence of the restriction over 10 years; annual growth expected upon adoption of a potential restriction over 10 years. • Percentage (or sales value) of the affected portfolio that would be in scope for substitution and/or reformulation with alternatives; and potential derogations from new legislative requirements; expected pass through of potential regulatory burden; considerations of customer responses from price changes based on historical evidence.
OPEX	• 2021 annual operating costs; annual growth expected in the absence of the restriction over 10 years; annual growth expected upon adoption of the proposed restriction over 10 years (for the retained business). • Recurring costs of substitution and/or reformulation, and derogations, across different cost categories. Qualitative questions associated with administrative burden from the wider regulatory context were also considered.

Policy, key business impacts or proxies	Information sought by the survey for evidence on operations in the EEA (not an exhaustive list)
CAPEX	• 2017-2021 average annual total capital investment; annual growth expected in the absence of the restriction over 10 years; annual growth expected upon adoption of the proposed restriction over 10 years. • Recurring costs of substitution and/or reformulation, and derogations, across different cost categories.
R&D	• Level of operating expenditure/ capital investment devoted to R&D expenditure in the EEA and expected evolution in the absence of the proposed restriction; annual growth expected upon adoption of the proposed restriction over 10 years.
Employment	• 2021 employment; annual growth expected in the absence of the restriction over 10 years; annual growth expected upon adoption of a potential restriction over 10 years.
Other economic impacts	• Qualitative effects on competitiveness and illicit imports.

Evidence from the consultation of stakeholders was elicited and triangulated across responses to multiple questions (e.g. more implicit versus explicit approaches to gather evidence from businesses' informed views), in order to compare and contrast the impacts and test the robustness of the information gathered.

The data obtained in this consultation is deemed sensitive under competition law. In order to ensure compliance, access to responses to the consultation is limited to study team members from Ricardo and the data is stored in a folder with limited access rights. ESA and participants do not have access to any data, other than that which they submitted themselves. In the analysis of the data, Ricardo follows good practice statistical rules ensuring that all data is aggregated[227] and anonymised to prevent reverse engineering.

Finally, it is noted that 2021 is taken as the baseline year for eliciting evidence of potential impacts from businesses through survey. Expectations for baseline growth and impacts over the next decade consider the decade starting in 2022. This means that the information gathered referred to potential impacts with regards to 2021 business operations, considering that the contractive effects of the pandemic over the EEA economy have been overcome by 2021. Nevertheless, the information gathered is triangulated with available projections from the European Commission[228] and with past trends of the baseline series of public data on the sectors in scope of the analysis as to the expected recovery from the pandemic to generate a baseline and Impact Assessment that aligns with said expectations.

[227] The aggregated data used always must come from more than five independent companies, the latter being understood as the collection of undertakings whose relations with the company participating to the statistical exercise come within the terms of one or more of the sub-paragraphs of Article 5(4) of the EU Merger Regulation. Any input of less than 5% of the total volume reported by companies cannot be taken into consideration. Even when aggregated, the data must not come from one company with more than 70% of the total volume. No price information is included in the report.

[228] European Commission, Winter 2022 Forecast. Available from: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_926.

A2 List of Fluoropolymers used in sealing devices

The table below shows the fluoropolymers typically used in the five main types of sealing device.

Table A 2 Fluoropolymers used in the five main types of sealing device.

Fluoropolymer	Packings	Mechanical Seals	Flange Gaskets	Expansion Joints	Elastomeric & Polymeric Seals
PTFE					
FKM					
FFKM					
FEP					
FEPM					
PCTFE					
PFA					
PVDF					

A3 List of alternative materials to fluoropolymers in sealing devices

The table below includes a non-exhaustive list of potential alternative materials to fluoropolymers in sealing devices, along with their properties, limitations, and example applications that were obtained from a rapid literature review.

Table A 3 Non-exhaustive list of potential alternative materials to fluoropolymers in sealing devices

Material	Properties	Limitations	Applications
Plastics			
Polyphenylene sulphide (PPS) [229]	- Maximum operating temperature of 204°C - Resistance to a range of chemicals including acids, bases, oils, solvents, and fuels - Resistance to high temperature steam - Low coefficient of thermal expansion which allows it to maintain good dimensional stability - Low creep and water absorption - Good durability and wear resistance	- Limited resistance to aromatic hydrocarbons (i.e. benzene, toluene), hydrochloric acid, methylene chloride, tetrachlorethylene, and triethanolamine[230]	Scroll pump seals; Automotive seals
Polyamide-imide (PAI) [231]	- Maximum operating temperature of 275C - Resistance to a range of chemicals including some acids, esters and ethers, alcohols, fuels, nitrile/nitro compounds - Highest mechanical strength and stiffness of any thermoplastic - Low creep - Very good impact resistance	- Absorbs water which affects dimensional stability - Cannot be used in humid environments[232]	Aerospace fasteners and components; Labyrinth seals in the oil and gas industry[233].

[229] Omniseal Solutions (2022) Meldin Polymers – High-Performance Thermoplastic Materials. Available at: https://www.omniseal-solutions.com/sites/hps-mac3-seals-seals/files/2022-08/Meldin-HT-Thermoplastics-Handbook.pdf

[230] Curbell Plastics (2014) Chemical Resistance Chart of Plastics. Available at: https://www.yumpu.com/en/document/view/28638990/chemical-resistance-chart-of-plastics-curbellplasticscom

[231] Omniseal Solutions (2022) Meldin Polymers – High-Performance Thermoplastic Materials. Available at: https://www.omniseal-solutions.com/sites/hps-mac3-seals-seals/files/2022-08/Meldin-HT-Thermoplastics-Handbook.pdf

[232] Ensinger (n.d.) PAI material - Polyamide-imide. Available at: https://www.ensingerplastics.com/en-gb/shapes/high-performance-plastics/torlon-pai-polyamide-imide

[233] Ensinger (n.d.) PAI material - Polyamide-imide. Available at: https://www.ensingerplastics.com/en-gb/shapes/high-performance-plastics/torlon-pai-polyamide-imide

Material	**Properties**	Limitations	**Applications**
	- Excellent fatigue resistance when exposed to cyclical stress - Excellent wear resistance - Very good thermal stability - Low coefficient of thermal expansion - Low thermal conductivity - Low coefficient of friction		
Polyimides[234][235]	- Maximum operating temperature of over 300C[236] - High dimensional stability at high temperatures - High purity - High electrical and thermal insulating properties - Resistance to aggressive chemicals	- Low impact strength - Poor resistance to alkalis and concentrated acids[237]	**Aerospace** - high electrical and thermal insulating properties make it suitable for use in structural aerospace parts. **Semiconductors** - high dimensional stability at elevated temperatures, high purity, and high resistance to solvents, oils, and other process chemicals make it suitable for semiconductor applications. **Automotive** – Self-lubricating grades are used in piston rings and thrust washers in transmissions and pumps for automotive, off-road, and agricultural vehicles. **Plastic manufacturing** – used as thermal insulator in hot runner nozzles used in injection moulding thermoplastics, such as PET bottles.
Nylon[238]	- Not prone to cracking - Good chemical resistance - Lightweight - Maximum operating temperature of 110C[239]	- High water absorption so seals can swell. Therefore, nylons seals can be used in humid/wet conditions - Cannot be used in chlorine environments[240]	Hydraulic and pneumatic sealing rings

[234] Omniseal Solutions (2022) Meldin – High-Performance Thermoset Polyimide Materials. Available at: https://www.omniseal-solutions.com/sites/hps-mac3-seals-seals/files/2022-06/Meldin-Thermoset-Polyimides-Handbook.pdf

[235] Curbell Plastics (2022) DuPont Vespel Polyimides – High Performance Polymers for Aerospace Valve Seats and Seals. Available at: https://www.curbellplastics.com/wp-content/uploads/2022/11/DuPont-Vespel-for-Aerospace-Valves.pdf

[236] Hait, P. W. (1967). The application of polyimide to ultrahigh vacuum seals. *Vacuum*, *17*(10), 547-550.

[237] Curbell Plastics (2022) DuPont Vespel Polyimides – High Performance Polymers for Aerospace Valve Seats and Seals. Available at: https://www.curbellplastics.com/wp-content/uploads/2022/11/DuPont-Vespel-for-Aerospace-Valves.pdf

[238] Poly Fluoro Ltd (2022) High Performance Seals, Valves, and Seats – Polymer Sealing Solutions. Available at: https://polyfluoroltd.com/blog/polymer-sealing-solutions-high-performance-seals-valves-seats

[239] Laminated Plastics (n.d.) Technical Data Sheet – Nylon. Available at: https://laminatedplastics.com/nylon.pdf

[240] The Chlorine Institute. (2021) Pamphlet 95 – Gasket for Chlorine Service. Available at: https://bookstore.chlorineinstitute.org/pamphlet-95-gaskets-for-chlorine-service.html

Material	Properties	Limitations	Applications
Composites			
H310 (thermoset polymer combined with carbon fibre) & H320 (thermoset polymer combined with glass fibre)[241]	- Operating temperature of 315C - Good mechanical strength at high temperatures	- High rigidity that can result in seal failure if used in high vibration applications[242].	Aerospace
Organic Materials			
Graphite[243]	- High chemical resistance - Does not age, shrink or harden - Resists thermal shock - High temperature and pressure resistance	- Oxidises leading to a loss of seal integrity and performance	Chemical industry[244]
Rubber			
Nitrile rubber (NBR)[245]	- Highly resistant to chemicals, such as oils, lubricants, and fuels - High UV resistance - Flexible in low temperatures - High tensile strength	- Effected by small amounts of ozone which reduces compatibility with outdoor exposure over long periods. - Commonly compounded with phthalate type plasticizers, which can migrate out of the rubber compound[246]. - Moderate wear and temperature resistance[247]	Automotive transmission belts; Aircraft, automotive and marine fuel systems; Oil seals; Static and dynamic hydraulic seals
Polyacrylate rubber (ACM)	- Greater heat resistance than NBR - Compatible with higher shaft speeds than NBR	- Poor water compatibility - Lo flexibility in low temperatures - Not compatible with many chemicals (e.g. acids, alkalis, amines,	Sealing automatic transmissions & power steering systems. Sealing petroleum oils up to 300°F.

241 Omniseal Solutions (n.d.) HYCOMP™ COMPOSITES H310® & H320® Materials. Available at: https://www.omniseal-solutions.com/materials/hycomp-composites/hycomp-composites-h310-h320-materials

242 Thomas (n.d.) Comparison of Thermoset Versus Thermoplastic Materials. Available at: https://www.thomasnet.com/articles/plastics-rubber/thermoset-vs-thermoplastics/

243 Triangle Fluid (2019) Benefits of Flexible Graphite. Available at: https://trianglefluid.com/benefits-of-flexible-graphite/

244 Longseal (n.d.) PTFE VS Graphite Packing: What's The Difference? Available at: https://www.nbseals.com/ptfe-vs-graphite-packing/

245 Advanced EMC Technologies (2016) Four Most Popular Rotary Shaft Seals Material Options And How They Compare. Available at: https://advanced-emc.com/four-most-popular-rotary-shaft-seals-material-options-and-how-they-compare/

246 Apple Rubber (2021) What Is Nitrile? A Guide to Nitrile O-Rings and Seals. Available at: https://www.applerubber.com/blog/what-is-nitrile-a-guide-to-nitrile-o-rings-and-seals/

247 Fluorocarbon UK (2019) High Performance Sealing Solutions. Available at: https://fluorocarbon.co.uk/content/files/downloads/flc_highperformancesealingsolutions_web_.2019%20v1.pdf

Material	Properties	Limitations	Applications
		chlorinated hydrocarbons)[248]	
Silicone[249]	- Wide operating temperature range (-60°C to +220°C) - Excellent chemical and weathering resistance - Non-toxic	- Poor tensile strength - Poor abrasion resistance - Poor tear resistance	Medical sector
Ethylene Propylene Diene Monomer (EPDM)[250,251]	- Temperature range of approx. -50°C to +150°C - Excellent water, ozone, and UV resistant properties - Good abrasion resistance - High resistance to range of chemicals	- Lower temperature range than fluoropolymers - Lower tear and abrasion resistance than fluoropolymers - Not suited to petroleum based fuels	Low pressure pipe seals and gaskets
Alloys			
Inconel®	- Maximum operating temperature of 538C to 649C[252] - Can maintain high tensile strength at high operating temperatures - Corrosion resistant - Can withstand extreme pressure - High chemical resistance - Highly resistant to sunlight and ozone degradation	- High modulus which can prevent the seal from conforming to small irregularities on mating metal surfaces which increases leakage rates[253]. - Heavier and noisier than other seal materials.	
Stainless steel; Copper- & nickel-based alloys	- Very high temperature and pressure resistance - Resistance to radiation[254]	- Metal seals require large sealing forces and some equipment cannot generate enough compressive sealing load[255]. - Heavier and noisier than other seal materials.	Applications involving high loads and pressure and very high or low temperatures.

248 Seal & Design Inc (n.d.) Polyacrylate Rubber (ACM). Available at: https://www.sealanddesign.com/products/elastomeric-compounds/polyacrylate-material/

249 Fluorocarbon UK (2019) High Performance Sealing Solutions. Available at: https://fluorocarbon.co.uk/content/files/downloads/flc_highperformancesealingsolutions_web_.2019%20v1.pdf

250 Delta Rubber (n.d.) Black EPDM Rubber DRE-80 Data Sheet. Available at: https://shop.deltarubber.co.uk/media/mageplaza/product_attachments/attachment_file/d/r/dre80_epdm_rubber_sheet_3.pdf

251 Simply Bearings (n.d.) EPDM O-Rings. Available at: https://simplybearings.co.uk/shop/O-Ring-Seals-EPDM-O-Rings/c4501_4707/index.html?page=1&selection=EPDM+Rubber+O-Rings

252 Eaton (2013) Resilient Metallic Seals. Available at: https://www.eaton.com/content/dam/eaton/products/engine-solutions/seals/documents/eaton-resillient-metallic-seals-brochure-tf100-35d-en-us.pdf

253 Curbell Plastics (2022) DuPont Vespel Polyimides – High Performance Polymers for Aerospace Valve Seats and Seals. Available at: https://www.curbellplastics.com/wp-content/uploads/2022/11/DuPont-Vespel-for-Aerospace-Valves.pdf

254 Ceetak (n.d.) Metal Seals. Available at: https://ceetak.com/products/metal-seals

255 Technische Anleitung zur Reinhaltung der Luft – TA Luft, GMBl 2021 Nr. 48-54, S. 1050 (Die Bundesregierung August 18, 2021).

A4 Methodology

This annex provides additional details of the methodology employed for the assessment of business impacts and knock-on economic effects that could potentially result from the implementation of the proposed restriction. Three aspects are explored:

- Baseline estimation
- Knock-on effects to the wider economy
- Annualization of impacts

A4.1 Baseline estimation

This study defined and characterised how different business figures of the EEA sealing device manufacturers and importers, and EEA sealing device downstream users, would likely evolve in the absence of the proposed restriction, drawing from Tool #57, Tool #58, Tool #59, and Tool #60 of the EC's Better Regulation Toolbox[256]. This includes:

- Defining the **'Do nothing' or baseline scenario**, that is, what the EEA sealing device manufacturers and importers, and EEA sealing device downstream users would look like in the absence of the proposed restriction;
- Identifying key economic and sectoral indicators that can be used to characterise the potential evolution of the EEA sealing device manufacturers and importers, and EEA sealing device downstream users; and
- Quantifying how these indicators would likely evolve over a period of 20 years (2020-2040).

First, policy experts from the study team defined what the 'Do nothing' scenario would look like in terms of EEA legislation. In particular, the study team experts confirmed the existing legislation and the legislative changes that are already expected for implementation over the period without the need for the EEA to take any further legal action.

From a business perspective, it was assumed that the existing framework would continue broadly as-is over the period, and past long-term growth trends can be maintained in the future.

Secondly, the team established a set of indicators of focus to characterise the baseline of the EEA sealing device manufacturers and importers, the EEA sealing device downstream users, and the EEA economy, which would become the quantitative baseline against which the policy options would be assessed. Table A 4 below outlines the selected indicators, based on their relevance and the evidence available from Eurostat, the EEA and OECD Statistics.

Table A 4 Sectoral indicators selected for baseline characterisation.

Theme	Indicators
Business volume and growth	• Sectoral output or production value or turnover (€ billions) • Sectoral Gross Value Added (€ billions), approximately capturing the sector's contribution to Gross Domestic Product • Gross investment (€ billions) • Operating expenditure (€ billions) • Research and Development expenditure (€ billions)
Employment	• Number of jobs supported by the sector (Number of jobs)

[256] European Commission, (2021) Tool #57 Methods to assess costs and benefits, Tool #58 EU Standard Cost Model, Tool #59 Cost estimates and the 'one in, one out' approach, and Tool #60 Baselines. Available from: https://ec.europa.eu/info/sites/default/files/br_toolbox_-_nov_2021_-_chapter_8.pdf

Historical evidence and data were collected from multiple, publicly available sources. Table A 5 provides an overview of these sources for each indicator.

Table A 5 List of economic indicators and statistics used in the definition of a baseline and analysis of impacts.

Indicator	Scope	Sources
Turnover	• Geo: EU-27 • Time: 2008-2021 • Other: Sealing device downstream using application product categories	• Eurostat Structural Business Statistics (SBS)
Production value	• Geo: EU-27 • Time: 2008-2021 • Other: Sealing device product categories	• Eurostat Prodcom Database
Gross Value added (GVA)	• Geo: EU-27 • Time: 2008-2020 • Other: Sealing device and downstream using application product categories	• Eurostat Structural Business Statistics (SBS)
Intermediate consumption/ Opex	• Geo: EU-27 • Time: 2008-2020 • Other: Sealing device and downstream using application product categories	• Eurostat Structural Business Statistics (SBS)
Capital expenditure	• Geo: EU-27 • Time: 2008-2020 • Other: Sealing device and downstream using application product categories	• Eurostat Structural Business Statistics (SBS)
Employment	• Geo: EU-27 • Time: 2008-2020 • Other: Sealing device and downstream using application product categories	• Eurostat Structural Business Statistics (SBS) • Eurostat LFSI_EMP_A
GDP	• GDP historic series and baseline projections for EU countries (2020-2040) • GDP deflator historic series and baseline projections for EU countries (2020-2040) • Population historic series and baseline projections for EU countries (2020-2040)	• OECD long-term macroeconomic projections • Eurostat NAMA_10 • Eurostat NAIDA_10

Some data gaps were identified, which rendered the data series incomplete for some of the economic indicators at the EU-27 sealing device sector level. These gaps were addressed by scaling down the variables available in the SBS (available for a wider sector scope) by the weight of the production volume for the sector from Prodcom over the production volume for the wider sector scope in SBS.

For those figures for the EEA Sealing device manufacturers and importers that are at the level of the EU-27 and/or the wider sector scope, their historical compound annual growth rate (CAGR) was calculated, and then applied to the figures declared in consultation by Sealing device producers and importers, which are estimated to represent their whole sector (i.e., Sealing device production and import). The resulting CAGRs were very in line with those reported to be expected in the next 10 years by survey respondents. The projection was done at each individual sector level for sealing device downstream users.

A4.2 Knock-on effects to the wider economy and Input-Output methodology

The indirect and induced effects, and thus, the total impacts on the economy driven by the effects of the proposed restriction on the sealing device manufacturing and importing sector have been estimated using an Input-Output methodology.

First, GVA measures the contribution that the EEA sealing device manufacturing and importing industry makes to the economy. The two methods of measuring GVA used in this analysis are:

- The production approach that estimates the value of the goods and services produced minus the value of inputs into their production (such as raw materials)
- The income approach that determines the incomes earned by businesses and workers in producing these goods and services

Secondly, the total impact of a policy change in the sectoral GVA equals the sum of:

- Direct impact, that is, the immediate effect of a policy change on the sectoral production and, thus, on its value added; and
- Indirect impacts, that is, any impacts on the sector's value chain, which would be reflected in changes to the intermediate demand for inputs to other sectors; and
- Induced impacts, that is, knock-on effects on the broader economy attributed to how the direct and indirect effects may result in changes to the compensation of employees, which would cause further changes in final demand and spending throughout the whole economy.

The direct effects have been estimated by drawing on the survey to sealing device manufacturers and importers and publicly available data.

The Leontief or Input-Output model, and the associated matrices of economic activity and interconnectedness, provides a methodology for estimating the indirect and induced effects, or the knock-on effects on the economy associated with the direct impacts on the sealing device sector, as pertaining to the wider chemicals sector.

This model allows us to estimate the multipliers or factors that represent the how one euro spent in one sector results in economic activity throughout the supply chain and/or other sectors and so on and so forth).

- Type I multipliers capture the direct and indirect effects only (that is, Type I multiplier – 1 would capture the indirect effects or the economic impacts throughout the supply chain).
- Type II multipliers also capture the induced effects, under the implicit assumption that final consumers do not change their final consumption patterns in response to changes in income (that is, Type II – 1 would capture the indirect and induced effects or the impact throughout the supply chain as well as the effects on the wider economy resulting from changes in compensation to employees).

For the production approach, the cumulative Type I and Type II multipliers have been estimated at around 1.9 and 2.2 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

For the income approach, the cumulative Type I and Type II multipliers have been estimated at around 1.3 and 1.8 respectively, based on evidence from Eurostat, national statistical databases from across Europe and expert judgment.

A4.3 Annualization of total impacts and costs

Where required, Equivalent Annual Costs or Impacts were calculated for the selected indicators.

First, the Net Present Value (NPV) of any impact or cost over the period 2024-2042 was estimated by summing the projected cost over the period and discounted at a real discount rate of 3.5% in line with the European Commission's Better Regulation Toolbox #64[257]. The following equation was employed.

Equation 4-1 $NPV = \sum_{t=0}^{n} \frac{C_t}{(1+r)^t}$, where n refers to the time period from 2023-2040, Ct refers to the costs or impacts in time period t, and r refers to the real discount rate.

Secondly, the NPV of the cost or impact was multiplied by an annualization factor, pertaining to the period of policy impact, which is 2024-2042. This factor is given by the following equation.

Equation 4-2 $AF = \mathrm{r}/[1-(1+r)^{-t}]$, where *r* refers to the real discount rate and *n* refers to the number of periods. Note that this formula and approach were adapted to account for the timetable of policy implementation. No impacts are expected before 2025.

[257] European Commission, (2021) *TOOL #64. DISCOUNT FACTORS* Available from: https://ec.europa.eu/info/sites/default/files/br_toolbox_-_nov_2021_-_chapter_8.pdf

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