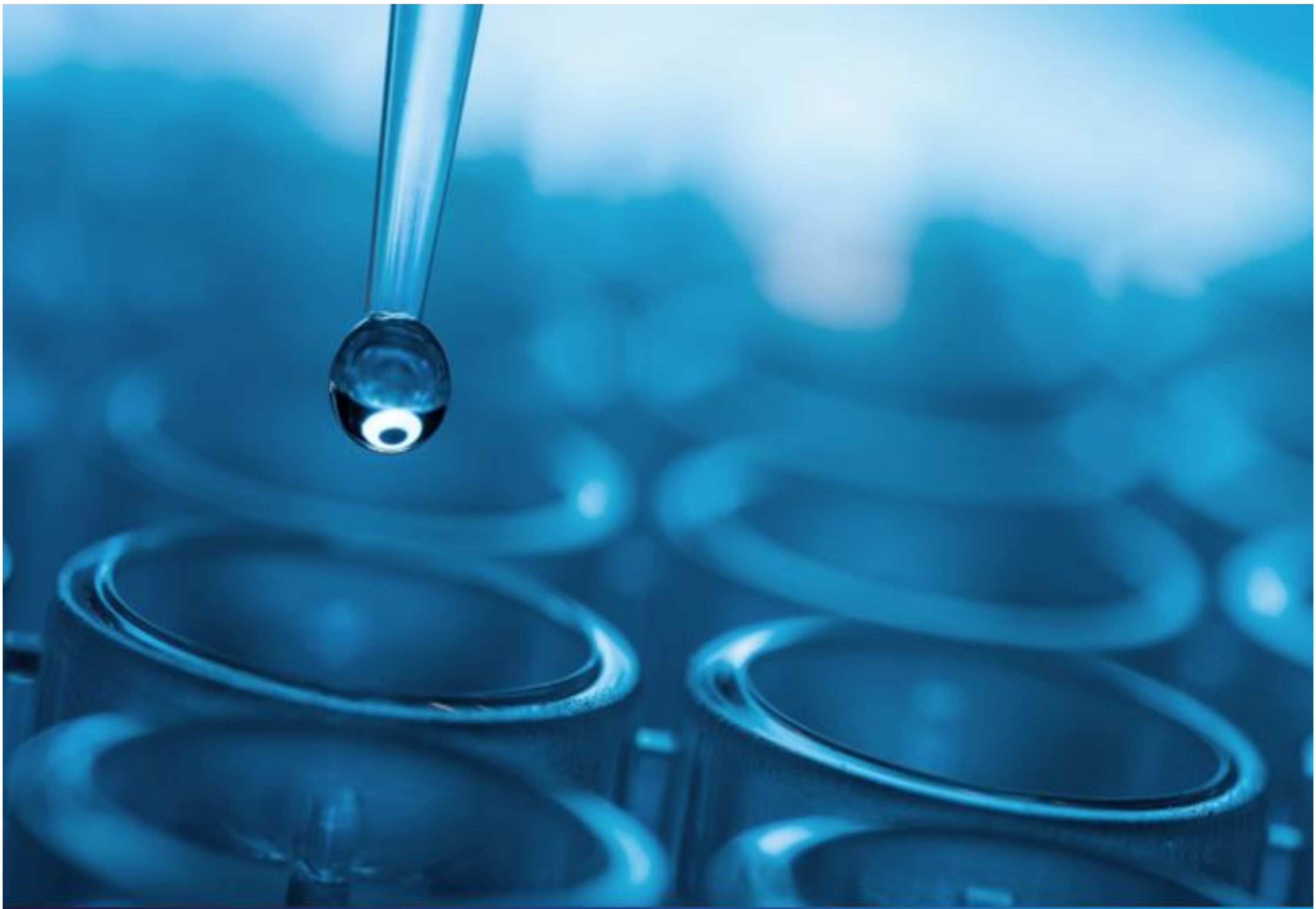

ASSESSMENT OF THE IMPACTS OF A NOMINATION TO THE STOCKHOLM CONVENTION OF OCTAMETHYLCYCLOTETRASILOXANE (D4); DECAMETHYLCYCLOPENTASILOXANE (D5); DODECAMETHYLCYCLOHEXASILOXANE (D6)

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Contact:
Becca Johansen, 21 Prince Street, 1st Floor North, Bristol, BS1 4PH, UK

T: +44 (0) 1235 753 104
E: becca.johansen@ricardo.com

Author:
Becca Johansen, Brais Louro, Marina Diez, Aishwarya Shreya Chakravarty, Francesco Fossati, Alba Arenas-Sánchez, Jodie Denmark, Liam Brown, Emily Bird,

Approved by:
Brais Louro

Signed

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Ricardo is certified to ISO9001, ISO14001, ISO27001 and ISO45001.

EXECUTIVE SUMMARY

Key Conclusions

The outputs of this assessment and comparison of impacts across three policy scenarios for the Stockholm Convention listing of D4, D5 and D6 suggest that:

- Achieving reductions in the emissions and/or the steady-state environmental stock of D4, D5 and D6 could require high abatement costs, many times over the highest values estimated from the recent REACH restrictions, which reflect current 'willingness to pay' of society for the reduction in emissions or the presence of persistent substances in the environment.
- All policy scenarios are likely to have an overall negative balance of economic, social, and environmental impacts and increasingly from PS1 to PS3. In addition, the negative impacts on economic and social dimensions could be significant, including billions of production activity and thousands of jobs lost in the EU when compared against the baseline.
- The overall benefits of the policy scenarios are assessed to be lower, in scale, than the costs, with Benefit: Cost Ratios estimated to be lower than one, and relatively lower for PS2 and more so for PS3.

These conclusions would not support the adoption of any of the policy scenarios considered in this Study and would instead suggest that alternative measures should be explored and defined, which could achieve the zero-pollution objectives of the European Union whilst maintaining coherence with the broader European Green and Digital transition agenda.

The European Chemicals Industry Council (Cefic) commissioned Ricardo to perform an independent "Assessment of the impacts on the EU-27 of a potential nomination to the Stockholm Convention on Persistent Organic Pollutants (The Stockholm Convention) of octamethylcyclotetrasiloxane (D4); decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6)". This assessment focuses on manufacturers and importers of D4, D5 and D6, silicone polymer producers and seven selected Downstream User sectors – aerospace and defence, transport, low-carbon energy, construction, healthcare and pharmaceuticals, electronics, and paper products.

This study is an update to an earlier study, dated May 2024, and is based on additional consultation activities with downstream users, allowing for deep-dive sectorial analysis for the following component groups and sectors: components – sealants, lubricants, adhesives, coatings; sectors – healthcare and pharmaceuticals, electronics, aerospace and defence, paper products.

BACKGROUND

The European Commission Directorate General (DG) for the Environment has expressed an intention to put forward a nomination for these substances for inclusion under Annex B of the Stockholm Convention.

D4 (CAS no. 556-67-2), D5 (CAS no. 541-02-6) and D6 (CAS no. 540-97-6) are three of the most commonly used cyclic volatile methyl siloxanes (cVMS) across the EU-27. The inorganic silicon-oxygen alternating backbone (Si-O-Si), in combination with the methyl groups on each silicon atom, provide the substances with a useful combination of inorganic and organic properties such as dielectric behaviour and hydrophobicity. The notable properties of these substances, which are liquids at room temperature, include high volatility, low viscosity, low water solubility and high thermal stability[1,2].

Once synthesised, D4, D5 and D6 have a number of applications and can be used as a monomer in the production of silicone polymers, which have various uses; directly as substances within mixtures placed on the EU-27 market; or as a reactant and intermediate in the manufacture of products such as semiconductors or glass fibres [3,4,5].

When used directly and for the production of polymers, cyclic volatile siloxanes are present in the final product as intended constituents or impurities. When used in the production of certain components such as semiconductors or glass fibres, the substances are not expected to be present in the final product.

THE PROBLEM

Two interlinked problems have been identified following review of the relevant literature from the European Commission. In summary, these are:

1. The existing REACH restriction (Entry 71) and the REACH Annex XV restriction report on the use of D4, D5 and D6, focused mainly on leave on cosmetics, is estimated to result in a reduction of approximately 90% of the direct emissions to the environment in the EU. However, as this regulatory action is only enforceable in the EU (+ EEA countries where relevant), the emissions of D4, D5 and D6 from such uses outside of the EU shall continue. It should be noted that the proposed restriction deliberately excludes certain key uses, such as industrial uses for the production of silicone polymers or production of articles and the formulation of mixtures, meaning that around 10% of emissions are expected to remain[6], whereas the Stockholm Convention policy scenarios considered in this Study, increase the scope to include the use of silicone polymers.
2. Despite that emissions are expected to be significantly reduced in the EU, the evidence provided by the Commission suggests that their high persistence in sediment, bioaccumulation potential in some parts of the food chain, and potential toxicity to sediment and soil organisms could potentially lead to significant adverse environmental effects such that global action is warranted, based on the precautionary principle.

THE OBJECTIVES OF THE INITIATIVE

The general objective of DG Environment to utilise the Stockholm Convention as a mechanism for regulation of D4, D5 and D6 is to globalise the existing and draft REACH restrictions to **ensure a high level of protection to the global environment, whilst mitigating trade and competition distortions that could result in a competitive disadvantage for the EU**, without affecting silicone polymer uses which have key functions in many applications that enable the European Green Deal. In addition, three specific objectives of the initiative include to:

- Limit the potential for transboundary exposure to D4, D5 and/or D6 from non-EU cosmetic and other consumer sources,

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[1] Navea et al., (2011) The atmospheric lifetimes and concentrations of cyclic methylsiloxanes octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) and the influence of heterogeneous uptake. Atmos. Environ., 45 (2011), pp. 3181-3191. DOI: 10.1016/j.atmosenv.2011.02.038

[2] Piechota G (2021) Siloxanes in Biogas: Approaches of Sampling Procedure and GC-MS Method Determination, Molecules, 26, 1953. http://dx.doi.org/10.3390/molecules26071953

[3] European Commission (2023). EU proposal to list D4, D5 and D6 to the Stockholm Convention on POPs. [online] Available at: https://echa.europa.eu/documents/10162/63ce2062-0f0b-130f-3cb1-5c84071e7082.

[4] European Chemicals Agency (2020) Background Document to the Opinion on the Annex XV dossier proposing restrictions on D4; D5 and D6, available from: https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978

[5] Silicones Europe (no date) Silicone Production. Available from: https://www.silicones.eu/science/production/chemistry-mix-formulation/

[6] ECHA (2020) Background Document to the Opinion on the Annex XV dossier proposing restrictions on D4; D5 and D6. Available: https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978

- Avoid (or mitigate) international trade and competition distortions, which would otherwise negatively affect the EU's industry, and
- Contribute to the transition towards the use of safer chemicals, improved resource efficiency and the circular economy.

Action on a global basis via the Stockholm Convention may limit the potential for trans-boundary exposure to D4, D5 and D6 from non-EU sources. However, it should be acknowledged that this would require all Parties to the Stockholm Convention to ratify the restrictions and exemptions to maintain a level-playing field internationally.

THE BASELINE AND PROPOSED POLICY SCENARIOS

Although the EU's draft nomination suggests a proposal to list the siloxanes in Annex B, there is no guarantee that this will be agreed. Nominating parties do not have inherent legal authority to dictate the final deposition of a nomination and conditional nominations cannot be made, such that the Annex or end control measures they deem appropriate cannot be specified. Instead, the nomination of D4, D5 and D6 to the Stockholm Convention triggers a multilateral procedure that would determine both the placement of the listing and the content of the associated control measures.

It should also be noted that although policy scenario 1 appears to be a globalisation of the current REACH restriction, it is more restrictive in reality, due to the additional conditions that are set on manufacturing, use and waste practices under the Stockholm Convention.

The Table below presents the baseline and three policy scenarios that have been assessed in this Study. These policy scenarios were derived by Cefic and their members based on indications of considerations by the Commission, as well as previous examples of nominations to the Stockholm Convention, chosen to illustrate the impact if policy scenario 1 could not be achieved. The scenarios assume that the Parties to the Stockholm Convention agree on a listing (policy scenarios 1, 2 or 3), and the subsequent implementation of such a listing in the EU via the Regulation on Persistent Organic Pollutants - EU/2019/1021[7] (POPs Regulation).

[7] Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (POPs Regulation). Available: Legislation - ECHA (europa.eu)

Table 0-1 Policy Scenarios for assessment

<table>
<tr><th>Policy scenario (PS)</th><th>Description</th><th>Assumed EU implementation conditions (POPs Regulation)</th></tr>
<tr><td>Baseline[8]</td><td>Current REACH restriction of D4, D5 and D6 in professional and consumer products (Annex XVII entry 70)[9]</td><td>N/A</td></tr>
<tr><td>PS1</td><td>Stockholm Convention Annex B listing with broad exemption
Exemptions granted for
• production of silicone polymers with the use of D4, D5 and D6 as intermediates;
• transport of D4, D5 and D6 for the sole purpose of the production of silicone polymers, with a threshold for D4, D5 and D6 of ≤0.1% w/w each for the placing on the market of polymers and formulations of polymers.</td><td rowspan="2">This would have the following EU implementation conditions:
- the transportation of D4, D5 and D6 only allowed for exempted uses i.e., to produce silicone polymers and polymer mixtures and the components containing them;
- the manufacturing process for D4, D5, D6, silicone polymers and mixtures containing them are required to take place under strictly controlled conditions;
- all silicone polymers, mixtures, and the components containing them placed on the relevant markets (including for industrial uses) must contain residues below 0.1% of D4, D5 and D6;
- the recycling of materials containing and derived from D4, D5 and D6 is prohibited;
- polymers, mixtures and the components containing them cannot be exported, to any non-Party to Stockholm Convention;
- the import and export from or to Parties to the Convention would be permitted for exempted purposes only if the receiving or sending country has implemented the specific exemption into National law; and
- the Stockholm Convention overrules any derogation provided in EU Legislation, unless these derogations are stricter in existing EU legislation.
- Exemptions only applicable to acceptable purposes listed under each PS.</td></tr>
<tr><td>PS2</td><td>Stockholm Convention Annex B listing with a limited number of acceptable purpose exemptions under a Stockholm Convention Annex B listing.
Exemptions for:
• acceptable purpose granted for the manufacture of D4, D5 and D6;
• transportation of D4, D5 and D6 only allowed for exempted uses;
• use as intermediate for the production of polymers used in specific applications.
The acceptable purpose exemptions include for use as an intermediate in the production of silicone polymers, with impurities ≤0.1% w/w, used in the following applications:
• as a silicone encapsulant in solar panels used in space satellites ;
• as an encapsulant in LED lighting;
• as a liquid silicone rubber to manufacture seals for aircraft windows;</td></tr>
</table>

[8] For the environment, emissions reductions from baseline regulatory interventions have been estimated. For the economic and social baseline, historical trends have been reviewed to determine the levels of economic activity and employment up to 2040.

[9] European Commission (2018) Commission Regulation (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5'). Available: Regulation - 2018/35 - EN - EUR-Lex (europa.eu)

Policy scenario (PS)	Description	Assumed EU implementation conditions (POPs Regulation)
	• as a liquid silicone rubber to manufacture medical tubing; • as a surfactant or stabiliser in polyurethane foams used in construction insulation; • as a sealant used to bond glass to steel in building facades; and • use of D4 in the manufacture of semi-conductor wafers.	
PS3	**Stockholm** Convention **Annex A listing** Prohibition on the manufacture and use of D4, D5 and D6.	This policy scenario would require the prohibition on the manufacture, import, export, placing on the market, use and transportation of D4, D5 and D6 in the EU-27. This prohibition also encompasses polymers, mixtures and articles that contain D4, D5 and/or D6. Transport of these substances, mixtures or articles is only permitted for waste disposal and recycling is not allowed.

THE IMPACT ASSESSMENT METHODOLOGY

The European Commission's Better Regulation Guidelines and Toolbox[10] defines *ex-ante* impact assessment as the process of "gathering and analysing evidence to support policymaking", that is, providing evidence that could inform policy decisions at the EU level ahead of implementing a policy action.

The methodology for this study has followed the European Commission's Better Regulation Guidelines where possible, noting that as this assessment has been carried out for the private sector some methodologies have been adapted for purpose[11]. The overarching methodology can be summarised in the following:

- **Define and characterise the baseline scenario,** against which the impacts of the policy scenarios will be assessed.
- **Identify and screen potential economic, social, and environmental impacts of the policy scenarios**, leading to a shortlist of the most significant impact categories for in-depth assessment as part of this Study.
- **Consult stakeholders and gather evidence of the baseline and potential impacts.** This comprised a literature review, and an online survey and follow-up interviews of manufacturers and importers of D4, D5 and D6 and silicone polymers, and 'downstream users' across selected sectors.
- **Assess the economic, social and environmental impacts of the policy scenarios,** quantitatively over the period 2023-2040 where possible (some economic and social impacts) and qualitatively otherwise (environmental impacts), using a scoring or rating Multi-Criteria Analysis (MCA) method.
- **Comparison of the policy scenarios.** The emission abatement costs, or 'cost-effectiveness' of the policy scenarios were estimated and compared against the equivalent for recent REACH restrictions. In addition, the quality scoring MCA method was employed to compare the direction (positive or negative) and magnitude (weak to strong, limited or unclear) of the impacts.

The following scoring and colour-coding was used to present the qualitative ratings:

Table 0-2 Coding used to present estimated impacts

Strongly negative	Negative	Weakly negative	No or limited impact	Weakly positive	Positive	Strongly positive	Unclear
-5	-3	-1	0	+1	+3	+5	N/A

Please note that uncertainties in the available evidence have been considered in depth, and the analysis presents likely medium estimates, as well as possible but unlikely lower and upper bounds, which are considered as part of the sensitivity analysis within this study.

[10] European Commission (2021) Better Regulation Guidelines and Toolbox. Available: Better regulation: guidelines and toolbox (europa.eu)

[11] For example, all processes prior to conducting the Impact Assessment have not been carried out as they are solely the responsibility of the Commission and so not relevant to this study, no open public consultation has been carried out and data has come from targeted consultation only.

THE ASSESSMENT OF IMPACTS, COSTS AND BENEFITS OF THE POLICY SCENARIOS

Economic impacts

The policy scenarios under consideration could affect large proportions of the remaining D4, D5, D6 and silicone polymer markets in the EU-27. All (100%) manufacturing and importing activity pertaining to the D4, D5, D6 and silicone polymer markets could be potentially affected, although there are different levels of exemptions built into some of the policy scenarios. Based on the evidence collected, the estimated percentage of sales that could be exempted or otherwise potentially affected under each policy scenario are summarised in the Table below.

Table 0-3 Percentage of sales turnover of the D4, D5, D6 and silicone polymer industries in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the sales turnover of D4, D5, D6 and silicone polymers industries which could be **potentially exempted**	80% (65%-95%)	15% (5%-25%)	0%
Percentage of the sales turnover of D4, D5, D6 and silicone polymers industries which could be **potentially affected**	**20% (5%-35%)**	**85% (75%-95%)**	**100%**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=26).

D4, D5, D6 and silicone polymers play critical roles in a range of 'downstream user' sectors, such as transport, construction, aerospace and defence, electronics, and healthcare. Significant parts of this sectoral activity in the EU-27 rely, in some way, on these substances and materials within their manufacturing processes and/or as critical components to intermediate and final products (such as cars, motors, airplanes, semi-conductors, medical devices, etc), with their substitution proving difficult due to their key functionalities. Based on the evidence collected through a consultation of private firms, it is estimated that around 75% (60-99%)[12] of the sales value of these 'downstream user' industries might rely, in some way, on D4, D5, D6 and silicone polymers.

The applications which might be affected across the policy scenarios varies. Stakeholders were also asked about the extent to which they believed the products they manufactured and/or sold in the EU-27 would be covered by the exemptions specified under each of the policy scenarios. The activity that relies on D4, D5, D6 and silicone polymers that is not exempted would, therefore, be potentially affected by the policy scenarios. These estimates are presented in the Table below.

Table 0-4 Percentage of sales turnover of the selected 'downstream user' industries in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of 'downstream user' **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers**…('reliant sales') –(1)		75% (60%-99%)	
Of these 'reliant' sales, the percentage that could be **potentially exempted** –(2)	70% (20%-99%)	40% (10%-80%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** –(3)	30% (1%-80%)	60% (20%-90%)	100%

[12] Please note that whilst there are variations across the survey respondent and sector; the central estimate of this indicator appears reasonable, given that submissions representing more than 70% of the turnover of all respondents reported that more than 75% of their portfolio might rely in some way on D4, D5, D6 and silicone polymers.

Indicator	PS1	PS2	PS3
Or, equivalently, the **proportion of all 'downstream user' sales that could be potentially affected** –(4)[13]	**20% (1%-80%)**	**45% (15%-95%)**	**75% (25%-100%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N>50[14]).

This means that 20% (1-80%) of all 'downstream user' sales in the EU-27 in scope of this study could be potentially affected under PS1; 45% (15-95%) under PS2 and 75% (25-100%) under PS3. The 'medium' estimates provide a possible and likely central estimate of the portfolio of 'downstream user' products that could be affected under each policy scenario, whereas the lower and upper bound estimates correspond to possible but unlikely estimates of the impact on the 'downstream' product portfolio and associated sales (based on the distribution of responses to the stakeholder consultation). That is, the available evidence suggests that there is a higher probability that the affected portfolio of 'downstream' products will be closer to the medium estimate than to the low or high estimates. Annexes 2 and 4 provide further details.

Deep dive analysis performed for the component product groups - sealants, lubricants, adhesives, and coatings, and the downstream user sectors – healthcare and pharmaceuticals, electronics, aerospace and defence, and paper products indicates that there are variations in reliance on silicone polymers, level of exemptions across PS1 and PS2, and overall affected portfolio. These variations, as presented using the central estimates, are displayed in Table 0-5.

Table 0-5 Sectoral deep dive central estimates for reliance on silicone polymers, exemptions and affected portfolio

Sector	Reliance on silicone polymers	Exemptions		Affected portfolio	
		PS1	PS2	PS1	PS2
Downstream user average	**75%**	**70%**	**40%**	**20%**	**45%**
Healthcare and pharmaceuticals	70%	90%	70%	10%	20%
Sealants	55%	90%	80%	5%	10%
Lubricants	25%	25%	15%	20%	20%
Adhesives	45%	98%	50%	1%	20%
Coatings	55%	85%	35%	10%	35%
Electronics	80%	80%	25%	15%	60%
Aerospace and defence	80%	50%	50%	40%	40%
Paper products	80%	80%	75%	15%	20%

Lower than average	Similar to average	Higher than average

Companies manufacturing, importing, distributing and/or using D4, D5, D6 and/or silicone polymers will respond by adjusting their products and/or operations in the EU-27, if these are technically and economically viable, or withdraw from the EU-27 market.

The evidence, however, suggests that viable adjustments, alternatives and substitutes exist, especially under PS1 and, to a much lower extent, under more restrictive scenarios PS2 and PS3,

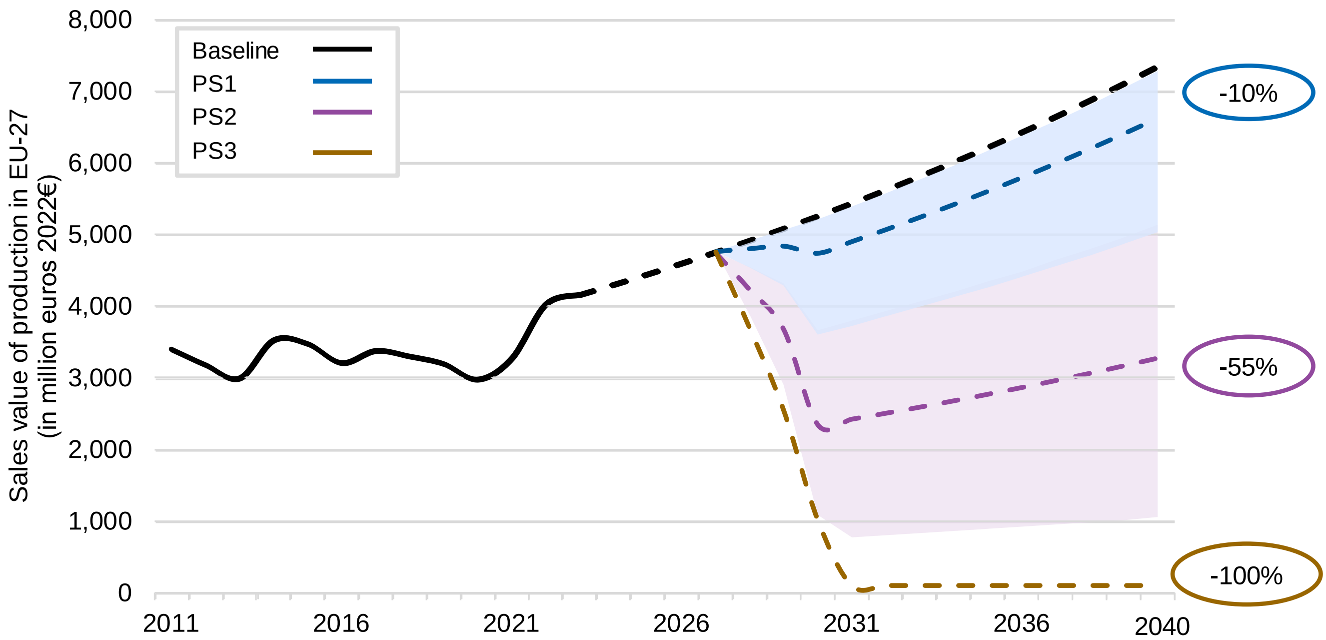
[13] Please note that these estimates (4) = (1) × (3). (1), (2), and (3) are estimates directly sourced from the analysis of the evidence submitted by the participants of the online survey.

[14] Please note that N > X than means that the sample observations are at least equal to X, however, there might be more observations for certain questions or sub-questions of relevance or under consideration as part of the outputs or analysis that is described.

albeit this is uncertain. However, the scale of these viable adjustments, alternatives and substitutes also remains uncertain.

The analysis of the evidence collected as part of the consultation concluded that businesses manufacturing D4, D5, D6 and silicone polymers in the EU-27 could transform part of their production under PS1 and PS2 (e.g., adjusting their manufacturing towards alternatives, removal technologies, etc), whilst such production activities would be technically and financially unviable under PS3. This transformation would be insufficient to mitigate the negative effects on the size of the EU-27 manufacturing industry, which have been estimated and are presented in the Figure below.

Figure 1 Sales value of the production of D4, D5, D6 and silicone polymers in the EU-27 across the baseline and Policy Scenarios (€ million)

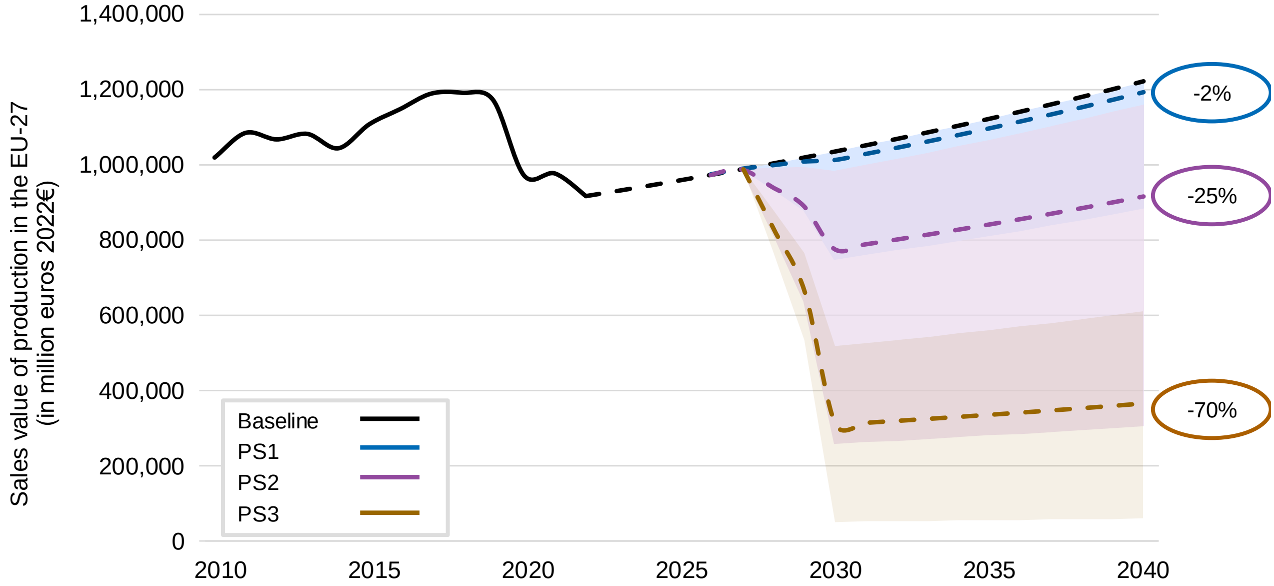


Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Even more substitution and transformative actions would be required across 'downstream' user sectors to continue to manufacture and place products on the EU-27 market. The evidence collected and analysis presented earlier was used to estimate the potential effects on the size of EU-27 operations across the 'downstream user' sectors in scope in comparison to the baseline. This is highlighted in the Figure below.

Figure 2 Sales value of the production of selected 'downstream user' sectors in the EU-27 across the baseline and Policy Scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

The downstream user deep dive analysis also identified variations in substitution potential across the sectors, although around 60% of the sectors investigated showed similar levels of substitution potential to the downstream user total average. Variations have also been identified in the sales value impact against the baseline across sectors, with sectors more closely aligned with the total downstream user average in PS1, and showing lower than total average downstream user sales value impacts in PS2 and PS3. Table 0-6 provides an overview of the central estimates from the sectoral deep dives.

Table 0-6 Sectoral deep dive central estimates for substitution potential and sales value impact against the baseline

Sector	Substitution potential			Sales value impact (% against the baseline)		
	PS1	PS2	PS3	PS1	PS2	PS3
Downstream user average	**90%**	**50%**	**10%**	**-2%**	**-25%**	**-70%**
Healthcare and pharmaceuticals	75%	40%	5%	-2%	-15%	-65%
Sealants	75%	40%	5%	-1%	-5%	-50%
Lubricants	90%	50%	10%	-2%	-10%	-25%
Adhesives	90%	50%	10%	0.1%	-15%	-40%
Coatings	90%	50%	10%	-1%	-20%	-50%
Electronics	90%	50%	10%	-2%	-30%	-70%
Aerospace and defence	75%	40%	5%	-10%	-25%	-75%
Paper products	90%	50%	10%	-2%	-10%	-70%

Thus, overall, the EU's economy could be negatively affected by the policy scenarios, with a reduction in the D4, D5, D6, silicone polymer and downstream user industries' production activity and contribution to the EU's GDP against the baseline. The EU industry's direct Gross Value Added (GVA) contribution could be lower by an estimated €4 billion/year, €40 billion/year or €130 billion/year under PS1, PS2 or PS3 respectively from 2023-2040. The total (direct, indirect and induced) GVA contribution could be lower by an estimated €8 billion/year, €60 billion/year or €240 billion/year under PS1, PS2 or PS3 respectively from 2023-2040.

This transformation could have positive effects on innovation, even if the scale of these benefits is smaller than the scale of the overall and negative economic effects of each of the policy scenarios. In fact, the estimated, overall negative impacts on the EU economy already take into account the mitigating effects achieved through research and development efforts to replace baseline products and manufacturing processes with alternatives that comply with the policy scenarios.

However, such a transformation would also result in notably higher costs of doing business in the EU, especially relative to third countries also party to the Stockholm Convention, which could further deteriorate the EU industry's global competitiveness position. These costs would include increased capital and operational expenditure requirements to adjust products, manufacturing plants/processes, acquire new and/or expand capacity of existing technological assets (e.g., removal technologies/processes, etc.) to achieve lower siloxane levels where appropriate and technically viable. These actions would also result in higher energy consumption, which coupled with relatively higher unit costs of energy in the EU-27 when compared to other key silicone producing countries, such as China, could result in even higher, relative costs of production.

As a result of this, The EU could further lose its share of the global silicone market, and its import dependency for key raw materials and technologies could continue to grow, faster than in the baseline. Respondents have also suggested that their EU activities may be relocated to e.g., China. If trading partners conform with the Stockholm Convention trade could continue with the EU, increasing the EU's reliance on imports.

Thus, under policy scenarios 1 and 2 especially, imports of silicone polymers manufactured more cost-effectively abroad to meet the requirements under the policy scenarios would, on the one hand, allow European 'downstream' manufacturers and/or consumers to retain access to raw materials, intermediate and/or final products of similar or equivalent quality and performance at lower prices. On the other hand, **critical European supply chains could face greater exposure to additional and/or potentially more severe risks, such as for example, healthcare and defence, or transport and low-carbon energy which play essential roles in the EU's green and digital transition. This reliance on import could weaken the EU strategic autonomy.**

These estimated impacts do not account for the role that silicone polymers could play as substitutes for certain fluoropolymers and other PFAS, which have been ubiquitous in consumer applications and might be increasingly restricted under REACH. **The availability of silicone polymers could thus offer a means to mitigate the potential economic and social implications of any further restriction of fluoropolymers and/or other PFAS, highlighting the relevance that silicone polymers could gain in the baseline scenario.** Thus, any negative effects on the availability of silicone polymers could have compounding negative implications in the context of other REACH restrictions under consideration.

More broadly, it is possible that designation of siloxanes as a global POP could indirectly trigger more expansive controls that could damage the global silicones market overall[15]. These controls could arise under list-based secondary standards, such as those used by various retailers and eco-labels, which are automatically triggered by a POPs listing decision. Moreover, many of these

[15] Beveridge & Diamond (2023) Potential Consequences of Siloxane Nominations to Stockholm Convention.

automatic consequences do not differentiate based on the exemptions or nuances in listing decisions (e.g., being listed in different Annexes especially A vs B, or D4, D5 and D6 being listed but polymer uses allowed). They lie outside of the Convention's control, and there is no legal mechanism by which the Stockholm Convention listing could mitigate these impacts.

The overall economic impact conclusions are summarised qualitatively in the Table below across three broad categories.

Table 0-7 Qualitative, economic impact ratings

Broad category	PS1	PS2	PS3
Conduct of businesses and administrative burden, functioning of the internal market, sustainable production, and position of SMEs	-2.0	-3.0	-5.0
Innovation and research	+1.0	+1.5	+1.0
Sectoral competitiveness, trade and investment flows and third countries	-1.0	-1.5	-2.0

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this assessment, it is concluded that all policy scenarios could have an increasingly negative, overall economic impact on the EU. The ratings have been reviewed and recalibrated against the -5/+5 scoring framework, for a comparison of the balance of impacts across impact categories, costs and benefits. The Table below presents the qualitative ratings given to the overall economic impacts of each of the Policy Scenario for these comparisons. The methodological Annexes explain the recalibration exercise.

Table 0-8 Overall economic impact ratings

Broad category	PS1	PS2	PS3
Overall economic impacts	-0.5	-1.0	-2.0

Source: Ricardo analysis based on the evidence presented in this Study.

Social Impacts

Secondly, the most significant impacts on the EU society would likely be negative, including a potential loss of hundreds of thousands of quality job opportunities when compared to the baseline – around 80,000 job losses under PS1, 890,000 job losses under PS2 and around 2,460,000 job losses under PS3 annually (including direct, indirect and induced effects). These estimates and uncertainties are summarised in the Table below.

Table 0-9 Annual average impacts on employment supported, in FTE, by the D4, D5, D6, silicone polymer and 'downstream user' industries from 2023-2040 (medium (low-high))

Indicators	PS1	PS2	PS3
Total (direct, indirect and induced) impacts on the **employment supported** by the industries in scope, against the baseline (FTE) / year	- 80,000 FTE (-970,000 – - 900)	- 890,000 FTE (-2,640,000 – -180,000)	- 2,460,000 FTE (-3,330,000 – -1,770,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

The medium estimates provide a possible and likely central estimate of the potential employment losses that could result under each policy scenario, whereas the lower and upper bound estimates correspond to possible but unlikely estimates of the potential impacts on employment (based on the distribution of responses to the stakeholder consultation). That is, the available evidence suggests that there is a higher probability that the potential employment losses will be closer to the medium estimates than to the lower or upper bounds. This is explained in more detail in Annex 2.

Responses to the consultation indicated that there may be negative social impacts linked to the availability, quality and performance, and cost of final products for consumers and households, which may affect their daily lives e.g. having to replace products more frequently.

In addition, regulatory actions and initiatives aimed at achieving the EU Green Deal objectives, such as the Net Zero Industry Act, the zero-pollution ambition, and the EU digital transition may result in an increase in demand for siloxanes and silicone polymers in the baseline. Should these substances not be available due to a Stockholm Convention listing, key technologies which facilitate the EU Green Deal would be significantly impacted through the loss of key intermediates in the manufacturing processes and key components. This includes, but is not limited to[16],

- Solar technologies, including solar photovoltaic, solar thermal electric and solar thermal technologies;
- onshore wind and offshore renewable technologies;
- battery and energy storage technologies;
- heat pumps and geothermal energy technologies;
- hydrogen technologies, including electrolysers and fuel cells;
- electricity grid technologies, including electric charging technologies for transportation and technologies to digitalise the grid;
- nuclear fission energy technologies, including nuclear fuel cycle technologies;
- renewable energy technologies, not covered under the previous categories;
- energy system-related energy efficiency technologies, including heat grid technologies;
- transformative industrial technologies for decarbonisation not covered under the previous categories;
- CO2 transport and utilization technologies;
- wind propulsion and electric propulsion technologies for transportation;
- nuclear technologies not covered under previous categories.

Each of the policy scenarios could also hinder the EU's digital transition through a range of technical complexities, but especially through potentially negative impacts on the EU manufacturing and/or importing of optical fibres and semiconductors significantly affecting key policy goals under the European Green Deal.

The social impact conclusions are summarised qualitatively in the Table below.

Table 0-10 Qualitative, social impact ratings

Broad category	PS1	PS2	PS3
Employment	-0.5	-1.5	-2.5
Consumers and households	-0.5	-0.5	-0.5
Technological development and the digital economy	-1.0	-2.0	-3.0

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this assessment, it is concluded that the policy scenarios could have increasingly negative overall social impact on the EU from PS1 to PS3. The ratings have been reviewed and recalibrated against the -5/+5 scoring framework, for a comparison of the balance of impacts across impact categories, costs and benefits. The Table below presents the qualitative ratings given to the

[16] Council of the European Union (2024) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act)

overall social impacts of each of the policy scenarios. The methodological Annexes explain the recalibration exercise.

Table 0-11 Overall social impact ratings

Broad category	PS1	PS2	PS3
Overall social impacts	-0.5	-1.0	-2.0

Source: Ricardo analysis based on the evidence presented in this Study.

Environmental impacts

Thirdly, it is most likely that neutral or potentially even net negative impacts on the environment could result from the adoption of any of the policy scenarios.

On the one hand, a reduction in emissions of D4, D5 and D6 could have environmental benefits on the quality of natural resources and biodiversity; however, there are conflicting evidence bases on the environmental fate and behaviour and toxicity of D4, D5 and D6. The evidence presented by the European Commission, based on ECHA's assessment, and existing peer-reviewed and grey literature suggests that there may be cause for concern with regard to the persistence, toxicity, bioaccumulation and long-range transport potential of D4, D5 and D6. However, additional evidence coming from the literature review performed for this Study, including peer-reviewed studies and data from standardised laboratory GLP studies extracted from ECHA's Registration dossiers or the actual study report when accessible (unpublished), suggests that the **toxicity risk of D4, D5 and D6 might be negligible due to laboratory conditions not being reflective of real-world environmental conditions**. Moreover, this additional evidence also suggests that the bioaccumulation potential of these substances appears to be unlikely due to the biological capacity of organisms to rapidly excrete and metabolise them. Finally, a body of evidence identified in the literature review questions the environmental fate and behaviour properties put forward by the European Commission June 2023 draft Annex D report. A scoring methodology was developed to assess the reliability and relevance of all of the sources of evidence / references considered, which resulted in >90% of the references being reliable and relevant to be used (see Annex 1). Given conflicting evidence bases, **two parallel assessments were carried out leading to two sets of qualitative ratings, Option A (Commission evidence presented in the draft Annex D report) and Option B (broader scientific evidence), for impact categories '*quality of natural resources'* and '*biodiversity*'.**

On the other hand, the evidence available suggests that there would likely be negative impacts on *'waste production, generation and recycling'* and *'resources, transport, energy and climate'*. Recycling could be negatively affected under all policy scenarios, given the presence of D4, D5, D6 as an impurity in waste products and may prevent innovation in chemical recycling of products containing impurities of D4, D5 and D6. The incineration of siloxanes and silicone polymers would continue, which could also have negative impacts on the environment. In addition, available evidence suggests that there could be a negative impact on resources, transport, energy and GHG emissions under the policy scenarios (increasing from PS1 to PS3) as a result of the baseline replacement with alternatives to silicones products that are lower performing and more energy intensive, leading to higher energy consumption and more GHG emissions, all other things held equal.[17]

The environmental impact conclusions are summarised qualitatively in the Table below.

[17] Denkstatt (2022) The role of silicones for the EU Green Deal. Available: CES-GD-Report_Vers.-2.6_denkstatt-20221024-final-version-1.pdf (silicones.eu)

Table 0-12 Qualitative, environmental impact ratings

Broad category	PS1	PS2	PS3
Quality of natural resources (water, soil, air)			
Option A (European Commission evidence)	+0.5	+1.0	+1.5
Option B (broader scientific evidence)	0	0	0
Biodiversity			
Option A (European Commission evidence)	+0.5	+0.5	+1.0
Option B (broader scientific evidence)	0	0	0
Waste production, generation and recycling	-0.5	-0.5	-0.5
Resources, transport, energy and climate	-1.0	-2.0	-3.0

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this assessment, it is concluded that all policy scenarios could have either neutral or negative, overall environmental impacts on the EU (Option A (European Commission evidence) and Option B (broader scientific evidence) respectively. The ratings have been reviewed and recalibrated against the -5/+5 scoring framework, for a comparison of the balance of impacts across impact categories, costs and benefits. The Table below presents the qualitative ratings given to the overall social impacts of each of the policy scenarios. The methodological Annexes explain the recalibration exercise.

Table 0-13 Qualitative, environmental impact ratings

Broad category		PS1	PS2	PS3
Overall environmental impacts, for Option A and Option B respectively	Option A (European Commission evidence)	0	0	-0.5
	Option B (broader scientific evidence)	-0.5	-0.5	-1.0

Source: Ricardo analysis based on the evidence presented in this Study.

LIMITATIONS AND UNCERTAINTIES

As is inherent with all *ex-ante* assessments, there are uncertainties and limitations to the impact analysis. In the case of this assessment, these are linked to the uncertainty of the policy proposal, the availability of quality data, and the relatively high level of complexity for how these policy scenarios may affect the EU's D4, D5, D6 and silicone polymer industries, the 'downstream user' sectors, wider society, and the environment. These are summarised in the Table below.

Table 0-14 Limitations and uncertainties in the assessment

Limitation/ uncertainty	Implications
Uncertainty in Policy Scenarios. The nomination to the Stockholm Convention has not been made and the final initiative remains uncertain and under development. The proposals for implementation through the EU POP Regulation have not been clarified.	Policy details are not yet clear, and assumptions have been required. These may not accurately reflect the regulatory changes that will ultimately enter into force.

<table>
<tr><th>Limitation/ uncertainty</th><th>Implications</th></tr>
<tr><td>Data available is in some cases limited. Limited historical evidence, literature, and sample of business participants in the stakeholder consultation.</td><td>There is conflicting evidence on the potential environmental impacts. Economic and social impacts heavily rely on the outputs of the business consultation. The sample has limitations, especially for the 'downstream user' sectors, which might include over-representation of relatively more affected companies. However, this is to some extent mitigated by our uncertainty analysis.</td></tr>
<tr><td>Complexity in the business response to Stockholm Convention listing and implications ('Impact pathway'). The business response to the policy scenarios is uncertain and partly depends on unknown, future innovation outcomes.</td><td rowspan="2">An informed simplification of the impact pathway, based on the project team expertise, was introduced, with inherent limitations. Emission reductions and steady-state environmental stock have been derived based on data reported in the Restriction dossier and supporting documents. All evidence identified has been considered and ranges presented.
Sensitivity analysis was also undertaken based on the lower and upper bounds of the core impacts, to explore the extent to which MCA conclusions might be affected.</td></tr>
<tr><td>Scientific discourse surrounding the environmental fate and behaviour of D4, D5 and D6 means that it is very difficult to estimate the true environmental costs and benefits.</td></tr>
<tr><td>There are known unknowns. For example, how technological progress may affect the EU chemicals sector and wider society and whether and how this would interact with the impacts of legislation.</td><td>Each of the sectors considered in this study are undergoing technological progress and the speed at which this may change the economic and social landscape is unknown. This means that the market may be unrecognisable within the assessment period, which cannot be accounted for within the analysis.</td></tr>
</table>

It is considered that the assumptions developed in this Study offer a workable and reasonable approach to assessing impacts of the policy scenarios considered, albeit with limitations. In addition, a broad range of uncertainties have been quantified and the sensitivities of conclusions to these uncertainties have been tested.

THE COMPARISON OF THE POLICY SCENARIOS

Finally, the outputs of this impact assessment were brought together into comparable ratings across the broad economic, social, and environmental impact categories and overall costs and benefits for the three policy scenarios for analysis. But, first, an estimation of the cost-effectiveness of each Scenario was developed to produce additional insights.

The costs of abating chemical emissions across each of the policy scenarios were estimated using a cost-effectiveness indicator, using a methodology developed by the ECHA and the Committee for Socio-Economic Analysis. In particular, estimates were developed for the two 'emissions' indicators: Option 1) the environmental emissions or releases of D4, D5, and D6 that could be reduced across each scenario; and Option 2) the reduction in the emissions of D4, D5 and D6 that could remain in the environment in the steady state. ECHA's guidance suggests that Option 2 would be more appropriate considering that only a small proportion of all D4, D5, and D6 releases will persist or remain in the environment in steady state. However, previous estimates did not consider this and thus there is limited evidence using comparable cost-effectiveness indicators.

Thus, the table below presents the output of this analysis, which highlights that annualised reductions in emissions could cost the EU around 25,000 €/kg or 960,000 €/kg when considering the reductions in emissions that remain in the environment.

Table 0-15 Cost-effectiveness of the Stockholm Convention listings

Substance(s)	€/kg of emission reductions or reductions in the releases that remain in the environment
D4, D5 and D6 - Option 1 'Emissions' (emissions reductions)	25,000 €/kg

Substance(s)	€/kg of emission reductions or reductions in the releases that remain in the environment
	(8,000 – 45,000 €/kg)
D4, D5 and D6 - Option 2 'Steady state' (reductions of emissions that remain in the environment in steady state)	960,000 €/kg (370,000 – 1,710,000 €/kg)

Source: Ricardo analysis based on the evidence presented in this Study. These are described in more detail in the rest of the Report and Annexes.

These estimates can be compared, at a high-level, against the estimated costs per kilogram (kg) of persistent chemical releases (or releases that remain in the environment) reductions from a list of recent REACH restrictions.

Table 0-16 Cost-effectiveness of recent REACH restrictions

Substance(s)	€/kg of releases or 'releases that remain in the environment' (*)
Lead in shot in wetlands	9 €/kg
Lead in PVC (under decision-making)	308 €/kg
D4, D5 in wash-off cosmetics	415 €/kg
DecaBDE	464 €/kg
Phenylmercury compounds	649 €/kg
PFOA-related substances	734 €/kg
PFOA	1,649 €/kg
D4, D5 and D6 (in the Annex XV dossier proposing restrictions)	104 €/kg (*)

Source: Committee for Risk Assessment (RAC), Committee for Socio-Economic Analysis (SEAC) (2019). Opinion on an Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6). (*) Previous assessments did not consider the steady state level of releases that remain in the environment, so estimates are not completely comparable with this.

In summary, the estimated abatement costs under these policy scenarios are many times higher than the highest values from the recent REACH restrictions (e.g., 5-25 times higher than for PFOA). As a result, it is considered that the policy scenarios under consideration are unlikely to be cost-effective ways of further reducing D4, D5 and D6 emissions and the potential environmental risk associated.

This could be explained by the role that silicone polymers play across multiple downstream user industries. For example, even though the weight of silicone polymers used in products may be low, e.g., 3 kg in an average internal combustion engine (ICE) car (note. electric vehicles tend to contain 3-4 times the amount dependent on care and battery size), and subsequent, potential emissions of D4, D5 and/or D6 would be considerably lower than for cosmetic applications, the final products rely on silicone polymers, sometimes in critical ways. In cases where product adjustments can be made and/or alternatives are available, significant investments may be required to achieve similar levels of final product performance, thus leading to high adjustment (or compliance) costs when compared to the limited emission reductions.

In addition, these and other outputs of the impact assessment were brought together across the broad economic, social, and environmental impact categories and summarised in the Table below. The colour-coding is used, again, to refer to the direction (positive or negative) and size (small or large) of any expected impacts.

Table 0-17 Overview of the economic, social, and environmental impacts for each Policy Scenario

Policy Scenario	Economic impacts	Social impacts	Environmental impacts	
			Option A (Commission evidence)	Option B (broader scientific evidence)
PS1 – Annex B listing broad exemptions	-0.5	-0.5	0	-0.5
PS2 – Annex B acceptable purpose exemption	-1.0	-1.0	0	-0.5
PS3 – Annex A prohibition	-2.0	-2.0	-0.5	-1.0

Source: Ricardo analysis based on the evidence presented in this Study.

In summary, all policy scenarios appear to have a negative balance of economic, social and environmental impacts, regardless of the evidence base used in the environmental assessment (Option A – Commission evidence, Option B – broader scientific evidence). The scale of social and environmental impacts remains largely unknown and has required drawing on expert input building on the limited available evidence, and opinion to develop conclusions. However, the estimated emissions abatement costs support this conclusion, as they appear to substantially surpass the highest abatement costs of any of the recently adopted REACH restrictions.

Finally, the balance of costs and benefits to EU society provides additional insights into the merits of each policy scenario and how likely they are to contribute to addressing the problems outlined earlier, as well as meeting the EU's general objectives in a cost-effective way. The colour-coding is used, again, to refer to the direction (positive or negative) and size (small or large) of any expected impacts.

Table 0-18 Costs and benefits of the Policy Scenarios based on the analysis performed in this Study

Policy Scenario	Costs	Benefits		Benefit: Cost Ratio (**)	
		Option A (EU Commission evidence)	Option B (broader scientific evidence)	Option A (EU Commission evidence)	Option B (broader scientific evidence)
PS1 – Annex B listing broad exemptions	-2.0	+0.5	<+0.5	0.3	0.2
PS2 – Annex B acceptable purpose exemption	-3.5	+1.0	+0.5	0.3	0.1
PS3 – Annex A prohibition	-5.0	+1.0	<+0.5	0.2	0.1

Source: Ricardo analysis based on the evidence presented in this Study. (**) A benefit: cost ratio of 1 would mean that the benefits could be more or less equivalent to the costs from the introduction of a policy scenario. Lower than 1 would mean that the benefits could be lower than the costs from implementing a policy scenario.

In summary, the benefits of each of the policy scenarios under assessment are assessed to be lower, in scale, than the costs. The assessment has highlighted a range of costs that could be incurred across economic and social dimensions, and some costs concerning even environmental dimensions, such as resources, energy and climate. In addition, some potential benefits have been identified, associated with innovation and research (economic), the quality of natural resources and biodiversity (environmental), especially under Option A (Commission evidence presented in the draft Annex D report) of the environmental assessment. **These benefits are considered to be of insufficient scale, which is represented by a benefit-to-cost ratio (BCR) lower than 1 across all policy scenarios, with a slightly lower BCR for PS2 and PS3.**

CONCLUSIONS

Finally, the outputs of this assessment and comparison of impacts across three policy scenarios for the Stockholm Convention listing of D4, D5 and D6 suggest that:

- Achieving reductions in the emissions and/or the steady-state environmental stock of D4, D5 and D6 could require high abatement costs, many times over the highest values estimated from recent REACH restrictions (e.g., 5-25 times higher than for PFOA), which reflect current 'willingness to pay' of society for the reduction in emissions or the presence of persistent substances in the environment.
- All policy scenarios are likely to have an overall negative balance of economic, social and environmental impacts and increasingly from PS1 to PS3. In addition, the negative impacts on economic and social dimensions could be significant, including billions of production activities and thousands of jobs lost in the EU when compared against the baseline.
- The overall benefits of the policy scenarios are assessed to be lower, in scale, than the costs, with Benefit: Cost Ratios estimated to be lower than one, and relatively lower for PS2 and PS3.

These conclusions would not support the adoption of any of the policy scenarios considered in this Study and would instead suggest that alternative measures should be explored and defined, which could achieve the zero-pollution objectives of the European Union whilst maintaining coherence with the broader European Green and Digital transition agenda.

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1. INTRODUCTION

This study presents an independent assessment of the impacts on the EU-27 of a potential nomination to the Stockholm Convention on Persistent Organic Pollutants (The Stockholm Convention)[18] of octamethylcyclotetrasiloxane (D4); decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6). The European Union (EU) has expressed an intention to put forward a nomination for these substances for inclusion under Annex B of the Stockholm Convention. The following introductory sections provide the political, legal and regulatory context, and an outline of the rest of this impact assessment Study.

1.1 POLITICAL AND LEGAL CONTEXT

The Stockholm Convention is an international treaty which aims to protect human health and the environment from the harmful effects of Persistent Organic Pollutants (POPs). POPs are organic chemical substances with persistent and bio-accumulative properties and potential toxicity to humans and the environment. As of 2023 there are 186 parties and 152 signatories to the Convention, this includes the European Union as well as individual European Member States. Therefore, the geographical scope of the Stockholm Convention is far wider than the regulatory responsibility of the European Commission.

The Stockholm Convention has three Annexes that use different mechanisms to regulate POPs:

- The inclusion of a substance in **Annex A** (Elimination) requires Parties to take measures to eliminate the production and use. Specific exemptions may exist; these must be agreed internationally, be time-limited and Parties must register their exemptions in writing to the Secretariat. Exemptions typically last for 5 years and expire automatically if they are not renewed, and Parties are encouraged to work towards withdrawing specific exemptions.
- A listing in **Annex B** (Restriction) restricts its production and use, considering any applicable acceptable purpose and specific exemptions. Acceptable purposes must also be registered in writing with the Secretariat but are distinct from exemptions in that they do not expire. There are currently two substances listed in Annex B, and these acceptable purposes are reviewed periodically with the aspiration of moving the substances onto Annex A.
- A listing under **Annex C** (Unintentional production) requires Parties to take measures to reduce unintentional release of substances[19].

The Stockholm Convention on Persistent Organic Pollutants entered into force in May 2004 with 12 recognised POPs. Since 2004, 24 new substances or substance groups have been listed under Annex A, B or C, with three substances/ substance groups currently under review[20].

To be listed under the Stockholm Convention, the nominating Party must demonstrate that a substance meets defined screening (Annex D) criteria **for persistence, bioaccumulation, adverse effects and the potential to undergo long-range environmental transport (LRET)** which must be agreed by a committee of scientific experts (the Persistent Organic Pollutants Review Committee, POPRC).**[21]**

If the Annex D screening criteria are deemed to be met, the substance progresses to the Annex E 'Risk Profile' stage. The Risk Profile builds upon the evidence submitted in Annex D to include information regarding sources of the substance, hazard assessment endpoints, environmental fate and monitoring data, amongst other things. The POPRC is responsible for determining if, as a result

[18] Ibid footnote 3
[19] Stockholm Convention (no date) All POPs listed in the Stockholm Convention. Available: Listing of POPs in the Stockholm Convention
[20] Stockholm Convention (no date) Chemicals proposed for listing under the Convention. Available: Chemicals proposed for listing under the Convention (pops.int)
[21] Stockholm Convention (2019) Text of the Convention. Available: Annex D - Text of the Stockholm Convention

of its long-range transport, a substance is likely to lead to significant human health and/or environmental effects 'such that global action is warranted'.

The final stage of the nomination process (Annex F, risk management evaluation) assesses the possible risk mitigation measures that may be employed for a substance and their associated socio-economic implications. The Risk Management Evaluation document comprises information regarding the efficacy and efficiency of possible control measures, the availability (or lack thereof) of alternatives, impacts on society and waste disposal implications. The Annex F report typically recommends a specific Annex (A, B or C) for listing and any proposed derogations to the listing, though exemptions may also be tabled at a meeting of the Conference of the Parties (COP).

The listing of a substance under a particular Annex and with any specific exemptions is decided at a meeting of the COP. Substance listings enter into force 18 months after the COP and national legislation must be updated accordingly. In the European Union, this mechanism for domestic implementation is provided in Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants.[22]

Discussions to nominate the listing of D4, and potentially D5 and D6, under the Stockholm Convention commenced in 2016 but the nomination was not endorsed by EU Member States. This was revisited in the meeting of the Competent Authorities for the implementation of EU POPs Regulations in June 2023, where a draft nomination was presented, and it was suggested to propose listing under Annex B of the Convention.[23] A consultation took place between June and August 2023[24] however, at the time of writing, an updated nomination report has not been publicly issued by the European Chemicals Agency (ECHA).[25]

The final nomination from the European Commission remains under development. If D4, D5 and D6 are listed under the Convention as per the current scope of the draft European Commission nomination, Parties to the Convention would be required to take measures to restrict or eliminate their production, use and release. The draft dossier concludes that D4, D5 and D6 meets the Annex D screening criteria and suggests that "*measures taken nationally or regionally are not sufficient"* to protect human health and the environment due to their propensity to undergo long-range environmental transport. Based on these conclusions, the draft Annex D report therefore rationalises that wider international action is necessary (see Section 2.2)[26].

1.2 REGULATORY CONTEXT

D4 and D5 have been subject to regulatory scrutiny in the EU for at least a decade. There are currently two Regulations that contain specific restrictive regulatory measures for D4, D5 and D6, Regulation No 1223/2009 on Cosmetic Products (CPR) [27], and Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[28].

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[22] European Commission (2019) Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants. Available at: Regulation - 2019/1021 - EN - EUR-Lex (europa.eu)

[23] European Commission (2016) Proposal for a COUNCIL DECISION on the submission, on behalf of the European Union, of a proposal for the listing of additional chemicals in Annex A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants. Available at : EUR-Lex - 52016PC0154 - EN - EUR-Lex (europa.eu)

[24]ECHA (2023) Previous consultations on proposals for new POPs. available from: Previous consultations on proposals for new POPs - ECHA (europa.eu)

[25] European Commission Expert Group (2023) 29th Hybrid Meeting. Available from : Register of Commission expert groups and other similar entities (europa.eu)

[26] Beveridge & Diamond (2023) Potential Consequences of Siloxane Nominations to Stockholm Convention.

[27] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance). Available: Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

[28] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Available: Regulation (EC) No 1907/2006 of the European Parliament concerning the REACH

The Cosmetic Products Regulation aims to ensure a high level of protection of human health in relation to the use of cosmetic products. Currently D4 is listed in Annex II of the CPR (amended in May 2019) and is prohibited for use in cosmetic products as it has a harmonised classification for human health, suspected reprotoxic substance (H361f)[29]. D4 (and D5) were originally assessed by the SCCS (SCCS/1241/10) and considered not to pose a risk for human health when used in cosmetic products at the in-use concentrations that were available at the time. This assessment noted the reprotoxic classification for D4 and the possible need for an environmental risk assessment[30]. Upon request of the European Commission, in January 2014 Cosmetics Europe submitted a safety assessment specifically dedicated to D5 in cosmetic products as D4 was no longer used for such applications in the EU[31]. The SCCS concluded that D5 was safe for use in some products but a reduction in concentrations were needed in others. This updated opinion on D5 included a risk assessment on D4 based on consumer exposure as a contaminant in D5 added to products. However, a full updated safety assessment was not conducted for D4 before being listed under Annex II of the Cosmetic Product Regulation.

An intention to restrict D4 and D5 under REACH was submitted by the United Kingdom in 2014. In 2018, D4 and D5 were restricted under Entry 70 of Annex XVII of REACH, which prohibits the placing on the market of D4 or D5 in wash-off cosmetic products in a concentration ≥0.1% w/w, after 31 January 2020[32]. In 2017, an intention to restrict D4, D5 and D6 in leave-on personal care products and other consumer/professional products (e.g., dry cleaning, waxes and polishes, washing and cleaning products) in concentrations >0.1% w/w, and D6 in wash-off and rinse-off cosmetic products containing D6 in concentrations >0.1% w/w was submitted by ECHA. This restriction has progressed into a broad restriction which not only restricts direct uses of D4, D5 and D6, but also limits their concentration as unintentional impurities in mixtures containing silicone polymers. The final opinions of the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) have since been provided, and in December 2023 the REACH Committee of the Commission voted in favour of a proposed restriction text. The restriction has since been published in the official journal. The restriction conditions are summarised in the Box below.

Box 1-1 REACH restriction of D4, D5 and D6 in consumer and professional products[33]

The REACH restriction for Octamethylcyclotetrasiloxane (D4, CAS no. 556-67-2), Decamethylcyclopentasiloxane (D5, CAS no. 541-02-6), and Dodecamethylcyclohexasiloxane (D6, CAS no. 540-97-6) contains the following restriction conditions (entry 70, Annex XVII).

1. Shall not be placed on the market
    a. as a substance on its own;
    b. as a constituent of other substances; or
    c. in mixtures;

    in a concentration equal to or greater than 0,1 % by weight of the respective substance after 6 June 2026.
2. Shall not be used as a solvent for the dry cleaning of textiles, leather and fur after 6 June 2026.
3. By way of derogation:
    a. for D4 and D5 in wash-off cosmetic products, paragraph 1, point (c), shall apply after 31 January 2020.

    For the purposes of this point, “wash-off cosmetic products” means cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009 of the European Parliament and of the Council1 that, under normal conditions of use, are washed off with water after application;

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[29] Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products. Available: http://data.europa.eu/eli/reg/2019/831/oj

[30] European Commission SCCS (2010) OPINION ON Cyclomethicone Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, D4) and Decamethylcyclopentasiloxane (Cyclopentasiloxane, D5) Available from: Opinion of the Scientific Committee on Consumer Safety on cyclomethicone (D4/D5) (europa.eu)

[31] European Commission SCCS (2016) Decamethylcyclopentasiloxane (cyclopentasiloxane, D5) in cosmetic products. Available from: Decamethylcyclopentasiloxane (cyclopentasiloxane, D5) in cosmetic products - European Commission (europa.eu)

[32] Ibid footnote 28

[33] Entry 70, Annex XVII, REACH Regulation. Annex XVII to REACH – Conditions of restriction. Available: 0ac1f453-ad41-4010-e837-a68273b896ca (europa.eu)

   b. for all cosmetic products other than the ones mentioned in paragraph 3(a), paragraph 1 shall apply after 6 June 2027;
   c. for devices as defined in Article 1(4) of Regulation (EU) 2017/745 of the European Parliament and of the Council2 and in Article 1(2) of Regulation (EU) 2017/746 of the European Parliament and the Council3, paragraph 1 shall apply after 6 June 2031;
   d. for medicinal products, as defined in Article 1, point 2, of Directive 2001/83/EC, and for veterinary medicinal products, as defined in Article 4(1) of Regulation (EU) 2019/64, paragraph 1 shall apply after 6 June 2031;
   e. for D5 as a solvent in the dry cleaning of textiles, leather and fur, paragraphs 1 and shall apply after 6 June 2034.
4. By way of derogation, paragraph 1 shall not apply to the:
   a. placing on the market of D4, D5 and D6 for the following industrial uses:
      - as a monomer in the production of silicone polymer,
      - as an intermediate in the production of other silicon substances,
      - as a monomer in polymerisation,
      - in the formulation or (re)packing of mixtures,
      - in the production of articles,
      - in non-metal surface treatment;
   b. placing on the market of D5 and D6 for use as devices, as defined in Article 1(4) of Regulation (EU) 2017/745, for the treatment and care of scars and wounds, the prevention of wounds and the care of stoma;
   c. placing on the market of D5 for professional use in the cleaning or restoration of art and antiques;
   d. placing on the market of D4, D5 and D6 for use as laboratory reagent in research and development activities carried out under controlled conditions.
5. By way of derogation, paragraph 1, point (b), shall not apply to the placing on the market of D4, D5 and D6:
      - as a constituent of a silicone polymer on its own,
      - as a constituent of a silicone polymer in a mixture derogated under paragraph 6.
6. By way of derogation, paragraph 1, point (c), shall not apply to the placing on the market of mixtures that contain D4, D5 or D6 as residues from silicone polymers, under the following conditions:
   a. D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in adhesion, sealing, gluing and casting;
   b. D4 in a concentration equal to or less than 0,5 % by weight, or D5 or D6 in a concentration equal to or less than 0,3 % by weight of either substance in the mixture for use as protective coatings (including marine coatings);
   c. D4, D5 or D6 in a concentration equal to or less than 0,2 % by weight of the respective substance in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745 and in Article 1(2) of Regulation (EU) 2017/746, other than the devices referred to in paragraph 6(d);
   d. D5 in a concentration equal to or less than 0,3 % by weight in the mixture or D6 in a concentration equal to or less than 1 % by weight in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745, for dental impression;
   e. D4 in a concentration equal to or less than 0,2 % by weight in the mixture, or D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture for use as silicone insoles for horses, or as horseshoes;
   f. D4, D5 or D6 in a concentration equal to or less than 0,5 % by weight of the respective substance in the mixture, for use as adhesion promoters;
   g. D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in 3D-printing;
   h. D5 in a concentration equal to or less than 1 % by weight in the mixture or D6 in a concentration equal to or less than 3 % by weight in the mixture, for rapid prototyping and mould making, or high performance uses stabilised by quartz filler;
   i. D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture, for use in pad printing, or manufacturing of printing pads;
   j. D6 in a concentration equal to or less than 1 % by weight of the mixture, for professional use in the cleaning or restoration of art and antiques.
7. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for use, or to the use, of D5 as a solvent in strictly controlled closed dry cleaning systems for textile, leather and fur, where the cleaning solvent is recycled or incinerated.

D4, D5 and D6 were identified as Substances of Very High Concern (SVHCs) since it was concluded that they fulfil the criteria for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) properties, and the substances were included in the Candidate List in June 2018. In the 10th recommendation round, D4, D5 and D6 were recommended by ECHA for inclusion in Annex XIV. In case such an Annex XIV listing would be brought forward by the Commission, companies would need to apply for an authorisation for continued use within specific applications[34].

An outline of key regulatory developments for D4, D5 and D6 in the EU is provided in the Figure below[35,36,37,38,39,40,41].

[34] European Chemicals Agency (2021) Recommendation of the European Chemicals Agency of 14 April 2021 for the inclusion of substances in Annex XIV to REACH. Available: Authorisation (europa.eu)

[35] European Commission (2016) request to the European Chemicals Agency to prepare a restriction proposal conforming to the requirements of Annex XV to REACH. Available: a0bdbb25-9641-9df1-9511-4208cac224ce (europa.eu)

[36] European Chemicals Agency (no date) Previous calls for comments and evidence. Available at: Previous calls for comments and evidence - ECHA (europa.eu)

[37] European Commission (2018) D6 – Update to the request for the European Chemicals Agency to prepare a restriction proposal conforming to the requirements of Annex XV to REACH. Available: 722217b2-95c1-a5a0-90c5-82f2afed48f9 (europa.eu)

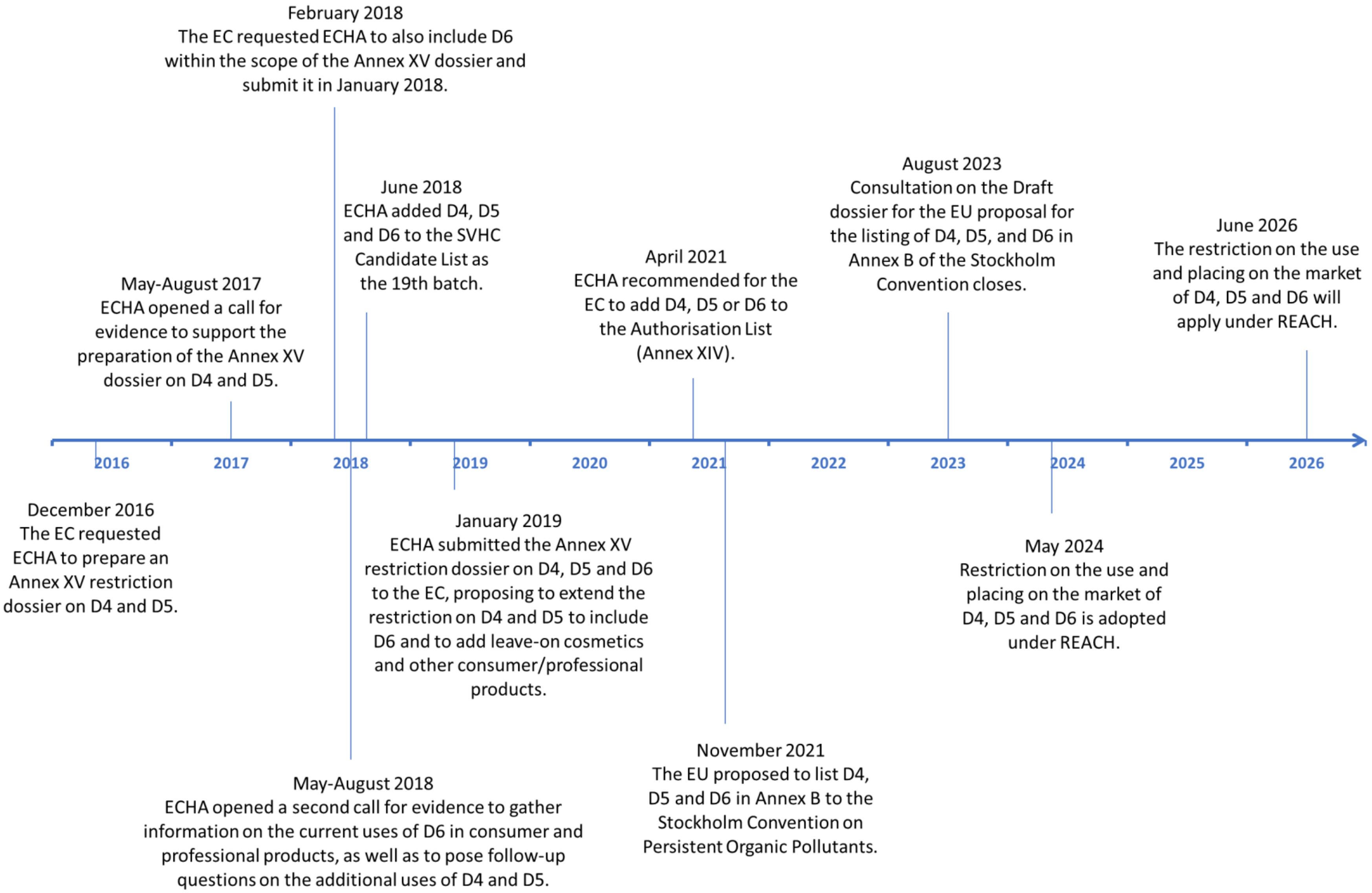
[38] European Chemicals Agency (2018) 10 new substances added to the Candidate List. Available: All news - ECHA (europa.eu)

[39] European Chemicals Agency (2019) Annex XV Restriction report proposal for a restriction D4, D5, D6. Available: D4-D5-D6_Annex XV_Interim report (europa.eu)

[40] European Chemicals Agency (no date) Previous consultations on proposals for new POPs. Available: ECHA – Comments submitted on draft Annex D proposal

[41] European Chemicals Agency (2021) ECHA proposes seven substances for authorisation to protect people and the environment. Available: All news - ECHA (europa.eu)

Figure 1-1 The EU and Stockholm Convention regulatory timeline for D4, D5 and D6



1.3 STRUCTURE OF THE REPORT

This rest of this impact assessment study is structured in four sections and followed by a set of complementary Annexes. The sections include:

- Section 2, setting out the problem definition,
- Section 3, presenting the policy scenarios under assessment and baseline,
- Section 4, describing the assessment of impacts of the policy scenarios and uncertainties, and
- Section 5, containing the comparison of the scenarios and the conclusions of the assessment.

2. PROBLEM DEFINITION

In this section, the problems that the European Union aims to address with the nomination of D4, D5, D6 to the Stockholm Convention, as well as its drivers and consequences, are considered and defined. In particular, the section presents:

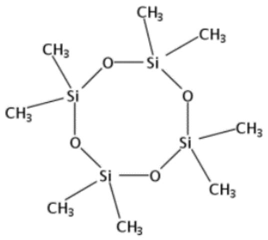
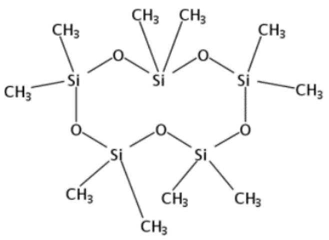
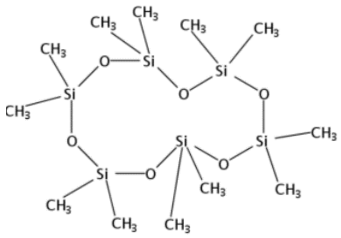
- an overview of the substances and their uses (Section 2.1);
- the problems as identified from literature and by authorities (Section 2.2);
- the drivers and consequences of these problems (Section 2.3);
- how the problems would evolve without further intervention (Section 2.4); and
- the objectives of the initiative (Section 2.5).

2.1 OVERVIEW OF THE SUBSTANCES AND THEIR USES

This section provides supporting contextual information on the substances of interest and their uses.

Octamethylcyclotetrasiloxane (D4, CAS no. 556-67-2), decamethylcyclopentasiloxane (D5, CAS no. 541-02-6) and dodecamethylcyclohexasiloxane (D6, CAS no. 540-97-6) are three of the most commonly used cyclic volatile methyl siloxanes (cVMS) across the EU-27. These substances have a similar cyclic structure and similar chemical and physical properties despite the variation in the total number of –(Si-O)- repeating units. The inorganic silicon-oxygen alternating backbone (Si-O-Si), in combination with the methyl groups on each silicon atom, provide the substances with a useful combination of inorganic and organic properties such as dielectric behaviour and hydrophobicity[42]. Additionally, the silicon-oxygen bonds are longer than carbon-oxygen bonds and the Si-O-Si bond angle is wider than the carbon-oxygen equivalent, which allows for a higher level of flexibility than organic structures and produces useful physical properties such as thermal stability.

Table 2-1 Substance information on D4, D5 and D6[43,44,45,46]

Substance	Octamethyl-cyclotetrasiloxane	Decamethyl-cyclopentasiloxane	Dodecamethyl-cyclohexasiloxane
Abbreviation	D4	D5	D6
CAS	556-67-2	541-02-6	540-97-6
Structure			
Vapor pressure, mm Hg at 25 °C	1.05	0.2	0.049

[42] Theresia Köhler et al. (2020) Industrial synthesis of reactive silicones: reaction mechanisms and processes, Organic Chemistry Frontiers, 7, 24, 4108-4120. Available: https://doi.org/10.1039/d0qo01075h

[43] Piechota G (2021) Siloxanes in Biogas: Approaches of Sampling Procedure and GC-MS Method Determination, Molecules, 26, 1953 Available: http://dx.doi.org/10.3390/molecules26071953

[44] European Chemicals Agency (no date) Substance Information - ECHA. [online] Available: https://echa.europa.eu/substance-information/-/substanceinfo/100.008.307 [Accessed 8 Nov. 2023]

[45] European Chemicals Agency (no date) Substance Information - ECHA. [online] Available: https://echa.europa.eu/substance-information/-/substanceinfo/100.007.969

[46] European Chemicals Agency (no date) Substance Information - ECHA. [online] Available: https://echa.europa.eu/substance-information/-/substanceinfo/100.007.967

Substance	Octamethyl-cyclotetrasiloxane	Decamethyl-cyclopentasiloxane	Dodecamethyl-cyclohexasiloxane
Octanol/water partition coefficient	5.1	5.2	5.86
Density (g/cm^3) at 20 °C	0.96	0.96	0.98
REACH registered tonnage (tonnes per annum)	≥ 100 000 to < 1 000 000	≥ 10 000 to < 100 000	≥ 1 000 to < 10 000

The notable properties of these substances, which are liquids at room temperature, include high volatility, low viscosity, low water solubility and high thermal stability[47,48]. The high thermal stability allows the substances to retain their physical properties over wide temperature ranges. This stability, crossed with the dielectric behaviour of the Si-O bonds, makes siloxanes useful electrical insulators.

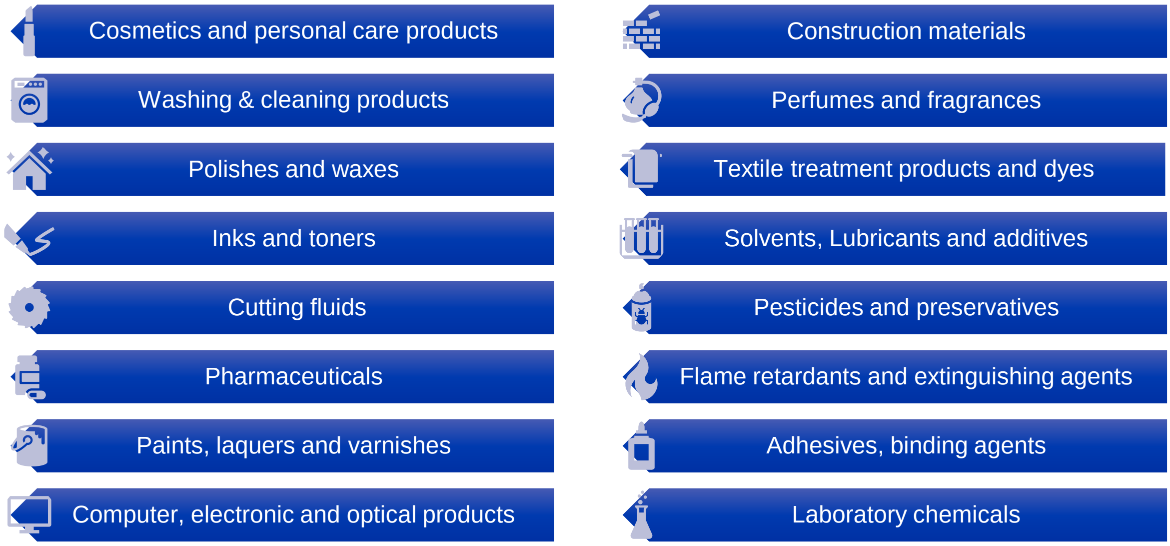
According to REACH Registration data, the manufactured/imported tonnage per year decreases from D4 to D5 to D6 as can be seen from Table 2-1. The substances are commonly synthesised and purified via a two-step process:

- **Step one**: The hydrolysis of dimethyldichlorosilane, which produces a mixture of volatile methyl siloxanes; both cyclic and linear can be produced during this step.
- **Step two**: The separation of fractions. The mixture is then separated into linear and cyclic fractions of different sizes through distillation.

Once synthesised, D4, D5 and D6 have a number of applications and can be used as a monomer in the production of silicone polymers, which have various uses, directly as substances within mixtures placed on the EU-27 market, or as a reactant/intermediate in the manufacture of products such as semiconductors or glass fibres [49,50,51]. In the former two of the three use approaches, direct and for polymers, the siloxanes are present in the final product as intended constituents or impurities. When used in the production of certain components such as semiconductors or glass fibres, the substances are not expected to be present in the final product[52]. The diagram below shows a selection of the professional and consumer uses of D4, D5 and D6 as stated in the ECHA registered substances database and sourced from REACH Registration dossiers (updated 2023), the SPIN database[53] sourced from notifications from the Nordic countries (updated in 2021), as well as in previous sector reports[54,55,56,57,58,59].

[47] Navea et al., (2011) The atmospheric lifetimes and concentrations of cyclic methylsiloxanes octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) and the influence of heterogeneous uptake, Atmospheric Environment, 45, 3181-3191. https://doi.org/10.1016/j.atmosenv.2011.02.038
[48] Piechota G (2021) Siloxanes in Biogas: Approaches of Sampling Procedure and GC-MS Method Determination, Molecules, 26, 1953. Available: http://dx.doi.org/10.3390/molecules26071953
[49] Ibid footnote 3
[50] ECHA (2020) Background Document to the Opinion on the Annex XV dossier proposing restrictions on D4; D5 and D6. Available: https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978
[51] Silicones Europe (no date) Silicone Production. Available from: https://www.silicones.eu/science/production/chemistry-mix-formulation/
[52] Silicones Europe (2023) SILICONES AND SEMICONDUCTORS. Available: CES_Infographic-semiconductors_Structure_A4_V2.pdf (silicones.eu)
[53] The Spin database focuses on the use of Substances in Products in the Nordic Countries, the data includes the product registries of Norway, Sweden, Denmark and Finland.
[54] Amex Foster Wheeler (2016) Socio-economic evaluation of the global silicones industry. Regional Summary – Europe. Available: https://dokumen.tips/documents/socio-economic-evaluation-of-the-global-silicones-industry-final-.html?page=1
[55] Amex Foster Wheeler (2017) Impact Assessment of D4 POP Listing, Final report.
[56] ECHA (no date) Substance Information - ECHA. [online] Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.008.307 [Accessed 8 Nov. 2023].
[57] ECHA (no date) Substance Information - ECHA. [online] Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.007.969
[58] ECHA (no date) Substance Information - ECHA. [online] Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.007.967
[59] SPIN (no date) Substances in preparation in Nordic Countries – Search. Available: SPIN Substances in preparations in nordic countries (spin2000.net) [Accessed November 2023]

Figure 2-1 Consumer uses of cyclic volatile siloxanes including direct use and silicone polymers.



As depicted above, D4, D5 and D6 can be found in many consumer and professional products. However, it should be noted that the available literature and databases do not specify if the use of these substances in consumer products results from intentionally adding D4, D5 and/or D6 and/or from impurities in silicone polymers.

The 2020 ECHA background document to the proposed broad REACH restriction for D4, D5 and D6 estimated that the direct use of these substances equated to a total of 21,987 tonnes per annum[60]. This is less than 9% of the total tonnage of D4, D5 and D6 imported or manufactured each year. Currently, the direct uses of D4, D5 and D6 includes dry cleaning (D5); art cleaning (D4[61], D5); non-metal surface treatments (D4); research (D4, D5, D6); and the primary direct use in formulations and mixtures for cosmetics and cleaning products (D5, D6).

Specific direct uses of D4 for non-metal surface treatments may result in the manufacture of products that, when placed on the market do not include D4, which is relevant for the use of D4 in the manufacture of electronics such as semiconductors and glass fibres[62]. A layer of D4 is applied to the surface of the electrical component through chemical vapour deposition or similar techniques. This layer provides both a layer of chemical and thermal protection to the electrical component. For example, in the treatment of glass fibres, D4 is expected to undergo complete chemical conversion.

As described in Section 1.2 on the Regulatory Context, specific derogations for direct uses, such as for dry cleaning or art cleaning have been implemented in the REACH restriction of D4, D5 and D6[63]. The scope of this restriction does not include the industrial use of D4, D5 and D6 to produce silicone polymers and a derogation has been suggested for certain polymers uses with high concentrations of the substances as impurities.

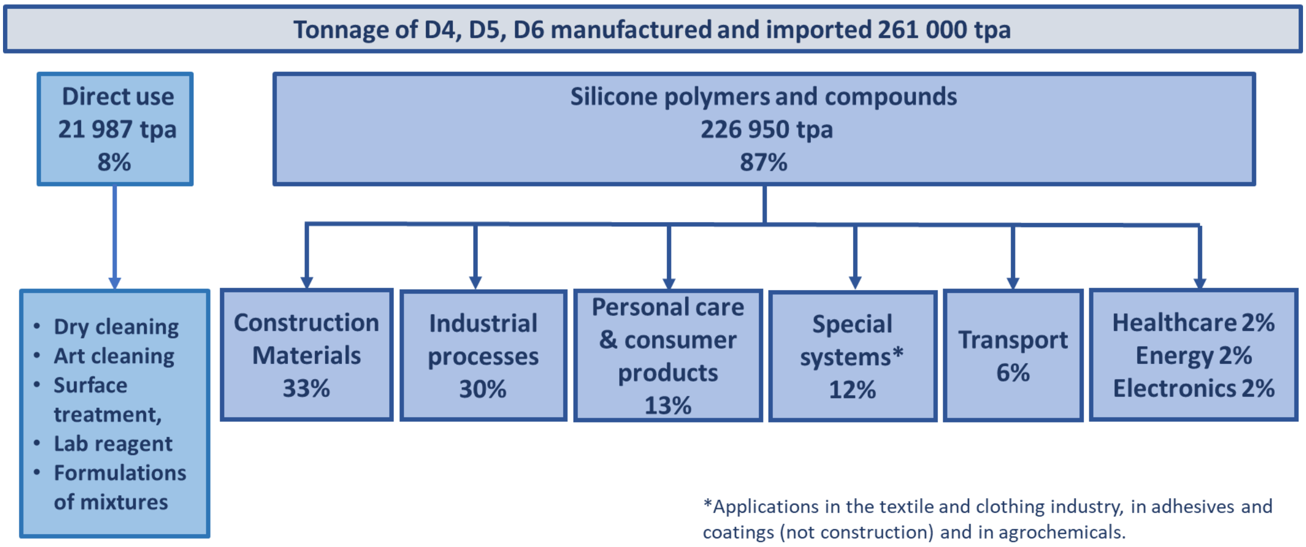
[60] Ibid footnote 50

[61] D4 has historically been used for art cleaning but it's use is now declining

[62] Silicones Europe (2023) SILICONES AND SEMICONDUCTORS. Available: CES_Infographic-semiconductors_Structure_A4_V2.pdf (silicones.eu)

[63] ECHA (2020) Final opinion of RAC and SEAC. Available from: REST_D4D5D6_Opinion_Format (europa.eu)

Figure 2-2 Overview of D4, D5 and D6 usage in the EU-27, including direct use (9%) and use to manufacture silicone polymers (91%), as well as the 'downstream user' sectors of silicone polymers according to tonnage.[64,65]



Source: Produced using the Background Document to the Opinions on the Annex XV dossier and the 2016 Silicones Europe Report by Amec Foster Wheeler which uses data from 2013.

One major use of D4, D5 and D6 in the EU-27 is as a monomer for polymer manufacture (see Figure 2-2). Use as monomers was estimated in 2020 (based on data from previous reports dating back to 2013) to equate to over 80% of all D4, D5 and D6 use per year. The percentages of resulting polymer use within each sector are based off the distribution estimated in the 2016 Amec Foster Wheeler report, however it is expected these will have changed over time, although no new information is available. The individual tonnages per year shows a higher use of D4 (204 950 tpa) in polymer manufacture compared to D5 (18 000 tpa) or D6 (4 000 tpa); this ratio of cVMS stems from the output of the chlorosilane hydrolysis process upstream. The polymerisation process occurs through a ring opening polymerisation mechanism when heat is applied in acidic or alkaline conditions[66]. D4 and D5 are the monomers produced in the highest concentration during the synthesis of cVMSs. The resulting mixture of siloxanes can be used for the polymerisation process where D4 is the more important monomer, due to it having the highest ring energy to drive the ring opening process.[67] Silicone polymers, such as Polydimethylsiloxane (PDMS) or modified PDMS, are commonly manufactured from D4, D5 and D6 through this ring opening polymerisation process. This synthesis approach leaves traces of the siloxanes in the final polymer as the reaction is unlikely to reach completion, even under optimised conditions.

PDMS is commonly referred to as silicone or dimethicone and is used across many applications due to its versatility and ability to be modified for various uses. PDMS can be used as a fluid where the viscosity, low or high, can be tailored through the reaction process. If the resulting polymer has a high molecular weight the PDMS fluid will be viscous, low molecular weight PDMS fluids will have low viscosity. Silicone fluids are used as lubricants, operational fluids, antifoaming agents, oils and gums, amongst many other uses[68]. In addition to fluids, silicone resins, elastomers, coatings, gels and sealants can be synthesised for various applications based on the level of polymer crosslinking.

[64] Ibid footnote 54
[65] Ibid footnote 4
[66] Ibid footnote 42
[67] ibid footnote 42
[68] Huber et al (1986) Silicone fluids: synthesis, properties and applications, Journal of Synthetic Lubrication, 3, 105. Available: Silicone fluids: Synthesis, properties and applications - Huber - 1986 - Journal of Synthetic Lubrication - Wiley Online Library

The level of crosslinking and the resulting polymer properties depend on the curing method (UV, heat, etc.) and the curing agent used[69].

Further polymers can be synthesised through the modification of PDMS, substituting methyl groups to tailor the polymer properties, for example, to increase solubility or heat resistance. Silicone polymers are so useful because they can operate under harsh conditions where they show high water, UV and chemical resistance, and electrical insulating properties. For uses such as optical fibre coatings, alternatives to silicone, such as acrylates, are available. However, for other uses, such as surgical instruments or medical devices, silicone polymers have a unique collection of properties such as a high level of biocompatibility and heat resistance[70].

The ring-opening polymerisation process to synthesise PDMS forms is an equilibrium reaction, and although the equilibrium can be shifted using reagents, 100% completion is unlikely. It was found in 2009 that D4, D5 and D6 impurities in PDMS sold in Europe were between 0.3% (D4) - 0.05% (D6) w/w with the impurity percentage decreasing from D4 to D5 to D6 across *silicone fluids and specialities* and *elastomers*. *Silicone fluids and specialities* had the highest impurities, with *elastomers* and *sealants* also containing siloxane monomers[71]. In a separate study, silicone samples tested from 2004 to 2009 in Germany showed that 18% of all samples contained over 0.5% w/w volatile substances, these substances include D4, D5 and D6 amongst other volatile substances[72]. In the more recent 2020 background document from ECHA it is stated that for many silicone polymer products the concentration will be below 0.1% w/w. However, it was found that silicone polymers used in sealants, adhesives and coatings contained 0.3-0.9% of D4, D5 or D6, with some medical devices including concentrations up to 3%[73]. These higher impurity concentrations are directly linked to the functionality of the silicone polymer in these applications.

To summarise, silicone polymers and cVMS individually are very adaptable substances/materials and thus are used across many applications and many sectors. The silicone oxygen bond provides a strong backbone for the polymer with high chemical and thermal resistance. These bonds also facilitate useful mechanical properties that can be manipulated to the application through the molecular weight or the percentage of crosslinking. This balance of flexibility and resistance make cVMS and silicone polymers highly adaptable and valuable to many industries such as construction, automotive, electronics, pulp and paper, oil and gas, medical, and aerospace and defence[74,75].

2.2 WHAT IS THE PROBLEM?

Two interlinked problems have been identified following review of the relevant literature from the European Commission. These are summarised below, with further detail provided in Sections 2.2.1 to 2.2.4.

- The existing REACH restriction (Entry 71) and the REACH Annex XV restriction proposal report on the use of D4, D5 and D6, focused mainly on leave on cosmetics, is estimated to result in a reduction of approximately 90% of the direct emissions to the environment in the EU. However, as this regulatory action is only enforceable in the EU (+ EEA countries where relevant), the emissions of D4, D5 and D6 from such uses outside of the EU shall continue. It should be noted that the second restriction deliberately excludes certain key uses, such as industrial uses for the production of silicone polymers or production of articles and the

[69] R. Janani et al (2023) From acrylates to silicones: A review of common optical fibre coatings used for normal to harsh environments, Progress in Organic Coatings, 180, 107557. https://doi.org/10.1016/j.porgcoat.2023.107557
[70] Ibid footnote 69
[71] The Environment Agency (2009) Environmental Risk Assessment Report. Available: https://assets.publishing.service.gov.uk/media/5a7cb898ed915d682236222b/scho0309bpqy-e-e.pdf
[72] Helling, R., Kutschbach, K., & Joachim Simat, T. (2010). Migration behaviour of silicone moulds in contact with different foodstuffs. Food Additives & Contaminants Part A, 27, 396–405. https://doi.org/10.1080/19440040903341869
[73] Ibid footnote 50
[74] Glosz K., Stolarczyk A., Jarosz T (2020) Siloxanes—Versatile Materials for Surface Functionalisation and Graft Copolymers. International Journal of Molecular Science, 21, 6387. doi: 10.3390/ijms21176387
[75] Ibid footnote 49

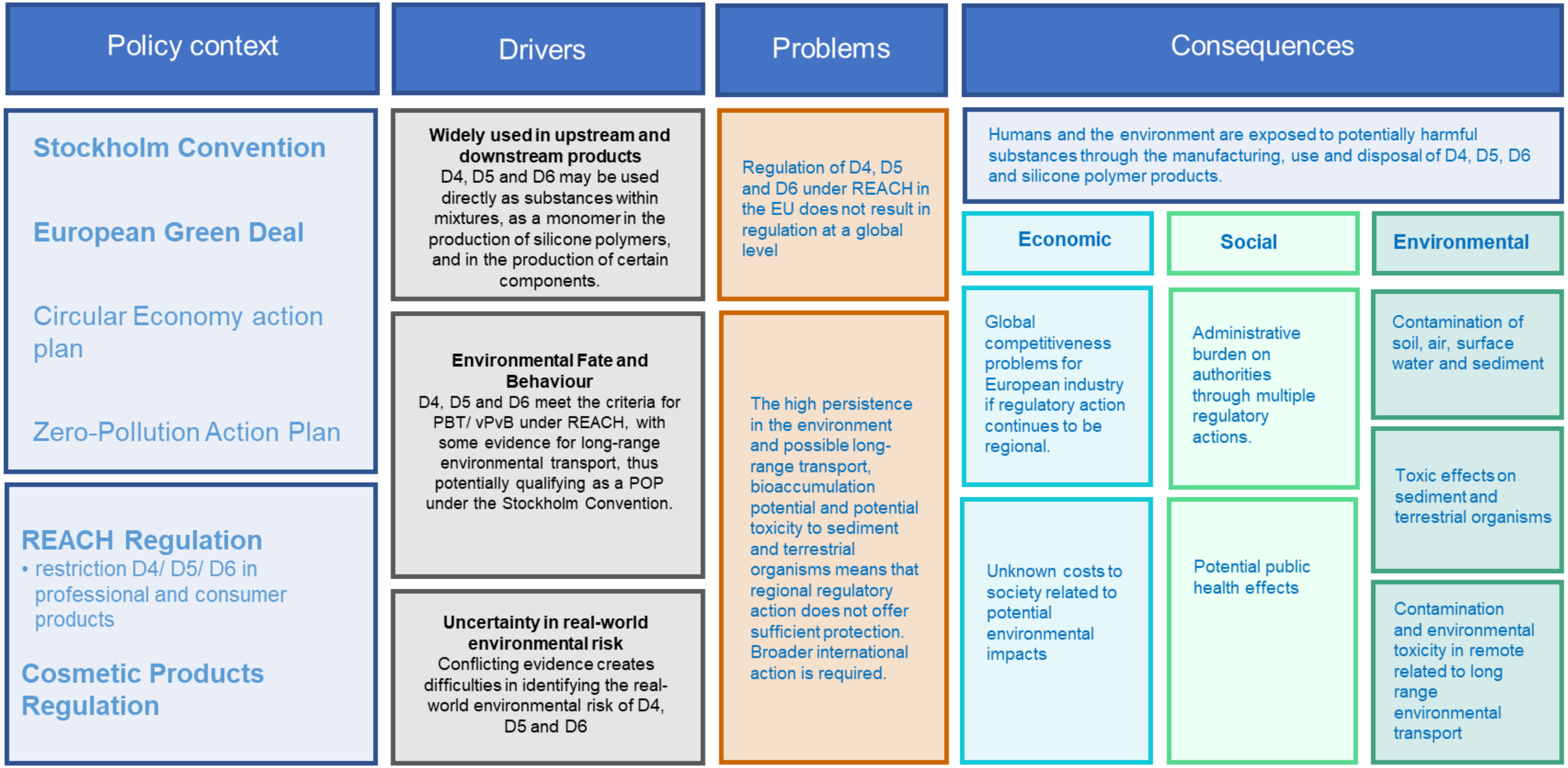
formulation of mixtures (see Section 1.2), meaning that around 10% of emissions are expected to remain[76], whereas the Stockholm Convention policy scenarios considered in this Study, increase the scope to include the use of silicone polymers.

- Despite that emissions are expected to be significantly reduced in the EU, the evidence provided by the Commission suggests that their high persistence in sediment, bioaccumulation potential in some parts of the food chain, and potential toxicity to sediment and soil organisms (see Sections 2.2.2 and 2.2.3) could potentially lead to significant adverse environmental effects such that global action is warranted, based on the precautionary principle[77,65].

The problem tree below depicts the problems and drivers highlighted by the European Union as reasoning for the nomination of these three substances to the Stockholm Convention. The drivers, problems and consequences identified in Figure 2-3 are covered in detail in Sections 2.2- 2.4.

[76] ECHA (2020) Background Document to the Opinion on the Annex XV dossier proposing restrictions on D4; D5 and D6. Available: https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978
[77] Ibid footnote 73

Figure 2-3 Problem tree for the nomination of D4, D5 and D6 to the Stockholm Convention



2.2.1 Emissions to the environment

As outlined in Section 2.1, the widespread use of D4, D5 and D6 in professional and consumer products can lead to significant emissions to the environment via direct use, the migration of silicone polymer impurities or from the depolymerisation of silicone polymers under harsh conditions[78,79,80]. Total releases of D4, D5 and D6 to the environment have been estimated to be approximately 18,000 tpa, with leave-on cosmetics and the use of D6 in wash-off cosmetics being the primary source of releases (approximately 90%, including silicone polymers in cosmetics).

As D4, D5 and D6 are poorly soluble in water, highly volatile and adsorb strongly to organic matter in sewage sludge, sediment and soil, the main release pathways are through evaporation to air during use, aeration steps in WWTP, and by deposit of sewage sludge on agricultural lands and landfills.[81,82]. They can also reach agricultural lands through their presence in silicone formulants added to pesticide products as adjuvants [83,84,85,86]. Leaching from soil is not expected to be significant. In wet soil, volatilisation is predominant, while in drier soil, hydrolysis is predominant[87,88]. In either case, there is low probability that cVMS will be persistent in soil due to their rapid dissipation rates[89,90,91].

Emissions from the manufacture of D4, D5 and D6 are considered negligible as a result of existing operating conditions and risk management measures[92], supported by measured onsite and offsite emissions assessed by the Environmental Agency at UK and EU level[93]. A number of literature sources indicate that D4, D5, D6 (and other cVMS) can form during the breakdown of PDMS under certain conditions, such as temperatures greater than 150°C[94,95,96,97] or high loading rates in soil (>2000 mg/kg) [98]. A significant amount of PDMS is used in ‘down the drain’ products, such as

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78 Environment Agency (2009a) Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane. Environment Agency Science Report, SCHO0309BPQZ-E-P, April 2009. ISBN 978-1-84911-031-0.

79 Environment Agency (2009b) Environmental risk evaluation report: Decamethylcyclopentasiloxane. Environment Agency Science Report SCHO0309BPQX-E-P, April 2009. ISBN 978-1-84911-029-7.

80 Environment Agency (2009c) Environmental risk evaluation report: Dodecamethylcyclohexasiloxane. Environment Agency Science Report SCHO0309BPQY-E-P, April 2009. ISBN 978-1-84911-030-3.

81 Ibid footnote 49

82 Ibid footnotes 78,79,80

83 Ibid footnote 49

84 Environment Canada, Health Canada (2008a). Screening Assessment for the Challenge. Octamethylcyclotetrasiloxane (D4). Chemical Abstracts Service Registry Number 556-67-2. Ottawa (ON): Government of Canada. November 2008.

85 Environment Canada, Health Canada (2008b). Screening Assessment for the Challenge. Decamethylcyclopentasiloxane (D5). Chemical Abstracts Service Registry Number 541-02-6. Ottawa (ON): Government of Canada. November 2008.

86 Final Screening Assessment for Dodecamethylcyclohexasiloxane (D6) (published on January 31, 2009). Public comments received on the draft screening assessment were considered in development of the final screening assessment.

87 European Chemicals Agency (2015) Persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7, CAS No: 556-67-2) and Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9, CAS No. 541-02-6). Annex 2-3

88 European Chemicals Agency (2018) Support document for identification of dodecamethylcyclohexasiloxane (D6) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: Annex XV report (europa.eu)

89 European Chemicals Agency (no date) Registration Dossier Octamethylcyclosiloxane. Available: Registration Dossier - ECHA (europa.eu)

90 European Chemicals Agency (no date) Registration Dossier Decamethylcyclopentasiloxane. Available: Registration Dossier - ECHA (europa.eu)

91 European Chemicals Agency (no date) Registration Dossier Dodecamethylcyclohexasiloxane. Available: Registration Dossier - ECHA (europa.eu)

92 Ibid footnote 50

93 Ibid footnotes 78,79,80

94 Lomakin S M, Koverzanova E V, Shilkina N G, Usachev S V, and Zaikov G E (2003) Thermal degradation of polystyrene–polydimethylsiloxane blends. Russian Journal of Applied Chemistry, 76, 472–482.

95 Nielsen J M, (1979) Degradation of methylsilicon fluids under a nitrogen atmosphere at 370°C. Journal of Applied Polymer Science: Applied Polymer Symposium, 35, 223– 234.

96 Patel M and Skinner A (2001) The effect of thermal ageing on the non-networked species in RTV5370 polysiloxane rubbers. Polymer Preprints, 42, 157–158.

97 Patel M and Skinner A (2003) The effect of thermal aging on the non-network species in room temperature vulcanized polysiloxane rubbers. American Chemical Society Symposium Series, 838, 138–150.

98 Lehmann R G, Varaprath S, Annelin R B, and Arndt J L (1995) Degradation of silicone polymer in a variety of soils. Environmental Toxicology and Chemistry, 14, 1299–1305.

personal care products and textiles. The properties of PDMS polymers are such that removal during wastewater treatment is likely to be mainly by adsorption onto sewage sludge, which when spread onto soil has potential as a route of exposure for terrestrial organisms and plants[99]. Other routes of exposure come from the use of PDMS in agricultural adjuvant, landfill from uses such as textile coatings, high temperature oil baths, wall-board coatings, rubber compounds, and powder treatment[100].

The amount of PDMS fluids thought to reach soil (either from diffuse emissions or the application of sewage sludge) is estimated as ~35,900 tonnes/year. Assuming that 0.5% of this degrades into cyclic siloxanes and other volatile products[101], the total amount of such products formed is estimated at around 179.5 tonnes/year. The amount of D4, D5 and D6 formed during the degradation is assumed to be around 25 per cent of the total cyclic siloxanes and other volatile products, then the amount estimated of such products individually is 44.88 tonnes/year. On the other hand, polymeric siloxane products disposed of in landfill have a substantial amount of cross-linking in the polymer, they are less degradable than PDMS fluids and so their potential to emit cyclic siloxanes from degradation is much lower. Little data appears to be available as to how cyclic siloxanes form from such products under conditions found in landfills (i.e., anaerobic). Therefore, despite this figure is highly speculative, considering an annual deposition of PDMS fluids in landfills around 26,500 tonnes/year, a degradation of 0.5% yielding to cyclic siloxanes, and with 25% of this comprising D4, D5 and D6 individually, the amount emitted for each compound could be around 33.13 tonnes/year. Thus the amount of D4, D5 and D6 emitted is estimated to be around 44.88-78.00 tonnes/year, per compound. This represents a volatile loss from the soil and should be considered as an emission to air, being <3% for D4 and D5, and <2% for D6 of the total emissions to air. Therefore, although there are large uncertainties in the approach used here to estimate the emissions from degradation of PDMS polymers, this does not appear to be a major source in the environment when compared with the emissions from direct uses[102].

Finally, a number of available studies show that cyclic siloxanes may be formed under high-temperature pyrolysis conditions, but the relevance of these studies to the conditions of incineration (i.e., in the presence of flames) is uncertain. However, it is thought that the conditions effectively destroy any cyclic products formed, and so the emissions of D4, D5 and D6 from incineration are expected to be small compared with those from other sources[103].

D4, D5 and D6 contain no chromophores that would absorb visible or UV radiation, so direct photolysis is not likely to be significant[104,105,106]. However, indirect photolysis resulting from gas-phase reaction with photochemically-produced hydroxyl radicals occurs (6-16 days), which can be considered relatively long half-lives in air[107,108] and it is related to the potential concern of these substances for long-range environmental transport[109]. However, this topic is still subject of scientific debate as explained below.

[99] Ibid footnotes 78,79,80

[100] Chandra G (1997) Organosilicon materials. The Handbook of Environmental Chemistry, Volume 3 Anthropogenic Compounds, Part H. Berlin: Springer-Verlag

[101] Lehmann R G, Varaprath S, and Frye C L, 1994, Degradation of silicone polymers in soil. Environmental Toxicology and Chemistry, 13, 1061–1064.

[102] Ibid footnotes 78,79,80

[103] Ibid footnotes 78,79,80

[104] ECHA (2018a) Support document for identification of octamethylcyclotetrasiloxane (D4) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: Annex XV report (europa.eu)

[105] ECHA (2018b). Support document for identification of decamethylcyclopentasiloxane (D5) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: Annex XV report (europa.eu)

[106] Ibid footnote 88

[107] ECHA (2015): Persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7, CAS No: 556-67-2) and Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9, CAS No. 541-02-6).

[108] ECHA (2018c). Support document for identification of dodecamethylcyclohexasiloxane (D6) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018.50

[109] Ibid footnote 50

Volatilisation and hydrolysis of D4, D5 and D6 are expected to be attenuated by adsorption to organic carbon[110] and a significant proportion is expected to distribute to sediment where persistence is expected[83]. Supporting this, the multimedia fate model SimpleBox, version 4.01[111] was used in the Background document to the Opinion on the Annex XV inclusion of these substances, to simulate its fate and environmental distribution, considering environmental emissions to air and water from all uses, including the presence of these compounds as impurities in different cosmetics, other product types and mixtures. Results showed notably larger percentages in the sediment compartment, especially for D6[112].

Consequently, the main compartments affected by the exposure to these substances are the air and sediment compartments. Despite the amount released being expected to be significantly reduced after the proposed REACH restriction enters into force, the concern remains based on the properties of these substances.

D4 has been identified as meeting the criteria for persistent, bioaccumulative, toxic (PBT) according to the REACH Regulation. **No harmonised classification and labelling (T) exist for D5 and D6 under REACH Regulation,** however, these compounds have been identified as very persistent and very bioaccumulative (vPvB) substances and as PBT when containing D4 above or equal to 0.1% w/w. This means that they also meet the criteria for identification as SVHC (Article 57(d) and Article 57(e)) and were included in the Candidate List in June 2018[113,114,115]. Additionally, data from Registration Dossiers for D4, D5, D6, peer reviewed scientific journals, and grey literature have provided the basis for assessment and conclusion against the compliance screening criteria of Annex D of the Stockholm Convention for persistence, bioaccumulation, long-range environmental transport, and adverse effects.

2.2.2 Persistence

The persistence criteria under Annex D of the Stockholm Convention[116] and REACH Annex XIII[117] are provided in Table 2-2.

Table 2-2 Persistence criteria according to Annex D Stockholm Convention and REACH Annex XIII

	Annex D Stockholm Convention	REACH Annex XIII
Persistent in water	Half-life >60 days	Half-life >60 days (marine water) Half-life >40 days (fresh or estuarine water)
Persistent in sediment	Half-life >180 days	Half-life >180 days (marine sediment) Half-life >120 days (fresh and estuarine water sediment)
Persistent in soil	Half-life >180 days	Half-life >120 days
Very persistent in water	-	Half-life >60 days (marine, fresh or estuarine water)

[110] Whelan MJ, van Egmond R, Gore D and Sanders D (2010) Dynamic multi-phase partitioning of decamethylcyclopentasiloxane (D5) in river water, Water Research 44, 3679−3686. https://doi.org/10.1016/j.watres.2010.04.029

[111] Hollander et al. (2016) SimpleBox 4.0: Improving the model while keeping it simple, Chemosphere, 148: 99-107. https://doi.org/10.1016/j.chemosphere.2016.01.006

[112] Ibid footnote 4

[113] European Chemicals Agency (no date) Candidate List of substances of very high concern for Authorisation. Available: Candidate List of substances of very high concern for Authorisation - ECHA (europa.eu) D4

[114] Ibid footnote 113

[115] Ibid footnote 113

[116] Stockholm Convention (2019) Text of the Convention. Available: Annex D - Text of the Stockholm Convention

[117] ECHA (2023) Guidance on Information Requirements and Chemical Safety Assessment - Chapter R.11: PBT/vPvB assessment. Available: IR_CSA_R11_v4.0_202312_en (europa.eu)

	Annex D Stockholm Convention	REACH Annex XIII
Very persistent in sediment	-	Half-life >180 days (marine, fresh or estuarine water sediment)
Very persistent in soil	-	Half-life >180 days

Table 2-3 presents an overview of the conclusions for persistence for D4, D5 and D6 based on the Annex D and REACH criteria.

Table 2-3 Persistence conclusions - Annex D and REACH

Substance	Annex D			REACH (vP criteria)		
	Water	Sediment	Soil	Water	Sediment	Soil
D4	x	x		x	x	
D5	x	x		x	x	
D6	x	x		x	x	

D4 half-life in water is relatively short, ranging from 2.9 to 16.7 days[118], values being dependant on pH and water temperature. In freshwater sediment, D4 has a degradation half-life of the order of 242 – 365 days at 24 °C, expected to be longer at lower temperatures[119,120,121]. It is therefore concluded that D4 meets Annex D criteria for a persistent substance, as well as Annex XIII criteria for a very persistent (vP) substance, in sediment (a decision cannot be made for water or soil).

D5 has an hydrolysis half-life between 64 and 315 days[122], values being also lower at higher pH and lower temperature. It has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24 °C, expected to be longer at lower temperature[123,124].Therefore, D5 meets the Annex D criteria for a persistent substance and Annex XIII criteria for a very persistent (vP) substance, in water and sediment (a decision cannot be made for soil). It is important to note that, the significance of hydrolysis for D4 and D5 has been proved on clean water test systems, but the high tendency of these compounds to adsorb to sediment and particles are important factors hindering hydrolysis and should be further taken into account.

Hydrolysis is unlikely to be a relevant degradative pathway for D6, with a half-life in water being >1 year at pH 7 and 25 °C. No information on simulation tests in water and sediment is available for D6. Read-across from D4 and D5 to D6 has been considered appropriate for the assessment of persistence. Based on the comparison of physico-chemical properties of D4, D5 and D6, D6 can be expected to be more persistent than D4 and D5[125].

D4, D5 and D6 degrade rapidly in dry soils (e.g., the soil half-life was estimated to be around 4.1 – 5.3 days for temperate soils at a relative humidity of 50 - 90% for D4, and 0.08 days and 1.86 days at a relative humidity of 32% for D5 and D6, respectively)[126]. However, the rate of reaction reduces

[118] ECHA (2015): Persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7, CAS No: 556-67-2) and Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9, CAS No. 541-02-6). Annex 2.78

[119] Xu S. (2009a) Aerobic transformation of octamethylcyclotetrasiloxane (14C-D4) in aquatic sediment systems HES Study No. 10885-108

[120] Xu S. (2009b) Anaerobic transformation of octamethylcyclotetrasiloxane (14C-D4) in aquatic sediment systems. HES Study No. 11101-108

[121] Ibid footnote 89

[122] Ibid footnote 79

[123] Ibid footnote 87 Annex 3.

[124] Xu S (2010) Aerobic and anaerobic transformation of 14C-decamethylcyclopentasiloxane (14C-D5) in the aquatic sediment systems. HES Study No 10886-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[125] Ibid footnotes 88,91

[126] Ibid footnote 49

markedly with increasing soil moisture content [127, 128]. The increase in moisture of the soil is thought to decrease the surface acidity and thus the hydrolysis rate. Yet, due to their physico-chemical properties, volatilization is expected to be the predominant loss pathway of these substances in humid soils[129]. For D6, the case might be slightly different, since its high potential of adsorption to sediment and soil (high Koc value) is expected to limit its potential for volatilisation, with half-lives up to ca. 200 days with 90% relative humidity[130]. Nevertheless, current data do not allow reliable half-lives to be derived that can be compared with the Annex D and Annex XIII criteria.

The inclusion of persistence among the screening criteria is strongly motivated by its relevance as an indicator of the reversibility of exposure upon cessation of emissions. As a counterpart, it is important to consider that air is considered the major receiving compartment of these substances, where they are degraded more rapidly than in other matrices. In case of a cessation of emissions, multimedia modelling studies[131] show a relatively fast initial reduction in concentrations even in sediment, which is caused by the degradation of the airborne cyclics.

In addition, recent studies[132,133] showing biotransformation of cyclics by sediment organisms, refer to the fact that "*Persistence is evaluated by measuring the compound's microbial degradation half-lives in water, sediment or soil (in the absence of eukaryotes)*", which leads to the conclusion by the authors that "*interactions between microbes and eukaryotes enhance microbial activity, which may further increase microbial degradation, thereby decreasing P below what is measured in standard tests*." Multimedia modelling allows incorporation of all these factors to understand the reversibility of these substances[134]. Therefore, reversibility seems to be possible, but further assessments are needed.

2.2.2.1 Long-range transport

Due to their physico-chemical properties, D4, D5 and D6 seem to have the potential to undergo long-range environmental transport (LRET) to remote regions via the atmosphere. Some modelling approaches predict long-range atmospheric transport for these substances with a low potential for deposition to surface media and monitoring data in remote regions could support the potential for transfer to a receiving environment, via air, water and migratory species[135, 136, 137, 138, 139, 140].

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[127] Xu S (1999) Fate of cyclic methysiloxanes in soils. 1. The degradation pathway. Environ. Sci. Technol., 33, 603-608. Available: Fate of Cyclic Methylsiloxanes in Soils. 1. The Degradation Pathway | Semantic Scholar

[128] Xu S and Chandra G (1999) Fate of cyclic methylsiloxanes in soils. 2. Rates of degradation and volatilization. Environ. Sci. Technol., 33, 4034-4039. Available: Fate of Cyclic Methylsiloxanes in Soils. 2. Rates of Degradation and Volatilization | Semantic Scholar

[129] Ibid footnote 87

[130] Ibid footnote 49

[131] Kim et al., (2018) Predicted persistence and response times of linear and cyclic volatile methylsiloxanes in global and local environments. Chemosphere, 195, 315-335. https://doi.org/10.1016/j.chemosphere.2017.12.071

[132] Selck, H., Windfeld, R., & Van Dinh, K. (2019) Biotransformation of benthic invertebrates impacts persistence and bioaccumulation of sediment-associated cyclic siloxanes (D4, D5, D6). In Society of Environmental Toxicology and Chemistry North America 40th Annual Meeting (pp. 91-91). Society of Environmental Toxicology and Chemistry

[133] Selck H. and Forbes V. 2018. Current risk assessment frameworks misjudge risks of hydrophobic chemicals. Environmental Science & Technolgy 52, 1690-1692.(Lower Reliab. Score as it doesn't refer specifically to cVMS, but used as it is closely related as biochemical processes affecting degradation of highly Hidrophobic organic compounds)

[134] Kim 2018. Predicted persistence and response times of linear and cyclic volatile methylsiloxanes in global and local environments. Chemosphere, 195:315-335.

[135] Genualdi S, Harner T, Cheng Y, MacLeod M, Hansen KM, van Egmond R, Shoeib M and Lee SC (2011) Global distribution of linear and cyclic volatile methyl siloxanes in air. Environmental Science & Technology, 45, 3349-3354. https://doi.org/10.1021/es200301j

[136] Krogseth IS, Kierkegaard A, McLachlan MS, Breivik K, Hansen KM, Schlabach M (2013). Occurrence and seasonality of cyclic volatile methyl siloxanes in arctic air. Environmental Science & Technology, 47, 502-509. https://doi.org/10.1021/es3040208

[137] NILU [Norwegian Institute for Air Research] (2014) Monitoring of Environmental Contaminants in Air and Precipitation, Annual Report 2013. Kjeller, NILU (Miljødirektoratet rapport, M-202/2014) (NILU OR, 29/2014). Available from: https://www.miljodirektoratet.no/globalassets/publikasjoner/M202/M202.pdf

[138] Sanchís J, Cabrerizo A, Galbán-Malagón C, Barceló D, Farré M and Dachs J (2015a) Unexpected occurrence of volatile dimethylsiloxanes in Antarctic soils, vegetation, phytoplankton, and krill. Environmental Science & Technology, 2015, 49, 4415–4424. https://doi.org/10.1021/es503697t

[139] Sanchís J, Cabrerizo A, Galbán-Malagón C, Barceló D, Farré M and Dachs J (2015b) Response to Comments on "Unexpected Occurrence of Volatile Dimethylsiloxanes in Antarctic Soils, Vegetation, Phytoplankton and Krill". Environmental Science & Technology, 2015, 49, 7510–7512. http://dx.doi.org/10.1021/acs.est.5b02184

[140] Augusto S (2019) Bioconcentration, Bioaccumulation, and Biomagnification of Volatile Methylsiloxanes in Biota. In: Homem, V., Ratola, N. (eds) Volatile Methylsiloxanes in the Environment. The Handbook of Environmental Chemistry, vol 89. Springer, Cham. https://doi.org/10.1007/698_2019_387

The presence of D4, D5 and D6 in remote areas may be explained by atmospheric transport and binding to aerosols, followed by a possible deposition (via rain and snow), gaseous deposition (e.g., on foliage) and dry aerosol-bound deposition (including on inorganic aerosols)[141]. Other supporting facts are the measured levels of D4, D5 and D6 in deep marine sediments from the Norwegian Arctic seawaters, the Canadian Archipelago, the Arctic Ocean, the Atlantic Ocean, and the Pacific Ocean could indicate a potential of D4, D5 and D6 for long-range transport via the adsorption onto suspended matter and subsequent transport to sediment via water in rivers and ocean currents[142]. Additionally, the presence of D4, D5 and D6 in migratory species in locations distant from known point sources such as Liefdefjorden, Billefjorden, Moffen and Bjørnøya in Svalbard[143,144,145] suggest that these species might be exposed from remote sources and impact could be transferred across regions. Based on this evidence, it can be suggested that the potential for long-range transport make emissions of these substances a transboundary pollution risk and measures taken nationally or regionally may not be sufficient to safeguard a high level of protection of the environment and human health. This may suggest that wider international action is necessary.

On the other hand, the Committee for Risk Assessment (RAC) notes that the long-range transport potential of D4, D5 and D6 are still the subject of scientific debate, and definitive conclusions cannot be made on this topic. The assumption is that all the monitoring data in remote regions is reliable, and not a result of artifact, contamination, or a local source, which have been identified as a challenge in assessing the reliability of remote monitoring data[146147]. Moreover, UK governmental reports from the Environmental Agency[148,149] support that D4 and D5 have long-range transport potential through air, but deposition on surface media is unlikely based on their physico-chemical properties; while D6 shows low long-range transport potential[150]. Canadian screening assessments for D4 and D6[151,152] support the long-range potential of these substances, but again, unlikely deposition. Therefore, although the Commission has presented evidence for potential long-range environmental transport, the evidence has been determined to be inconclusive and so LRET is not assessed further in this Study.

Based on their potential release scenarios and partitioning properties, two transport media can be considered for cVMS: air and water. However, based on the results of two model simulations carried out and submitted as part of the Global Silicones Council (GSC) comments to ECHA's draft dossier for D4, D5 and D6, the removal of cVMS from water in the natural environment is rapid, suggesting that water cannot be considered as an effective transport medium. For example, using measured

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[141] McLachlan MS (2018) Atmospheric Fate of Volatile Methyl Siloxanes. In: Homem, V., Ratola, N. (eds) Volatile Methylsiloxanes in the Environment. The Handbook of Environmental Chemistry, vol 89. Springer, Cham. https://doi.org/10.1007/698_2018_371

[142] Kneller B, Nasr-Azadani MM, Radhakrishan S, Meiburg E (2016). Long-range sediment transport in the world's oceans by stably stratified turbidity currents. JGR Oceans. Volume121, Issue12 December 2016, 8608-8620. https://doi.org/10.1002/2016JC011978

[143] Campbell R (2010) A collaborative assessment of cyclic volatile methylsiloxanes (D4, D5, D6) concentrations in the Norwegian Environment. HES Study No. 11061-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[144] Warner NA, Evenset A, Christensen G, Gabrielsen GW, Borgå K and Leknes H (2010) Volatile siloxanes in the European Arctic: Assessment of sources and spatial distribution. Environ. Sci. Technol., 44, 7705-7710. https://doi.org/10.1021/es101617k

[145] Warner NA, Kozerski G, Durham J, Koerner M, Gerhards R, Campbell R and McNett DA (2013). Positive vs. false detection: A comparison of analytical methods and performance for analysis of cyclic volatile methylsiloxanes (cVMS) in environmental samples from remote regions. Chemosphere, 93(5), 749–756. doi: 10.1016/j.chemosphere.2012.10.045

[146] Krogseth IS and Warner NA. (2019). Volatile Methyl Siloxanes in Polar Regions. Pp 279-314. In: Homem V and Ratola N (eds) Volatile Methylsiloxanes in the Environment. The Handbook of Environmental Chemistry, Vol 89. Springer, Cham. https://doi.org/10.1007/698_2019_388

[147] AMAP 2017

[148] Environment Agency (2009a) Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane. Environment Agency Science Report, SCHO0309BPQZ-E-P, April 2009. ISBN 978-1-84911-031-0.

[149] Environment Agency (2009b) Environmental risk evaluation report: Decamethylcyclopentasiloxane. Environment Agency Science Report SCHO0309BPQX-E-P, April 2009. ISBN 978-1-84911-029-7.

[150] Environment Agency (2009c) Environmental risk evaluation report: Dodecamethylcyclohexasiloxane. Environment Agency Science Report SCHO0309BPQY-E-P, April 2009. ISBN 978-1-84911-030-3.

[151] Environment Canada, Health Canada (2008a). Screening Assessment for the Challenge. Octamethylcyclotetrasiloxane (D4). Chemical Abstracts Service Registry Number 556-67-2. Ottawa (ON): Government of Canada. November 2008.

[152] Environment Canada, Health Canada (2008c). Screening Assessment for the Challenge. Dodecamethylcyclohexasiloxane (D6). Chemical Abstracts Service Registry Number 540- 97-6. Ottawa (ON): Government of Canada. November 2008.

partition coefficients[153] and media-specific half-lives[154] as inputs, the characteristic travel distance (CTD), a long-range transport potential (LRTP) metric, of D4 in water is around 9 km when using the OECD Tool[155]. Similarly, an estimated CTD value of 167 km could be obtained using the TaPL3 model[156] based on the default conditions, including the standard temperature of 25 °C, an average concentration of suspended sediment particulate of 7.5 mg m^{-3}, water depth of 5 m, and water flow velocity of 1 m s^{-1} (86 km/d). Using the same approach, the CTD values in the water were found to vary from 88 km for D5 to 597 km for D6. Kneller et al., 2016 suggests that sediment particles can be transported longer distance in turbulent currents in the ocean compared to non-turbulent flow. However, to link this particle transport to cVMS transport in the ocean, one needs to know how a cVMS-containing sediment plume may be carried by turbulent currents. Adsorption/desorption studies have demonstrated that when D4, D5 and D6 adsorb to sediment particles, they have very fast desorption kinetics[157] and the desorbed D4, D5 and D6 have relatively fast hydrolysis kinetics in sea water (due to high pH). Therefore, sediment-bound cVMS will be dissipated rapidly once desorbed. In the TaPL3 model, the organic carbon in the suspended particulates (e.g., re-suspended sediment as default conditions) has been considered [as default conditions] and thus this modelling also includes the role that suspended natural sediment particles might play in the long-range transport of cVMS in water. The estimated short CTD values indicate that the re-suspended sediment particulates in the natural water body could not be an effective carrier for long-range transport of cVMS, especially for D4 and D5.

Additionally, scientific experts defend that all monitoring data available on these substances should be assessed for reliability and in remote regions assessed for being associated with a potential local source. This should be done to ensure the reliability of the data and that the presence is representative of long-range environmental transport.

2.2.3 Environmental hazards

2.2.3.1 Aquatic organisms

D4 has a harmonised classification of Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects[158]. The lowest chronic toxicity value from the studies accepted by the RAC was a NOEC of 7.9 µg/L for aquatic invertebrates. Following the criteria for long-term (chronic) hazard, D4 warrants classification as Aquatic Chronic 1; H410 with an M-factor of 10 (not rapidly degradable and chronic toxicity in range of 0.01mg/l < NOEC ≤ 0.001mg/l)[159,160,161].

D4 shows potential long-term chronic effects on fish, aquatic invertebrates (including sediment organisms) and algae. A 14-day NOEC of 4.4 µg/L was found in a prolonged acute test based on mortality. However, the same study also showed a 93-day long-term NOEC of ≥4.4 µg/L on fish early life stage based on embryo viability, hatching success, larval survival and growth with the same

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153 Xu (2014) Critical review and interpretation of environmental data for volatile methyl siloxanes: partition properties, Env Sci & Technol,, 48, 11748-11759. https://doi.org/10.1021/es503465b
154 Xu S and Wania F (2013). Chemical fate, latitudinal distribution and long-range transport of cyclic volatile methylsiloxanes in the global environment: a modelling assessment, Chemosphere, 93, 835–843. https://doi.org/10.1016/j.chemosphere.2012.10.056
155 Wegmann, F., Cavin, L., MacLeod, M., Scheringer, M., & Hungerbühler, K. (2009). The OECD software tool for screening chemicals for persistence and long-range transport potential. Environmental Modelling & Software, 24(2), 228-237.
156 Beyer, A., Mackay, D., Matthies, M., Wania, F., Webster, E. 2000. Assessing Long-range Transport Potential of Persistent Organic Pollutants. Environ. Sci. Tech. 34: 699-703
157 Kozerski. G. E., Xu. S., Miller. J., Durham. J. (2014) Determination of soil-water sorption coefficients of volatile methylsiloxanes. Environmental Toxicology and Chemistry. 33. 9. 1937-1945
158 Ibid footnote 44
159 Ibid footnote 50
160 ECHA (2018) Agreement of the MSC on the identification of octamethylcyclotetrasiloxane (D4) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: 680ea46d-b626-1606-814e-62f843fe2750 (europa.eu)
161 ECHA (2018) Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier proposing harmonised classification of OCTAMETHYLCYCLOTETRASILOXANE. Available: echa.europa.eu/documents/10162/2af6a9de-216c-dc41-859d-95aa8c9c14a7

species (this was the highest concentration tested and no adverse effects were observed) [162,163]. Therefore, it cannot be ruled out that effects might have been observed at higher concentrations (as suggested by the prolonged acute test). The RAC have assumed that the long-term NOEC for fish is around 4 – 6 µg/L, although note that there is some uncertainty in this value. The authors highlight the low representativeness of the experimental design in this study with respect to real environmental conditions. Moreover, Mackay et al. (2015)[164], supported by Fairbrother and Woodburn (2016)[165], Bridges and Solomon (2016)[166] and Nusz et al. (2018)[167], defend that observed effects are related to a narcosis mode of action (MoA), which is dependent on fish species and conditions that would support enough uptake of D4 to lead to the nonspecific effect of narcosis. These conditions would not happen under typical environmental conditions where, when D4 is released to water, the competing processes would prevent uptake of D4 to a high enough concentration to elicit the non-specific membrane effects.

D4 is potentially toxic to aquatic invertebrates (Daphnia magna) following chronic exposure with a 21-day NOECsurvival of 7.9 µg/L[168]. There has also been discussion regarding the validity of the initially reported NOEC value for survival of 7.9 µg/L. The overall survival rate of 77% in the high dose group is the arithmetic mean of just 2 replicates, where in fact only in 1 replicate was there a survival rate below 80% (replicate 1: 67%; replicate 2: 87%)[169].

An EC_{10} value very close to the solubility limit of D4 (around 51 µg/L) was found for algae[170]. This result was interpreted by the Commission as a moderate chronic toxicity to algae. QSAR data in Environment Agency (2009a)[171] further confirm that algae should not be more sensitive to D4 than fish or invertebrates.

The available aquatic toxicity data for fish, invertebrates and algae show that D5 does not cause toxic effects in neither short- nor long-term studies at concentrations up to (or close to) its water solubility limit[172]. However, there is potential long-term toxicity for sediment organisms, and for terrestrial organisms.

For D6, there is no data for short-term toxicity for fish or aquatic invertebrates. Based on data from long-term studies there isn’t potential long-term toxicity for fish, aquatic invertebrates and algae, showing no effects at maximum concentration tested or effects at concentrations above the solubility limit[173].

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[162] Ibid footnote 104

[163] Sousa JV, McNamara PC, Putt AE, Machado MW, Surprenant DC, Hamelink JL and Kent JK (1995) Effects of octamethylcyclotetrasiloxane (OMCTS) on freshwater and marine organisms. Environmental Toxicology and Chemistry, 14, 1639–1647. https://doi.org/10.1002/etc.5620141003

[164] Mackay, D., Cowan-Ellsberry, C. E., Powell, D. E., Woodburn, K. B., Xu, S., Kozerski, G. E., & Kim, J. (2015) Decamethylcyclopentasiloxane (D5) environmental sources, fate, transport, and routes of exposure. Environmental toxicology and chemistry, 34(12), 2689-2702. https://doi.org/10.1002/etc.2941

[165] Fairbrother, A., & Woodburn, K. B. (2016). Assessing the aquatic risks of the cyclic volatile methyl siloxane D4. Environmental Science & Technology Letters, 3(10), 359-363. DOI: 10.1021/acs.estlett.6b00341

[166] Bridges and Solomon (2016) Quantitative weight-of-evidence analysis of the persistence, bioaccumulation, toxicity, and the potential for long-range transport of the cyclic volatile methyl siloxanes. Journal of Tox and Envir Health, Part B Critical Reviews, 19, 345-379. https://doi.org/10.1080/10937404.2016.1200505

[167] Nusz, J. B., Fairbrother, A., Daley, J., & Burton, G. A. (2018) Use of multiple lines of evidence to provide a realistic toxic substances control act ecological risk evaluation based on monitoring data: D4 case study. Science of the Total Environment, 636, 1382-1395. https://doi.org/10.1016/j.scitotenv.2018.04.335

[168] Ibid footnote 163

[169] Ibid footnote 89

[170] Trac LN, Schmidt SN and Mayer P (2018). Headspace passive dosing of volatile hydrophobic chemicals – Aquatic toxicity testing exactly at the saturation level. Chemosphere, 211, 694–700. https://doi.org/10.1016/j.chemosphere.2018.07.150

[171] Ibid footnote 78

[172] Ibid footnote 87 Annex 3

[173] Ibid footnote 91

2.2.3.2 Sediment organisms

The lowest NOEC on survival/reproduction for D4 is <0.73 mg/kg dry weight (dw), obtained in a 28-day study with *Lumbriculus variegatus*[174]. If the results are normalised to a standard organic carbon (OC) content of 5%, the NOEC standard is <1.5 mg/kg dw. For comparison with pelagic organisms (assuming that the effects occur due to exposure via pore water), the equivalent pore water concentration is estimated to be around <2 µg/L using the methods outlined in the REACH Guidance[175]. This value is well below the solubility limit of the substance (56.2 µg/L), indicating that D4 may be toxic to sediment organisms. However, that study had significant flaws, including non-synchronized worms, high pH, and insufficient equilibration time. In addition, the NOEC from this study has been described as a statistical outlier when compared to several other benthic invertebrate studies available for D4[176,177]. In this line, the study by Picard (2009)[178] with a 28-day NOEC on survival/growth of 13 mg/kg dw for *L. variegatus* seem to be a more representative endpoint, as no significant protocol deviations are identified, and natural sediment is used in the assessment.

D5 is potentially toxic to sediment organisms. The lowest NOEC from long-term studies with sediment are 70 mg/kg dw for *Ch. riparius* based on development rate[179]. A lower value based on mortality of *H.azteca* equal to 62 mg/kg dw was found in Norwood et al. 2013[180], but this value was revised and a NOEC of 130 mg/kg dw was found for this species in a second study, in which the influence of sediment characteristics (organic carbon content, particle size) was better assessed[181]. If the *Ch.riparius* results are normalised to a standard organic carbon content of 5%, the lowest NOECstandard is 109 mg/kg dw for *Ch. riparius*. The equivalent pore water concentration is estimated to be around 0.014 mg/L using the methods outlined in the REACH Guidance. This value is below the solubility limit for D5 in pure water, indicating that D5 may be toxic to sediment organisms. Discussion around this conclusion defend that, first, the equivalent pore water concentration is actually calculated as 14.79 µg/L (~15 µg/L). Second, at this calculated pore water concentration there were no effects, since the equilibrium partitioning calculation uses the organic carbon normalized NOEC from the study. In contrast, the equivalent pore water concentration based on the organic carbon normalized LOEC is 33.8 µg/L, significantly above the limit of water solubility of D5 (17 µg/L).

For D6, potential long-term toxicity for sediment organisms is expected. The lowest NOEC for long-term sediment toxicity studies is <22 mg/kg dw for *Chironomus riparius*[182]. The normalised to a standard OC content of 5% is a NOECstandard < 41 mg/kg dw for *Ch. riparius*. For comparison with pelagic organisms (assuming that the effects occur due to exposure via pore water), the equivalent pore water concentration is calculated to be around <0.7 µg/L (below its water solubility of 5.3 µg/L), indicating potential toxicity of D6 to sediment organisms. It is worth noting that in some studies across

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[174] Krueger HO, Thomas ST and Kendall TZ (2009) D4: A prolonged sediment toxicity test with Lumbriculus variegatus using spiked artificial sediment. Project Number 570A-110B. Wildlife International Ltd, Maryland. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC).

[175] Ibid footnote 49

[176] Bridges and Solomon (2016) Quantitative weight-of-evidence analysis of the persistence, bioaccumulation, toxicity, and the potential for long-range transport of the cyclic volatile methyl siloxanes. Journal of Tox and Envir Health, Part B Critical Reviews, 19, 345-379. https://doi.org/10.1080/10937404.2016.1200505

[177] Woodburn et al (2018) Benthic invertebrate exposure and chronic toxicity risk analysis for cyclic volatile methylsiloxanes: comparison of hazard quotient and probabilistic risk assessment approaches. Chemosphere, 192, 337-347. https://doi.org/10.1016/j.chemosphere.2017.10.140

[178] Picard C (2009) D4 – Sediment-water Lumbriculus toxicity test using spiked natural sediments, following OECD Guideline 225. 27 August 2009. Springborn Smithers Laboratories, Wareham, Massachusetts, Study No 13937.6013. Unpublished study submitted to CES 96 (Centre Européen des Silicones, European Chemicals Industry Council (CEFIC)).

[179] Krueger HO, Thomas ST and Kendall TZ (2008) D5: A Prolonged Sediment Toxicity Test with Chironomus riparius using Spiked Sediment. Final Report, Project Number 570A-108, Wildlife International Ltd, Maryland. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[180] Norwood. W. P., Alaee. M., Sverko. E., Wang. D., Brown. M., Galicia. M. (2013) Decamethylcyclopentasiloxane (D5) spiked sediment: Bioaccumulation and toxicity to the benthic invertebrate Hyalella azteca. Chemosphere 93, 5, 805-812

[181] Springborn Smithers (2009) Decamethylcyclopentasiloxane. Available: Registration Dossier - ECHA (europa.eu)

[182] Wildlife International Limited (2009) D6: Prolonged sediment toxicity test with Chironomus riparius using spiked artificial sediment. Unpublished study. Project No. 570A-109B. Wildlife International, Ltd. 8598 Commerce Drive Easton, Maryland 21601, USA. In Registration Dossier - ECHA (europa.eu)

the range of siloxanes with sediment toxicity data available, the observations indicate in general no effects, or an organic carbon normalised NOEC ≥30 mg/kg dw. Consideration of the possible contributing factors that could have caused high toxicity in these studies, led to an understanding of the importance of certain factors of the test design, particularly the use of artificial sediment with a peat-based carbon source, and elevated pH in the test system [183] (as for D4 and D5). Similar to the comment with regards to the D4 *Lumbriculus* study (Krueger et al. 2009)[184], the response from the D6 *Chironomus* study conducted with artificial sediment[137] was not replicated when the study was conducted with natural sediment[185]. The NOEC from this study is 260 mg/kg dw and the equivalent pore water concentration is calculated to be 30 µg/L, well above the water solubility of 5.3 µg/L.

It should be noted that for all 3 siloxanes, studies using natural sediment with a pH of <8 show no effect or a higher NOEC than those for artificial sediment. This has to do with the binding affinity of these substances to OC which, when using natural sediment, is more representative of real-world environment behaviour. As stated in the paper by Bridges and Solomon (2016), the use of peat as the only source of organic matter in studies with artificial sediment, is a major weakness of sediment studies and does not mimic what might occur in the natural environment. Moreover, in the study by Woodburn et al. (2018) a quantitative risk assessment of D4, D5 and D6 with benthic invertebrate species was performed. These researchers used standard risk evaluation methods and a fugacity approach to allow a comparison of divergent field data collected in concentrations expressed on a mass or lipid basis to toxicity levels typically expressed on the basis of volume or mass; both simple HQ and more detailed probabilistic risk assessment (PRA) methods were examined. The results noted that risk outcomes were consistent between HQ and PRA methods. No risk was predicted for D4 or D5 and negligible risk (HQ ~1) predicted for D6; sediment fugacities indicate that a negligible risk (1%) exists for benthic species exposed to D6.

2.2.3.3 Terrestrial organisms

As regards toxicity to terrestrial organisms, limited toxicity test data are available for D4. Some effects were observed on the reproduction of the earthworm *Eisenia fetida*, with 56-day NOEC value of 75 mg/kg dw, a LOEC value of 130 mg/kg dw and an EC_{50} value of >130 mg/kg dw on reproduction, based on mean measured test item concentrations. No effects on survival or weight were reported. No significant effects were observed on soil microbiota[186].

D5 has been shown to cause effects in long-term toxicity tests on two plant species (barley *Hordeum vulgare* and durum wheat *Triticum durum*), springtails *Folsomia candida* and earthworms *Eisenia andrei*. A 28-day LC_{50} value of >4074 mg/kg dw and a 56-day NOEC of ≥4074 mg/kg dw have been determined for the effects of the test substance on reproduction and growth, respectively, of *Eisenia andrei*[187]. A NOEC of 377 mg/kg dw has been determined by the Registrant on the basis of a visual examination of the data for both mortality and reproduction of *Folsomia candida*[188]. The lowest reported IC_{50} was 209 mg/kg dw for barley (individual dry mass of barley roots after 14 days); other effects were noted at higher concentrations on shoot and root length)[189,190]. Significant loss through volatilisation would be expected in the test system used and so the actual exposure concentrations (and hence effect concentrations) may be significantly lower than those based on the initial concentration. On the other hand, it should also be noted that plant root development is species

[183] Ibid footnote 91
[184] Ibid footnote 174
[185] Springborn Smithers Laboratories (2010). D6 – Toxicity Test with Sediment-Dwelling Midges (Chironomus riparius) Under Static Conditions, Following OECD Guideline 218. Springborn Smithers Laboratories, 790 Main Street, Wareham, Massachusetts., Springborn Smithers Unpublished Study No. 13937.6108.
[186] Ibid footnote 89
[187] Unnamed study report (2011) D5 toxicity to soil organisms Eisenia andrei. Available: Registration Dossier - ECHA (europa.eu)
[188] Velicogna J, Ritchie E, Princz J, Lessard ME and Scroggins R (2012) Ecotoxicity of siloxane D5 in soil. Chemosphere, 87, 77-83. https://doi.org/10.1016/j.chemosphere.2011.11.064
[189] Ibid footnote 90
[190] Ibid footnote 87 Annex 3

dependant and can be influenced by various factors such as soil type, nutrient availability, and environmental conditions[191].

For D5, no adverse effects have been observed in an avian reproduction test using Japanese quail (*Coturnix coturnix japonica*) at concentrations up to 1,000 mg/kg feed[192].

Limited toxicity data has been identified for D6 with regard to terrestrial organisms, including birds.

Hereby the fulfilment of the T criterion for Annex D criteria can be supported, as it represents a potential risk for a harm to the environment. However, when actual measured concentrations from existing studies are considered, the level of risk should be considered carefully. Available measured D4 concentration in water (influent, effluent and surface water) were always below the NOEC threshold (see Registration Dossier Octamethylcyclosiloxane), with the exception of a study performed in Norway[193] in which the maximum concentrations found were 9.1 and 12 µg/L. No data on D5 measured concentrations in water have been found for this Study. D6 concentration in surface water were always below the NOEC threshold (see Reg. Dossier for D6).

With respect to sediment reported data for D4, a median value equal to 0.0223 mg/kg dw can be considered as a reference, with values ranging from 0 - 0.63 mg/kg dw. There were several studies showing concentrations around 0.3 mg/kg dw; still, this remains below the lowest NOEC of <0.73 mg/kg dw. No data on D5 sediment concentration has been obtained for this Study. For D6, a median value equal to 0.008 mg/kg dw can be considered as a reference, with values ranging from 0 - 0.197 mg/kg dw. There were several studies showing concentrations around 0.1-0.2 mg/kg dry dw; still, this remains below the lowest NOEC of <22 mg/kg dw.

Due to the high volatility and fast degradation described for D4 in soil, together with the lack of measured data, conclusions on the risk to soil organisms should be also taken with care. There is no indication as to the expected concentration range of D5 in biosolids in the literature; however, concentrations of D5 in agricultural fields recently spread with biosolids, have been measured at <1 µg g^1 based on dry mass[194] . Environmental data on soil concentrations for D6 was not found for this Study.

2.2.3.4 Bioaccumulation

Despite the fact that toxicity can be properly justified only in some cases, for all 3 substances, attention should be paid to the potential risks associated with bioaccumulation and biomagnification along the food-chain.

The Annex D criteria for bioaccumulation are considered to be met for D4, D5 and D6 as BCF values exceed 5000 L/kg and log Kow are greater than 5 in all cases.

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[191] Sierra Cornejo, N., Hertel, D., Becker, J. N., Hemp, A., & Leuschner, C. (2020) Biomass, morphology, and dynamics of the fine root system across a 3,000-m elevation gradient on Mt. Kilimanjaro, Frontiers in plant science, 11, 13. https://doi.org/10.3389/fpls.2020.00013

[192] Stafford JM (2012) Japanese quail (Coturnix coturnix japonica) reproduction toxicity range-finding test with decamethylcyclopentasiloxane. Unpublished Study Number 12023.4101, Smithers Viscient Laboratory, Snow Camp, North Carolina. Study sponsor: Silicones Environmental Health and Safety Committee. Available: Registration Dossier - ECHA (europa.eu)

[193] Norwegian Environment Agency and COWI (2017). Screening programme 2017 Testing laboratory: Not reported. Study No. M-1063. Report date: 2018

[194] Alaee, M., Steer, H., Wang, D., Young, T., Pacepavicius, G., Tait, T., Smythe, S.A., Ng, T., Kinsman, L., Williams, Z., Barclay, K., 2010. D5 sampling and analysis; logistic overview May – October 2010. Siloxane Express Workshop, Burlington, ON September 27–28, 2010 (Internal Environment Canada Document).

Key steady-state BCF data are 12,400 L/kg for Fathead Minnow (*Pimephales promelas)*[195] and in the range of 3000 – 4000 L/kg Common Carp (*Cyprinus carpio)*[196,197,198].The result for *P. pomelas* clearly meets the REACH Annex XIII criteria for very bioaccumulative (vB) substance and the Annex D criteria. Yet, the depuration half-life for *C.carpio* was estimated to be between 6.5 and 8.8 days and the kinetic BCF growth-corrected in the two studies were in the range 4120–6930 L/kg. Laboratory accumulation studies with the sediment worm *Lumbriculus variegatus* gave biota-sediment accumulation factors (BSAF) of 19–28 for D4[199]. It should be noted that study limitations have been identified because no special measures were taken to avoid loss from volatilisation during the spiking of the sediment or the uptake phase, and the actual number of measurements was low. If it is assumed that exposure was mainly via pore water, the equivalent BCF for D4 is in the approximate range 7000−11 000 L/kg, although there is considerable uncertainty in these estimates[200].

Evidence for bioaccumulation of D5 can particularly be found in fish and aquatic invertebrates, with steady-state BCF for Fathead Minnow > 7060 L/kg[201] and >10 000 L/kg in Common Carp[202]. Moreover, a long depuration half-life between 19 and 22 days was estimated for D5 for this species. A bioaccumulation factor (BSAF) of 0.53–4.1 for *Lumbriculus variegatus* has been also reported[203], but study limitations as in Krueger et al. (2008)[204] have been detected. As for D4, the calculated equivalent BCF D5 is in the approximate range 2400−10 000 L/kg[205].

The uptake of D6 by fish has been demonstrated, however the available feeding studies are not sufficiently accurate to allow a reliable accumulation to be determined. The most reliable reported steady-state BCFs are of 1160 l/kg in Fathead Minnow[206] and kinetic BCF values of 4419 – 12 632 l/kg in Common Carp[207].

There is also evidence that D4 and D5 can be found in a wide range of organisms, particularly fish and aquatic invertebrates but also birds and mammals[208]. Concentrations are generally relatively low, up to 900 µg/kg wet weight for D4 in some wild fish species at locations with significant local

[195] Fackler PH, Dionne E, Hartley DA and Hamelink JL (1995) Bioconcentration by fish of a highly volatile silicone compound in a totally enclosed aquatic exposure system. Environ. Toxicol. Chem., 14, 1649-1656. https://doi.org/10.1002/etc.5620141004
[196] Ibid footnote 89
[197] CERI (2007) Bioconcentration study of octamethylcyclotetrasiloxane (test item number K-1788) in carp. Study No 505113. Chemicals Evaluation & Research Institute (CERI). In Registration Dossier - ECHA (europa.eu)
[198] CERI (2010) Bioconcentration study of octamethylcyclotetrasiloxane (test item number K-1788) in carp. Study No 505177. Chemicals Evaluation & Research Institute (CERI) (report in Japanese). In Registration Dossier - ECHA (europa.eu)
[199] Krueger HO, Thomas ST and Kendall TZ (2008) Octamethylcyclotetrasiloxane (D4): A bioaccumulation test with Lumbriculus variegatus using spiked sediment. Final Report, Project Number: 570A-111, Wildlife International Ltd, Maryland. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).
[200] Ibid footnote 49
[201] Drottar KR (2005) 14C-Decamethylcyclopentasiloxane (14C-D5): Bioconcentration in the Fathead Minnow (Pimphales promelas) under Flow-Through Test Conditions. Unpublished HES Study No. 9802-102. Auburg, MI: Health and Environmental Sciences, Dow Corning Corporation.
[202] CERI (2010) Bioconcentration study of decamethylcyclopentasiloxane (test item number K-1842) in carp. Study No 505175. Chemicals Evaluation & Research Institute (CERI) (report in Japanese). In Registration Dossier - ECHA (europa.eu)
[203] Krueger HO, Thomas ST and Kendall TZ (2008) D5: A bioaccumulation test with Lumbriculus variegatus using spiked sediment. Final Report, Project Number: 583A-110, Wildlife International Ltd, Maryland. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).
[204] Ibid footnote 199
[205] Ibid footnote 49
[206] Drottar KR (2005) 14C-Dodecamethylcyclohexasiloxane (14C-D6): Bioconcentration in the Fathead Minnow (Pimphales promelas) under Flow-Through Test Conditions. Unpublished HES Study No. 9882-102. Auburg, MI: Health and Environmental Sciences, Dow Corning Corporation. In Registration Dossier - ECHA (europa.eu)
[207] CERI (2010c) Test Report 2, 2, 4, 4, 6, 6, 8, 8, 10, 10, 12, 12-Dodecamethyl-cyclohexasiloxane. Chemicals Evaluation and Research Institute, Japan. In Registration Dossier - ECHA (europa.eu)
[208] Ibid footnote 87

sources[209,210,211,212], and up to 1-3 mg/kg wet weight for D5[213,214,215] .This is within an order of magnitude of contamination levels (D4) or similar (D5) of other substances (HBCDD and pentaBDE) that are considered to meet the vB criteria.

Toxicokinetic data also indicate that there is evidence that D4 and D5 accumulate in adipose tissue/fat of rats[216]. However, Andersen et al., 2008 defended that D4 and D5 were not bioaccumulating in mammals. Although cVMS are lipophilic and will distribute to fat, they are also eliminated via exhalation and metabolism in the liver with excretion of water-soluble metabolites in the urine and therefore do not bioaccumulate[217]. Other studies defend that siloxanes can be metabolised by benthic organisms[218,219], fish and mammals[220,221], preventing their bioaccumulation.

When considering trophic transfer of cyclic methylsiloxane (cVMS) materials, some studies show that biomagnification or trophic magnification (BMF or TMF>1) is possible for some aquatic food webs; while others also evidence low biomagnification potential and trophic dilution.

BMF key reliable value for D4 in fish was established at 0.47 or 4.6 (growth corrected kinetic lipid normalised) for Rainbow Trout (*Oncorhynchus mykiss*)[222,223,224]. For D5, a dietary growth-corrected and lipid-normalised BMF up to 3.9 was measured in Rainbow Trout *Oncorhynchus mykiss*[225] and 0.96−1.21 for *C. carpio* [226]. As a counterpart, assessment of those studies shows that Rainbow trout in the studies from Dow Corning (2007)[175] and Dow Corning (2006)[178] grew >10 times during the test period of the study. The growth rate was 81% and 74% of total depuration rate, respectively for D4 and D5. In contrast, with a slow-growing carp in CERI (2011)[179], the BMF of D4 was 0.37-0.41 (or 0.51-0.51 with growth correction) and 0.92-0.96 (or 0.48 with growth correction) for D5. Due to the fast growth of the fish, the BMF values are said to be less reliable than those with slow growing fish. In addition, Gobas and Lee (2019) demonstrated that growth corrected kinetic BCF & BMF values can violate the rules of mass balance and result in skewed data[227]. Thus, BMF values obtained from non- or slow-growing fish with no growth correction might be more consistent and reliable. Moreover,

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209 EVONIK Industries (2007) Analysis of cVMS in Fish. Slide presentation. Essen: Evonik Industries.
210 TemaNord (2005) Siloxanes in the Nordic Environment. TemaNord 2005:593, Nordic Council of Ministers, Copenhagen. Available from: http://norden.divaportal.org/smash/get/diva2:702777/FULLTEXT01.pdf
211 Schlabach M, Andersen MS, Green N, Schøyen M and Kaj L (2007) Siloxanes in the environment of the Inner Oslofjord. Report 986/2007, Norwegian Pollution Control Authority, Oslo. https://www.nilu.no/wp-content/uploads/dnn/27-2007-msc.pdf
212 Durham J, Leknes H, Huff D, Gerhards R, Boehmer T, Schlabach M, Green N, Campbell R and Powell D (2009) An inter lab comparison of cyclic siloxanes in codfish collected from the Oslo Fjord. Poster presented at the SETAC Europe 19th Annual meeting, 31 May-4th June 2009, Göteborg, Sweden (as quoted in Norman Bulletin (2009)).
213 Ibid footnote 209
214 Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2009c) Interim Report: Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in the aquatic marine food webs in inner and outer Oslofjord, Norway. Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).
215 Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2010b). Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in the aquatic marine food webs of the inner and outer Oslofjord, Norway. HES Study No. 11060-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).
216 Ibid footnote 49
217 Andersen. 2008. Are highly lipophilic volatile compounds expected to bioaccumulate with repeated exposures? Tox Letters, 179:85-92
218 Ibid footnote 132
219 Ibid footnote 133
220 Gobas, F. A., Powell, D. E., Woodburn, K. B., Springer, T., & Huggett, D. B. (2015). Bioaccumulation of decamethylpentacyclosiloxane (D5): A review. Environmental Toxicology and Chemistry, 34, 2703-2714. https://doi.org/10.1002/etc.3242
221 Gobas, F. A., Xu, S., Kozerski, G., Powell, D. E., Woodburn, K. B., Mackay, D., & Fairbrother, A. (2015) Fugacity and activity analysis of the bioaccumulation and environmental risks of decamethylcyclopentasiloxane (D5). Environmental Toxicology and Chemistry, 34(12), 2723-2731. https://doi.org/10.1002/etc.2942
222 Dow Corning (2007) 14C-Octamethylcyclotetrasiloxane (14C-D4): Dietary bioaccumulation in the rainbow trout (Oncorhynchus mykiss) under flow-through test conditions. Unpublished HES Study No. 10166-101, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).
223 Ibid footnote 89
224 Ibid footnote 87 Annex 2
225 Dow Corning (2006) 14C-Decamethylcyclopentasiloxane (14C-D5): Dietary Bioaccumulation in the Rainbow Trout (Oncorhynchus mykiss) under Flow-Through Test Conditions. Unpublished HES Study No. 10057-108. Auburg, MI: Health and Environmental Sciences, Dow Corning Corporation. In Registration Dossier - ECHA (europa.eu)
226 CERI (2011). D4 and D5 Dietary Accumulation Study in Carp. Report 642-10-S-5608, Chemicals Evaluation & Research Institute (CERI) (report in Japanese). In Registration Dossier - ECHA (europa.eu)
227 Gobas, F.A.P.C. and Lee, Y.-S. 2019. Growth-Correcting the Bioconcentration Factor and Biomagnification Factor in Bioaccumulation Assessments. Environ Toxicol Chem, 38: 2065-2072. DOI: 10.1002/etc.4509

Powell et al. (2009c)[228] reported BMF values below 1 for the majority of selected predator-prey specific relationships, independently of the level of exposure in marine environments. In this case, biomagnification factors greater than 1 were observed only for the cod-shrimp predator-prey relationships.

Additionally, Gobas et al. 2015 demonstrated that fugacity and activity ratios of D5 derived from bioaccumulation measures indicate that D5 does not biomagnify in food webs, likely because of biotransformation[229]. The fugacity and activity analysis further demonstrates that NOECs of D5 normally cannot occur in the environment.

TMF values for D4 could not be reliably calculated in a study on freshwater benthopelagic food webs of Lake Mjøsa, Norway[230] and a pelagic food web study in Lake Mjøsa, Randsfjorden[231], since most samples showed concentrations below the detection limit, and analytical methods were not validated in the second study. The study on benthopelagic food webs showed TMF values for D5 ranging from 1.3 to 3.6 (depending on the trophic levels considered), while the study on pelagic food webs reported values between 2.1 to 3.1 (yet a concern on the validity of the analytical method remains from cVMS experts). Confidence intervals for D6 TMF estimates are typically rather wide, but a median TMF above 1 was obtained in Lake Mjøsa and Lake Randsfjorden for pelagic food webs[169], despite this, values based on benthopelagic food webs were <1 or concentrations non-detected[168]. The fish samples analysed refer to fillets or livers rather than whole fish, and thus the levels found may not reflect the levels present in whole fish. On the other hand, these studies collected biota samples from different locations in the aquatic environments that would exhibit considerable exposure level gradients due to varying distances from WWTPs and populated areas. Since the TMF values were derived with an assumption that all biota species would be exposed to the same environmental conditions so that chemical transfers could be determined throughout the food web, the uneven environmental conditions might undermine the accuracy of TMF calculations.

McGoldrick et al., 2014 also found TMF values above 1 for D4, D5 and D6, with probabilities ranging from 40 - 65% when both zooplankton and the top predator (Walleye) were excluded in one of the food web configurations in the western basin of Lake Erie, Canada[232]. However, there are some uncertainties with this study resulting from the relatively small sample sizes and the inclusion of species with a relatively high contribution from pelagic carbon sources, in what was essentially a benthic food web. This study suffers from a possible underestimation of the concentrations in fish at the higher trophic levels compared with lower trophic levels. Other studies showing TMF values >1 for D5 and D6 are Jia et al. (2015)[233] in Dalian Bay in Northern China and Powell et al. (2014)[234] in Lake Champlain in the USA.

On the other hand, several test studies and peer-reviewed studies performed by Dow Corning Corporation evidence the potential for trophic dilution of these substances in marine and freshwater

[228] Ibid footnote 214. Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2009c) Interim Report: Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in the aquatic marine food webs in inner and outer Oslofjord, Norway. Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[229] Ibid footnote 221

[230] Borgå K, Fjeld E, Kierkegaard A and McLachlan M (2012) Food web accumulation of cyclic siloxanes in Lake Mjøsa, Norway. Environ. Sci. Technol., 46, 6347–6354. https://doi.org/10.1021/es300875d

[231] Borgå K, Fjeld E, Kierkegaard A and McLachlan MS (2013) Consistency in trophic magnification factors of cyclic volatile methyl siloxanes in pelagic freshwater food webs leading to brown trout. Environmental Science & Technology, 47, 14394-14402. DOI: 10.1021/es404374j

[232] McGoldrick, D. J., Chan, C., Drouillard, K. G., Keir, M. J., Clark, M. G., & Backus, S. M. (2014). Concentrations and trophic magnification of cyclic siloxanes in aquatic biota from the Western Basin of Lake Erie, Canada. Environmental pollution, 186, 141-148. https://doi.org/10.1016/j.envpol.2013.12.003

[233] Jia, H., Zhang, Z., Wang, C., Hong, W. J., Sun, Y., & Li, Y. F. (2015) Trophic transfer of methyl siloxanes in the marine food web from coastal area of northern China. Environmental Science & Technology, 49, 2833-2840. DOI: 10.1021/es505445e

[234] Powell DE, Durham J, Kim J and Seston RM (2014) Interim report – trophic transfer of cyclic volatile methylsiloxanes (cVMS) and selected polychlorinated biphenyl (PCB) across the aquatic food web of Lake Champlain, USA. Unpublished HES Study No. 12349-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Sponsor CES (Centre Européen des Silicones).

environments[235,236,237]. The studies performed in the marine environment also refer to the high level of agreement for TMF values between the food chains in the low and high exposure areas, demonstrating that trophic transfer of the cVMS materials was not related to exposure. Results tended to be slightly higher in the marine environment than in freshwater, with D4 showing the highest values.

Overall, it is apparent that different conclusions can be drawn depending on the food chain configuration that is assumed, as well as biological aspects like biotransformation and dietary uptake, environmental factors such as spatial concentration gradients (that lead to variations in exposure levels), seasonal effects, and the absence of a steady-state condition. However, it is important to note that high bioaccumulation in a part of the food chain may have unpredictable effects throughout other parts of the food chain as well.

2.2.4 Human hazards

Due to the structural differences of D4, D5 and D6, different effects have been observed in animal studies. The differences in these effects and their applicability to human health are outlined below for each substance:

2.2.4.1 D4

D4 has a harmonised classification of Repr. 2 (H361f - suspected of damaging fertility) under Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP)[238]. This effect is based on a two-generation study in male and female Sprague-Dawley rats exposed by whole-body vapour inhalation of D4 at doses up to 700 ppm (6 hours/day, 7 days/week) throughout mating in both males and females, and through gestation and lactation in females. A No Observed Adverse Effect Level (NOAEL) was determined as 300 ppm for effects on female fertility based on decreases in the number of corpora lutea, number of uterine implantation sites, total number of pups born, and mean live litter size at doses of 500 ppm.

ECHA experts discussing the mechanism and relevance of these findings to human health determined that "*the mechanism behind the reproductive effects of D4 could be relevant to human health*"[239]. The mechanism of effects on female fertility is thought to be caused by an insufficient or blocked pre-ovulatory LH surge which fails to induce complete ovulation in the rat and causes the fertility effects observed. However, some experts, including at the Government of Canada, believe that based on the current understanding of oestrous cyclicity_and neural/hormonal regulation of ovulation in humans, the effects of D4 on fertility as observed in the rat are unlikely to be relevant to humans, or of unknown relevance[240,241,242,243].

When considering relevance for human health, the exposure concentration should also be considered. No effects were seen in rats at 300 ppm and toxicity was observed at the 500 ppm test

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[235] Ibid footnote 218. Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2009c) Interim Report: Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in the aquatic marine food webs in inner and outer Oslofjord, Norway. Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[236] Powell, D. E., Schøyen, M., Øxnevad, S., Gerhards, R., Böhmer, T., Koerner, M., ... & Huff, D. W. (2018). Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) in the aquatic marine food webs of the Oslofjord, Norway. Science of the total environment, 622, 127-139.

[237] Powell DE, Woodburn KB, Drottar K, Durham J and Huff DW (2009a). Trophic dilution of cyclic volatile methylsiloxane (cVMS) materials in a temperate freshwater lake. Unpublished HES Study No. 10771-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[238] European Chemicals Agency (no date) Summary of Classification and Labelling D4. Available: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/121828

[239] Ibid footnote 104

[240] Government of Canada (no date) Siloxane D4 (cyclotetrasiloxane, octamethyl-_ - information sheet. Available: https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-2/cyclotetrasiloxane-octamethyl.html

[241] Robinan Gentry, Allison Franzen, C. Van Landingham, Tracy Greene, Kathy Plotzke (2017) A global human risk assessment for octamethylcyclotetrasiloxane (D_4), Toxicology Letters, 279, 23-41. https://doi.org/10.1016/j.toxlet.2017.05.019

[242] Australian Government (2016) Cyclotetrasiloxane, octamethyl-: Human health tier II assessment. Available: https://www.industrialchemicals.gov.au/sites/default/files/Cyclotetrasiloxane%2C%20octamethyl-_Human%20health%20tier%20II%20assessment.pdf

[243] Ibid footnote 241

dose, and testing included whole-body vapour exposure. It is very unlikely that the general public or workers would be exposed to concentrations of D4 at this level. Margins of safety (MOS) for workers, consumers and the general public who may be exposed to D4 either in the workplace, through the use of consumer products containing D4, or to D4 released to the environment have been shown to exceed 1000, indicating that a risk to health is very unlikely regardless of whether the fertility effect is relevant to humans[244].

Repeated oral, inhalation and dermal studies have indicated that D4 exhibits low acute and chronic toxicity and exposure is not considered to cause serious damage to health[245].

2.2.4.2 D5

No harmonised classifications under the CLP Regulation or REACH registration dossiers notifications relating to human health are available for D5[246].

Studies assessing acute toxicity following oral, inhalation and dermal studies have indicated low toxicity. Repeated oral, inhalation (at concentrations up to the maximum reproducible vapour pressure of approximately 160 ppm) or dermal exposure is not considered to cause serious damage to health. D5 may be a mild respiratory irritant, but this is not considered to cause a serious health effect[247].

Liver hypertrophy has been observed in rats following exposure to D5, however the mechanism of action is considered to not be relevant to human health. D5 has also been shown to be potentially carcinogenic in female rats. However, based on the carcinogenicity mechanism, this chemical is not considered to be a carcinogen in humans. It is not genotoxic and is not considered to cause reproductive or developmental toxicity following inhalation exposure at concentrations up to the maximum reproducible vapour pressure of approximately 160 ppm[248].

2.2.4.3 D6

Similarly, to D5, no harmonised classifications under the CLP Regulation or REACH registration dossiers notifications relating to human health are available for D6[249].

Low acute toxicity of D6 has been observed in animal studies following oral and dermal exposure. No studies assessing inhalation exposure are available, however repeated exposure is not expected to cause serious damage to health via any exposure route[250].

D6 is a respiratory irritant, with local effects observed in the lungs of rats at 10 ppm following whole-body vapour inhalation exposure (6 hours/day, 7 days/week); a No Observed Adverse Effect Concentration (NOAEC) of 1 ppm was determined based on this effect. This effect however can be considered to be not relevant to humans as it is likely linked with aerosol exposure under confined conditions and is very unlikely to be reproducible under normal conditions[251].

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[244] Ibid footnote 241
[245] Allison Franzen, Tracy Greene, Cynthia Van Landingham, Robinan Gentry (2017) Toxicology of octamethylcyclotetrasiloxane (D_4), Toxicology Letters, 279, 2-22. https://doi.org/10.1016/j.toxlet.2017.06.007
[246] European Chemicals Agency (no date) Summary of Classification and Labelling D5. Available: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/114212
[247] Australian Government (2016) Cyclopentasiloxane, decamethyl-: Human health tier II assessment. Available: https://www.industrialchemicals.gov.au/sites/default/files/Cyclopentasiloxane%2C%20decamethyl-_Human%20health%20tier%20II%20assessment.pdf
[248] European Chemicals Agency (2016) Background Document to the Opinion on the Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5). Available: https://echa.europa.eu/documents/10162/23cd6eda-688d-44ea-99b0-a254a8f83ba5
[249] European Chemicals Agency (no date) Summary of Classification and Labelling D6. Available: https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/113127
[250] Australian Government (2016) Cyclohexasiloxane, dodecamethyl-: Human health tier II assessment. Available: https://www.industrialchemicals.gov.au/sites/default/files/Cyclohexasiloxane%2C%20dodecamethyl-_Human%20health%20tier%20II%20assessment.pdf
[251] Ibid footnote 250

D6 is not considered to be genotoxic, carcinogenic, or be a reproductive or developmental toxicant.

Overall, it can be considered that D5 and D6 are of low concern to human health. The fertility effect exhibited by D4 has the potential to cause harm to humans depending on whether the effect is considered relevant or not. However, based on the concentration at which the effects were observed in rats (300 ppm) and the conditions of exposure (whole-body vapour) the effect is very unlikely to be reproducible to humans under normal conditions.

Sections 2.2.2 and 2.2.3 highlight the uncertainties and continuous discussion that continue in the scientific community on reversibility and persistence after emission cessation; actual toxicity of organisms under realistic conditions; accuracy of biomagnification calculations and study design; as well as long-range transport potential. The literature reviewed as part of the problem definition development has been scored for reliability and relevance to ensure that the evidence used is justifiable. This has resulted in the environmental impact and benefit evaluation considering 1) the risks primarily identified by the Commission, and 2) the significantly lowered risk on persistence, bioaccumulation, toxicity and long-range transport as defended in the cited contrasting studies.

2.3 WHAT ARE THE PROBLEM DRIVERS AND CONSEQUENCES?

As outlined in Sections 2.2.2 and 2.2.3, D4, D5 and D6 are SVHCs with PBT/vPvB properties leading to potential negative impacts on the environment. There are three main drivers to this problem identified in Section 2.2. Firstly, the substances are widely used; secondly, their persistent properties mean that even with cessation of emissions, environmental impacts will continue for a period of time; and thirdly, that there is no consensus on the impacts of the substances to the environment.

2.3.1 Driver 1 – Widely used in upstream and downstream products

D4, D5 and D6 are used across a wide range of applications (see Figure 2-1). In the EEA, these substances are three of the most heavily used cVMSs, with REACH registered tonnages in the range of ≥ 100 000 to < 1 000 000 (D4)[252]; ≥ 10 000 to < 100 000 (D5)[253]; ≥ 1 000 to < 10 000 (D6)[254]. As mentioned previously in Section 2.1, these **substances can be used as a monomer in the production of silicone polymers, directly as substances within mixtures, and as a reactant/intermediate in the manufacture of products such as semiconductors or glass fibres**. Such applications can be found in a variety of sectors such as cosmetics and personal care, construction, automotive, low carbon energy, electronics, pulp and paper, oil and gas, medical devices and pharmaceuticals, and aerospace and defence[255].

The broad number of uses across multiple sectors has raised concerns regarding the emissions of D4, D5, D6 to the environment during the use and waste phases. The direct use of these cVMS in cosmetic products is known to be a significant source of environmental emissions and is being addressed under REACH, yet emissions from impurities in silicone polymers is lesser known. The current and future REACH restrictions of D4, D5, D6 seek to reduce emissions by around 90% in the EEA, but due to the global use of these substances and their PBT properties, concerns remain.

There are regions, such as the United States, which are not party to Stockholm Convention and for which any restrictions on the manufacturing, use and disposal of D4, D5, D6 stipulated by the Convention, would not apply. This would mean that operations related to D4, D5 and D6 could continue in countries which are not a Party to the Convention (with trade restriction to Stockholm Convention countries).

[252] European Chemicals Agency (no date) Substance Infocard Octamethylcyclotetrasiloxane. Available: https://echa.europa.eu/it/substance-information/-/substanceinfo/100.008.307 [Accessed 29.11.2023]
[253] [253] European Chemicals Agency (no date) Substance Infocard Decamethylcyclopentasiloxane. Available: https://echa.europa.eu/it/substance-information/-/substanceinfo/100.007.969 [Accessed 29.11.2023]
[254] European Chemicals Agency (no date) Substance Infocard Dodecamethylcyclohexasiloxane. Available: https://echa.europa.eu/it/substance-information/-/substanceinfo/100.007.967 [Accessed 29.11.2023
[255] Ibid footnote 3

2.3.2 Driver 2 – Persistence in the environment

D4, D5 and D6 meet the criteria for persistence under the Stockholm Convention and the criteria for very persistent under REACH. This property means that, even when emissions from the use and waste phases cease, there will be stock built up in the environment and the environmental impacts will take time to reduce to zero. This is evidenced in the Background Document to the REACH restriction for D4, D5, D6 where the total undegraded stock residing in the regional and continental scales after regional releases were estimated. It should be noted that these stocks would change depending on emissions over time and removal rates.

The persistence of these substances is also linked to their long-range environmental transport potential, which is still the subject of scientific debate. While it remains to be seen whether emissions of these substances used outside the EU can cause exposure within the EU; detections have been found in remote areas, including in the Arctic, Antarctica and are frequently found in biota globally. On the other hand, scientific concern remains on the need for a proper reliability assessment of those studies, as well as the confirmation that exposure is not a result of artifact, contamination, or a local source. If the criteria are determined to be met, this means that the release of these substances to the environment is trans-boundary. Meaning that just one jurisdictional regulatory mechanism, such as regulatory mechanisms utilised by the European Commission, will not suffice to regulate these substances effectively. To regulate D4, D5 and D6 and to mitigate their negative effects to the environment, a cross-jurisdictional regulatory mechanism may be required[256].

2.3.3 Driver 3 – Uncertainty in data

As outlined in Section 2.2.2 and 2.2.3, D4, D5 and D6 demonstrate potential negative impacts to the environment. The third driver contributing to the potential negative impacts of D4, D5 and D6 is the uncertainty in some data of their adverse effects. This uncertainty stems first from a lack of data from field studies conducted on the fate and behaviour of D4, D5 and D6 and the potential adverse effects on aquatic, sediment and terrestrial organisms under more realistic conditions.

Toxic impact on fish and invertebrates exposed in the water column is discussed. Concentrations reported in the studies following laboratory guidelines have been recognised to not represent realistic environmental conditions in exposure and duration[257,258]. Moreover, some authors also defend that when D4 is released to water, the competing processes would prevent uptake of D4 to a high enough concentration to elicit the non-specific membrane effects[259].

Adverse effects of D4, D5 and D6 on sediment organisms are also discussed, supported by the fact that studies performed under natural conditions showed higher toxicity thresholds[260]. Discussion is presented above on the fact that some authors defend that degradation could be faster under natural conditions, where eukaryotic organisms could take also contribute to the biodegradation process[261]. Additionally, there are possible contributing factors that could have caused high toxicity in these studies, such as the use of artificial sediment with a peat-based carbon sources, and elevated pH in the test system[262]. Moreover, the key reference *Lumbriculus variegatus* study for D4 presented flaws such as non-synchronized worms or insufficient equilibration time.

The impact of D5 on terrestrial organisms cannot be robustly concluded as no records on soil concentration have been accessed and seem to be very limited, related to the fact that these compounds do not tend to stay in soil, being volatilised or degraded depending on environmental

[256] Ibid footnote 3
[257] Ibid footnote 163
[258] Hobson, J.F. and E.M. Silberhorn. 1995. Octamethylcyclotetrasiloxane (OMCTS), a case study: Summary and aquatic risk assessment. Environ. Toxicol. Chem. 14:1667-1673. https://doi.org/10.1002/etc.5620141006
[259] Ibid footnotes 164,165,166,167
[260] Ibid footnotes 178,185
[261] Ibid footnotes 132,133
[262] Ibid footnotes 89,90,91

conditions. Higher persistence is expected for D6 in this compartment, but again no data is available. Also, plant toxicity has been said to be species and environmental condition dependant[263].

Another point for uncertainty is the wide range of values obtained on bioaccumulation data, depending on the index used (BCF, BMF, TMF), the application of growth correction factor; and in case of trophic magnification assessment food web selected, position with respect to emission source, sample treatment (whole body or section). Additionally, several authors defend the potential for elimination and biotransformation by invertebrates[264] and the upper parts of the food chain[265].

The consequence of the lack of consensus for the impact to environmental health across D4, D5 and D6 is that the accuracy of and ability to conduct further assessments is limited. It is difficult in the current state to accurately determine the negative impacts to the environment from emissions and exposure to D4, D5 and D6. The subsequent consequence is that if the impacts to environment cannot accurately be determined, it could negatively impact the accuracy of determining the benefits (e.g., economic) and drawbacks of restricting D4, D5 and D6. This introduces a risk that adverse effects of these substances could be determined in the future, that could require more appropriate regulation for D4, D5 and D6.

2.4 HOW WOULD THE PROBLEM EVOLVE WITHOUT FURTHER INTERVENTION

Since D4, D5 and D6 are three of the most heavily used cVMSs across the EU-27, form the basis for commonly used products and are alternatives to other heavily regulated substances, it can be expected that manufacturing and use of these substances would potentially increase over time. This could result in environmental steady-state stocks being increased and the potential adverse effects continuing in the long term[266]. This being said, there are regulatory actions being taken on a European scale to reduce emissions via REACH restriction and in turn reducing environmental stocks. Without further intervention, these substances may not be regulated to the same extent by non-EU countries. When considering the persistence and long-range transport of these substances, a lack of additional intervention and the continued manufacture and use of D4, D5 and D6 in non-EU countries could result in ongoing negative consequences on the EU-27, as described in Figure 2-3.

2.5 THE OBJECTIVES OF THE INITIATIVE

The general objective of DG Environment to utilise the Stockholm Convention as a mechanism for regulation of D4, D5 and D6 is to globalise the existing and draft REACH restrictions to **ensure a high level of protection to the global environment, whilst mitigating trade and competition distortions that could result in a competitive disadvantage for the EU**, **without affecting silicone polymer uses which have key functions in many applications that enable the European Green Deal.**

D4, D5 and D6 are manufactured and used on a global basis which results in emissions on a global scale. The draft EU Stockholm Convention Annex D report for D4, D5 and D6 states that since these substances demonstrate persistence and long-range environmental transport, measures taken nationally or regionally are not sufficient to safeguard the environment and human health. Therefore, international action is necessary[267].

Action on a global basis via the Stockholm Convention may also limit the potential for trans-boundary exposure to D4, D5 and D6 from non-EU sources. However, it should be

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[263] Ibid footnote 191
[264]Ibid footnotes 133,219
[265] Ibid footnotes 217,220,221
[266] To note, cVMS do degrade in the environment over time and their persistence is not indefinite.
[267] Ibid footnote 3

acknowledged that this would require all Parties to the Stockholm Convention to ratify the restrictions and exemptions to maintain a level-playing field internationally.

Three specific objectives of the policy initiative have been identified and include to:

- Limit the potential for transboundary exposure to D4, D5 and/or D6 from non-EU cosmetic and other consumer sources,
- Avoid (or mitigate) international trade and competition distortions, which would otherwise negatively affect the EU's industry, and
- Contribute to the transition towards the use of safer chemicals, improved resource efficiency and the circular economy.

3. PRESENTATION OF THE POLICY SCENARIOS TO ACHIEVE THE OBJECTIVES

This section presents the baseline against which the impacts of the policy scenarios will be assessed (Section 3.1) and then describes the three policy scenarios under consideration in this assessment (Section 3.2). The baseline and policy scenarios presented here are key components of the assessment of the impacts covered in Section 0.

3.1 BASELINE AGAINST WHICH THE SCENARIOS ARE MEASURED

This section describes the baseline against which the three policy scenarios have been assessed[268]. The section summarises the current regulatory baseline considered in this assessment, the market and social context and the estimated evolution of these factors over time in a business-as-usual scenario. The methods employed are outlined in the Annexes.

3.1.1 Regulatory context and evolution

As outlined in Section 1.2, as of early 2024, there are two restriction regulatory measures currently in force which impact the use of the substances D4, and D5 in the EU-27. These are the listing of D4 in the CPR under Annex II and the restriction of D4 and D5 under Entry 70 of Annex XVII of REACH.

The previously enforced regulatory measures in the EU-27 focus on the use of D4 and D5 in cosmetic products. The new, REACH restriction includes a broader scope of D4, D5 and D6 and additional applications including household products and professional cleaning products, however it does not implicate all uses as it focuses on professional, and consumer uses only.

Under this regulatory baseline, without the addition of D4, D5 or D6 to either Annex of the Stockholm Convention, the following activities are permitted to continue in the EU-27:

- Placing on the market of D4, D5 and D6 for the following uses:
  - Industrial use as a monomer in the production of silicone polymer
  - Industrial use as an intermediate in the production of other organosilicon substances
  - Industrial use as a monomer in emulsion polymerisation
  - Industrial use in formulation and/or (re-) packing of mixtures
  - Industrial production of articles
  - Industrial use in non-metal surface treatment
  - Industrial use as laboratory reagent in Research & Development activities
- Placing on the market of D5 and D6 for use as medical devices, for the (i) treatment/care of scars and wounds, (ii) prevention of wounds, and (iii) care of stoma.
- Placing on the market of D5 for professional use in the cleaning or restoration of art and antiques.
  - Mixtures that contain silicone polymers with residues of:
  - D4 or D5 or D6 in a concentration ≤1% w/w, for use in adhesion, sealing, gluing and casting.
    - D5 in a concentration ≤ 0.3% w/w or D6 in a concentration ≤1% w/w, for use as medical devices (as defined in Directive 93/42/EEC or in the Regulation (EU) 2017/745) for dental impression.
    - D4 in a concentration ≤0.5% w/w, or D5 or D6 in a concentration ≤0.3 % w/w for use as protective coatings (including marine coatings).

[268] This baselining activity is aligned with Tool #60 (Baselines) of the European Commission, 2021. Better Regulation Toolbox

    - D5 in a concentration ≤1% w/w or D6 in a concentration ≤3% w/w, for (i) rapid prototyping and mould making, and (ii) high performance uses stabilised by quartz filler.
- D4 or D5 or D6 in a concentration ≤0.2% w/w, for use as (substance-based) medical devices as defined in Directive 93/42/EEC or in the classification rule 21 set in Annex VIII to the Regulation (EU) 2017/745.
    - D4 in a concentration ≤0.2% w/w, or D5 or D6 in a concentration ≤1 % w/w for use as silicone insoles for horses, or as horseshoes.
    - D4 or D5 or D6 in a concentration ≤0.5 % w/w, for use as adhesion promoters.
    - D6 in a concentration ≤1 % w/w, for professional use in the cleaning or restoration of art and antiques.
    - D5 or D6 in a concentration ≤1 % w/w, for use in pad printing, or manufacturing of printing pads.
    - D4, or D5, or D6 in a concentration ≤1 % w/w, for use in 3D-printing.
- Use of D5 in strictly controlled closed dry-cleaning systems for textile, leather and fur where the cleaning solvent is recycled or incinerated.[269]

In summary the regulatory baseline includes a focus on professional and consumer uses, in particular cosmetic and cleaning products, with derogations for silicone polymers and other specific uses.

The inclusion of D4, D5 and D6 in either Annex of the Stockholm Convention will have implications for industrial uses, the use of silicone polymers and lead to a broader geographical coverage of regulatory measures on D4, D5 and D6. These additional requirements linked to manufacture, use and waste go beyond the measures included under the current and proposed REACH restrictions.

3.1.2 Economic and social context and potential evolution

This section describes key economic and social historical and potential developments (2011-2040) pertaining to the manufacture, placing on the market and use of D4, D5, and D6 and silicone polymers in the EU-27 and a selection of key downstream user sectors.

Sector boundaries and definitions for the purpose of this Study were developed by selecting relevant product categories from the list employed in 'PRODuction COMmunautaire' (PRODCOM) and the statistical classification of economic activities (NACE). The table below presents a summary of the sectoral boundaries, which is further detailed in the Annexes.

Table 3-1 Sectoral boundaries and definitions

Sectors	Definition at a high-level
D4, D5, D6 and silicone polymers	PRODCOM classification "Silicone Polymers, in primary form" (sector code 3910)
Downstream user sectors in scope	A selection of mutually exclusive PRODCOM and NACE codes were identified pertaining to manufacturers and importers of components and final products pertaining to the: • **Transport** (*selection from sector codes 27 "Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus" and "Manufacture of other electrical equipment"; 28 "Manufacture of other special-purpose machinery", 29 "Manufacture of motor vehicles" and "Manufacture of bodies (coachwork) for motor vehicles; manufacture of trailers and semi-trailers"; and 30 "Building of ships and boats", "Manufacture of railway locomotives and rolling stock", "Manufacture of air and spacecraft and related machinery", and "Manufacture of transport equipment n.e.c."*)

[269] Ibid footnote 50

Sectors	Definition at a high-level
	• **Aerospace and defence** (*selection from sector codes 27, "28 Manufacture of other general-purpose machinery", 29 "Manufacture of motor vehicles" and 30 "Manufacture of air and spacecraft and related machinery"*) • **Parts of construction** e.g., machinery (*selection from sector code 28 "Manufacture of other general-purpose machinery", "Manufacture of metal forming machinery and machine tools" and "Manufacture of other special-purpose machinery"*) • **Parts of healthcare** e.g., medical devices (*selection from sector codes 21 "Manufacture of pharmaceutical preparations", 26 "Manufacture of irradiation, electromedical and electrotherapeutic equipment", and 32 "Manufacture of medical and dental instruments and supplies"*) • **Low carbon energy,** focussing on manufacturing in the EU-27 (*selection from sector codes 25 "Manufacture of steam generators, except central heating hot water boilers", 27 "Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus" and "Manufacture of batteries and accumulators" and 28 "Manufacture of general-purpose machinery"*) • **Electronics,** focussing on manufacturing in the EU-27 (*selection from sector codes 26 "Manufacture of electronic components and boards", "Manufacture of computers and peripheral equipment", "Manufacture of communication equipment", "Manufacture of consumer electronics", "Manufacture of instruments and appliances for measuring, testing and navigation; watches and clocks", "Manufacture of irradiation, electromedical and electrotherapeutic equipment" and "Manufacture of optical instruments and photographic equipment"; 27 "Manufacture of electric motors, generators, transformers and electricity distribution and control apparatus", "Manufacture of wiring and wiring devices", "Manufacture of other electrical equipment"; 28 "Manufacture of other general-purpose machinery", "Manufacture of metal forming machinery and machine tools"; and 29 "Manufacture of parts and accessories for motor vehicles"*) • **Paper products,** focussing on manufacturing in the EU-27 (*selection from sector codes 17 "Manufacture of pulp, paper and paperboard" and "Manufacture of articles of paper and paperboard"*) Specific industries of 'components' or 'intermediate products' were also considered such as: • **Sealants** (*publicly available sources were identified with sectoral definitions*[270]) • **Lubricants** (*selection from sector code 20 "Manufacture of other chemical products"*) • **Insulation** (*selection from sector code 27 "Manufacture of wiring and wiring devices" and "Manufacture of wiring and wiring devices"*) • **Adhesives** (*selection from sector codes 17 "Manufacture of pulp, paper and paperboard", 20 "Manufacture of other chemical products", 21 "Manufacture of pharmaceutical preparations", and 22 "Manufacture of plastic products"*) • **Coatings** (*selection from sector code 25 "Treatment and coating of metals; machining"*) • **Paints** (*selection from sector codes 20 "Manufacture of paints, varnishes and similar coatings, printing ink and mastics", and 25 "Treatment and coating of metals; machining"*)

Source: Ricardo suggestions based on a review of PRODCOM and NACE sector classifications and input from stakeholders.

Based on these sectoral definitions, the following sections describe the **industry's size and developments in terms of turnover and Gross Value Added (GVA) to the economy; expenditures and investment; international trade dynamics; employment and other characteristics relating to consumption and use of products within these sectors**. The evidence presented in this Study is based on the analysis of data from a range of sources, including Eurostat datasets such as PRODCOM and Structural Business Statistics (SBS), and multiple external sources such as, e.g., socio-economic analysis reports from the Global Silicone Council

[270] Ibid footnote 4
FEICA (2019) Adhesives and Sealants: Enablers of a sustainable society. Available: https://www.feica.eu/information-center/feica-publications/preview/611/adhesives-and-sealants-enablers-sustainable-society?id=ef38f028-9dfd-439d-bbc3-1cbc93f9723c&filename=Adhesives+and+Sealants%2C+Enablers+of+a+sustainable+society.pdf

and overall industry and market studies[271,272,273] for insights and validation. Historical evidence presented is based on these Eurostat datasets and the sectoral definitions outlined above, and evidence-based assumptions have been developed to produce the forecasts, all of which are presented in the following sections.

It is acknowledged that this scope will not include all of the activities that require and/or are enabled by D4, D5 and D6 and the Study is focussed and dependent on the available evidence. The uncertainties of the baseline estimations are thus notable and considered both quantitatively and qualitatively where possible.

3.1.2.1 The size of the EU-27 industries: D4, D5 and D6, the silicone polymers and downstream users

The D4, D5 and D6 and silicone polymer industry play a notable role in the EU-27 economy. In particular, silicone polymers, with D4, D5 and D6 impurities, have a diverse range of applications, in many cases critical, spanning multiple 'downstream user' sectors, such as healthcare, transport, construction and electronics.

The scale of manufacturing activity in the EU-27 across the upstream and downstream industries in scope, as defined above, has been estimated to surpass €1 trillion (in constant, 2022 euros[274]). This includes the manufacturing activity across upstream industries, that is, companies specializing in the production of D4, D5, and D6 and/or silicone polymers; and 'downstream user' companies, which rely at least partly on these upstream products to manufacture components and final products for sale in or export out of the EU-27.

The **sales value of production of D4, D5 and D6 and silicone polymers in the EU-27 has been estimated at around €4 billion in 2022**. Between 2011-2022, the manufacturing industry's sales turnover has grown at a real CAGR of around +2.5%. Based on the available evidence, it is considered that this industry would continue or even exceed this growth pathway in the EU-27 moving forward. **External sources suggest that the sector's manufacturing activity might increase at a real annual rate of +3.5% in the next two decades, partly driven by the role that silicone polymers play in the green and digital transition.** It is thus estimated that the industry could reach a production sales value of around €8 billion by 2040 (in constant 2022 euros). This is presented in Figure 3-1 below.

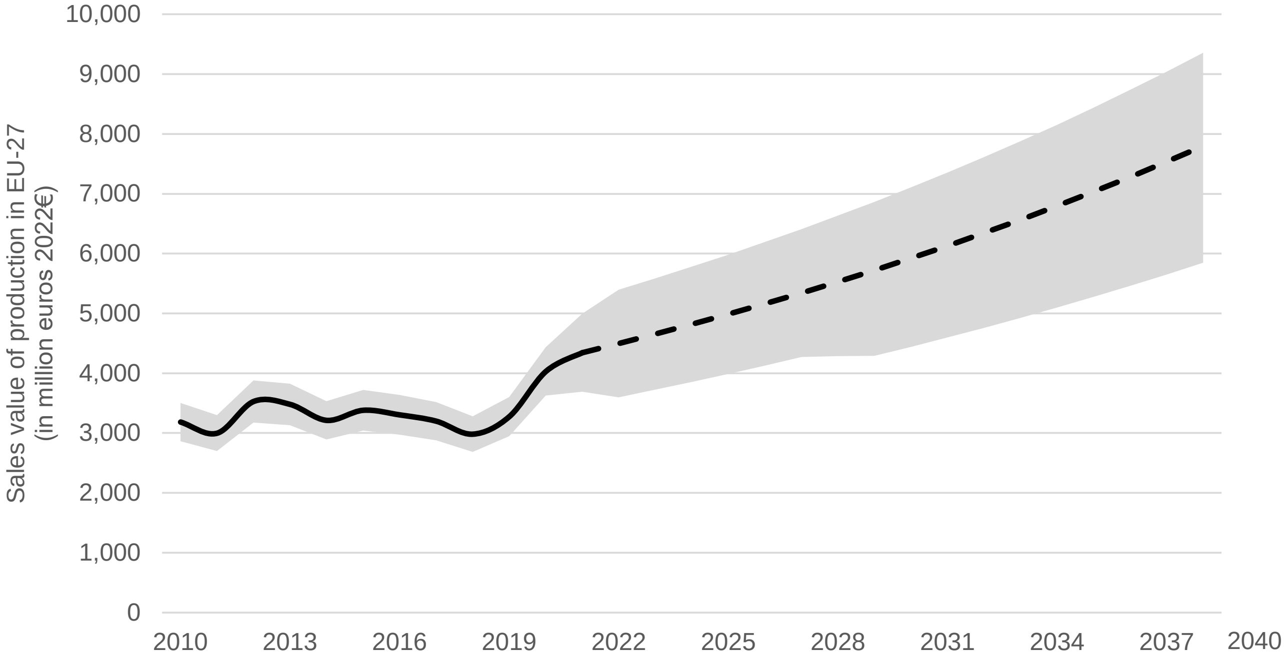
[271] Ibid footnote 54

[272] Amec Foster Wheeler (2017). Global Silicones Council. Impact Assessment of D4 POP Listing.

[273] Global Silicones Council (2020) Silicone Research. An Industry Commitment. Available: https://globalsilicones.org/wp-content/uploads/2020/10/Silicone-Monitoring-initiatives.pdf

[274] Please note that all euro figures presented in this study will be in constant 2022 euro terms.

Figure 3-1 Baseline sales value of the production of D4, D5, D6 and silicone polymers in the EU-27 (€ million)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

A survey conducted for this study of silicone polymer manufacturers and importers captured over 80% of the EU-27 levels of baseline production. The survey outputs suggests that there might be more than 485,000 metric tonnes of silicone polymers produced in the EU-27 each year (based on 2022 data). Previous studies into silicone markets in Europe also presented estimates of a similar scale. For example, Silicones Europe published a study[275] into the socio-economic impact of the silicones industry in Europe, which estimated that in 2013 almost 590,000 metric tonnes of silicone products were sold in Europe to eight key downstream markets. This is not completely comparable: in this study, silicone products were defined as products which are derived from silicone polymers, silanes and siloxanes; in addition, it focusses on sales to eight key downstream markets rather than total production in the EU-27. However, this assessment also provides a reference point for consideration on the volume of production of silicone polymers and other silicone products.

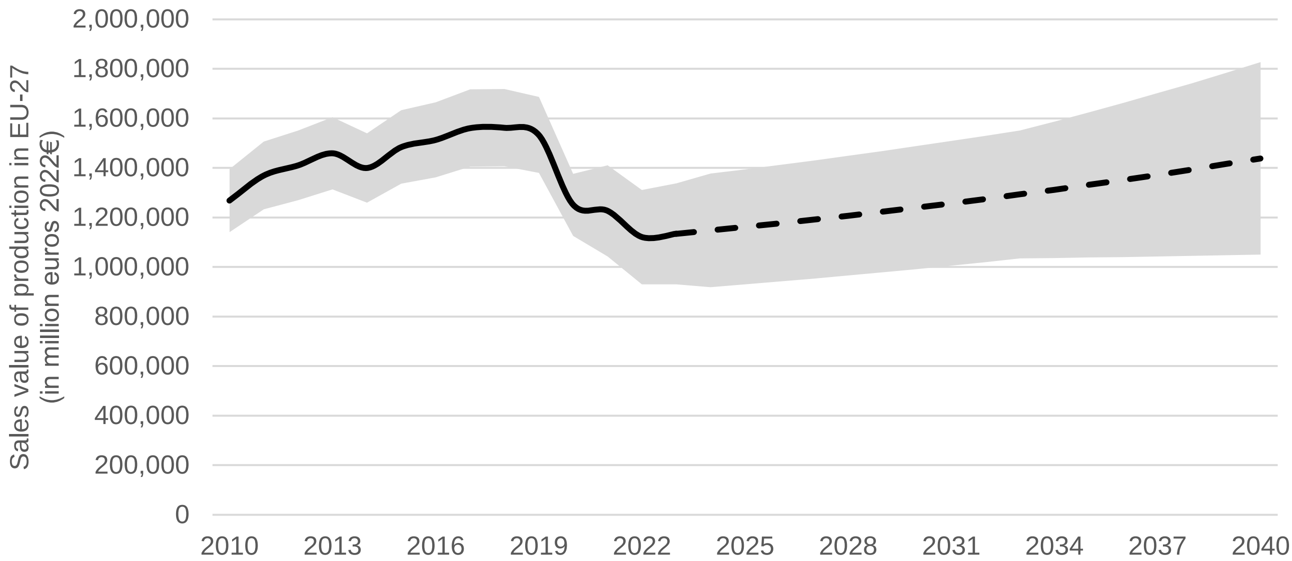
As noted, **silicone polymers are versatile materials that play diverse, and in many cases critical, roles across downstream industries**, such as healthcare, transport, construction, electronics, low-carbon energy, and others. For example, in the manufacturing of intermediate products or components, they are commonly used as insulating materials due to their excellent thermal stability and electrical insulation properties. This contributes to the protection from heat and electrical interference required for electronic components. In the healthcare sector, silicone polymers are valued for their biocompatibility, flexibility, and durability. As an example, silicone polymers are used in various medical devices such as components of medical implant devices, catheters, and prosthetics, where their inert nature minimises the risk of adverse reactions and ensures compatibility with biological tissues. Silicone polymers are also used in the pharmaceutical sector as antifoaming agents during pharmaceutical processing and in biopharma tubing.

The production value of these and other EU-27 downstream manufacturing sectors in which silicone polymers play a role has been estimated to surpass €1 trillion in 2022. Over the period 2010-2022, the downstream user industry in the EU-27 has suffered an average decline in production value, with a real CAGR of around -1%, albeit prior to the pandemic, from 2010-2019, the industry was growing at an annual real CAGR of around +2%. Based on expert elicitation and the

[275] Silicones Europe (2018).

analysis of available evidence, a long-term growing trend with a real CAGR of +1.5% has been assumed. This would imply that, over the coming decade, the downstream manufacturing industries might return to a scale that is closer to maxima during the last decade, or around €1.4 trillion (in constant 2022 euros). The baseline data and forecasts for the sales value of downstream production activity are presented in Figure 3-2 below.

Figure 3-2 Baseline sales value of the production of 'downstream user' products in the EU-27 (€ million)

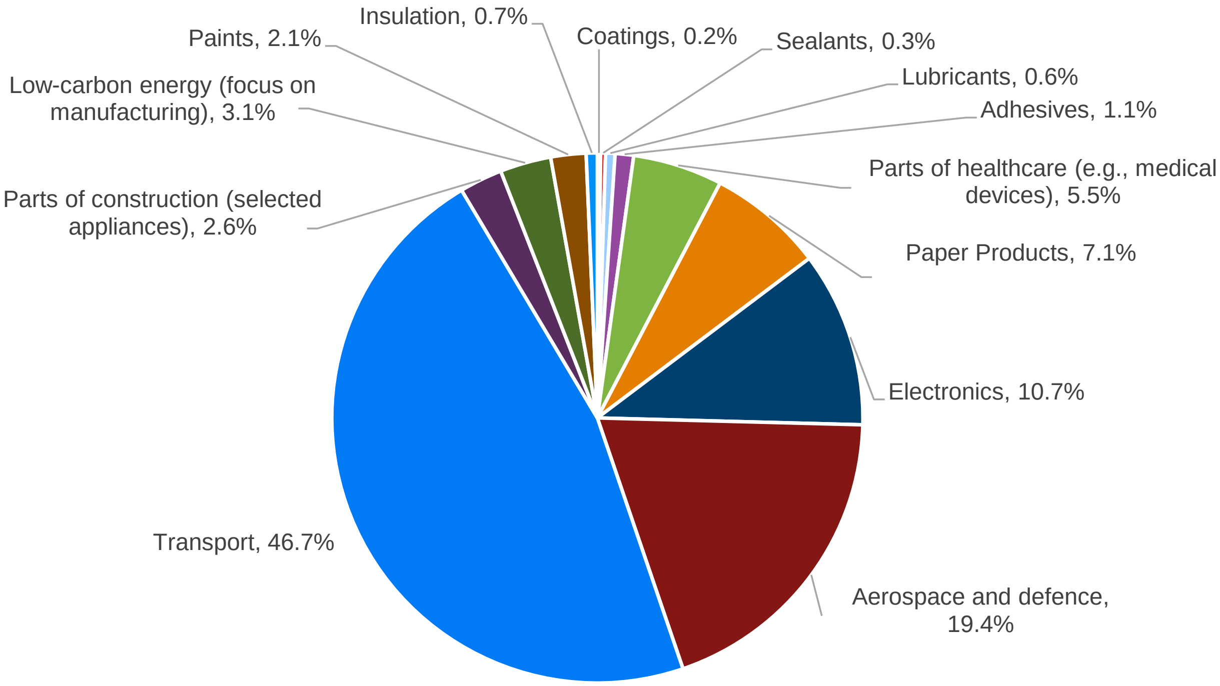


Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources. Values are provided in 2022 prices.

The 'downstream user' industries that rely, in some way, on the D4, D5, D6 and silicone polymer (or upstream) industry are wide ranging. Figure 3-3 below illustrates a selection of sectors in scope, with *transport* emerging as one of the largest sectors with ties to the upstream industry, accounting for around 47% of the downstream production sales value in scope of this Study. This is followed by *aerospace and defence*, accounting for around 20% of the total downstream production value, and electronics, with around 11%. Together, these sectors represent around 80% of the downstream production value in scope of this Study[276].

[276] Please note that we acknowledge there might be overlaps across the sectors included in the 'downstream market', especially given that some more 'final product' and 'component' sectors are brought together. We have, however, checked that the sectors codes selected under each individual sector in scope were as mutually exclusive as possible; and, upon review, concluded that whilst there could be some overlaps (e.g. a proportion of some component sectors might sell and thus be captured in some of the final product sectors in scope), these are unlikely to affect the scale and order of magnitude of the overall estimates for manufacturing footprint of the downstream user industry in scope (especially given that the final product sectors in scope account for more than 90% of the baseline production activity).

Figure 3-3 Breakdown of downstream user production sales value by sector (2022)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

The evidence would suggest that there are more than 100,000 firms operating in these upstream and downstream industries, and the majority are likely to be small and medium sized enterprises (SMEs). In 2022, around 99.8% of all enterprises in the EU-27 were SMEs[277], and these accounted for around 51.8% of the Gross Value Added to the EU-27 economy. Based on the available evidence, our view is that the sectors in scope of this Study are likely to have a similar structure, albeit this has not been confirmed. A consultation of industry players within the upstream and downstream markets in scope of this Study was engaged primarily by larger firms, albeit some SMEs also participated (see the Annexes for a consultation synopsis).

The investment in capital and operating expenditures of companies across these upstream and downstream industries are significant, with strong backward and forward links to the rest of the EU-27 economy. In 2022, these industries invested around 3-5% of their production value in capital within the EU-27, which is **equivalent to an average of around €150 million in the upstream market and around €35 billion annually in the downstream user markets in scope of this Study**. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their operating expenditures were equivalent to 80-90% of the production sales value, surpassing an average of €995,000 million in 2022. This also includes a significant investment in Research and Development (R&D) within the EU-27. The EU-27 manufacturing industry plays a pivotal role in continued progress and innovation at a global scale.

These estimates present us with a scale and order of magnitude of the manufacturing activities in scope of this Study. They are plagued with limitations, especially those inherent to any forecasting exercise. These sectors are affected by a wide range of international dynamics in a context of accelerated transformation and technological advancement; thus, their production pathways could be severely affected in ways that is not easy to foresee at this stage. Overall, it is concluded that the estimates presented of the size of the EU-27 manufacturing activities in scope offer a practical and

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[277] European Commission (2023) Annual report on European SMEs 2022/2023. Available: https://op.europa.eu/en/publication-detail/-/publication/12f499c0-461d-11ee-92e3-01aa75ed71a1/language-en

reasonable counterfactual against which to consider the effects of the policy scenarios under assessment.

3.1.2.2 Contribution to Gross Domestic Product of these industries

Overall, the D4, D5, D6 and silicone polymer industries and the 'downstream user' sectors generated an estimated €265 billion of direct Gross Value Added (GVA) in 2022, around 20-30% of their production value and a notable contribution to the EU-27 Gross Domestic Product (GDP). This reflects the direct contributions of the D4, D5, D6 and silicone polymer industry and its downstream users (the 'value chain'), which is amplified by intermediate purchases of goods and services (the indirect effect) and the economic contribution of expenditures and consumption by the employees supported by this industrial activity (the induced effect). The total estimated footprint of this 'value chain' on the EU-27 economy, including the direct, indirect and induced effects, could surpass €490 billion of GVA[278]. It is assumed that GVA would continue to grow more or less in line with the industry's production value, in real terms, around +1-2% per annum.

3.1.2.3 Sectoral competitiveness and international trade

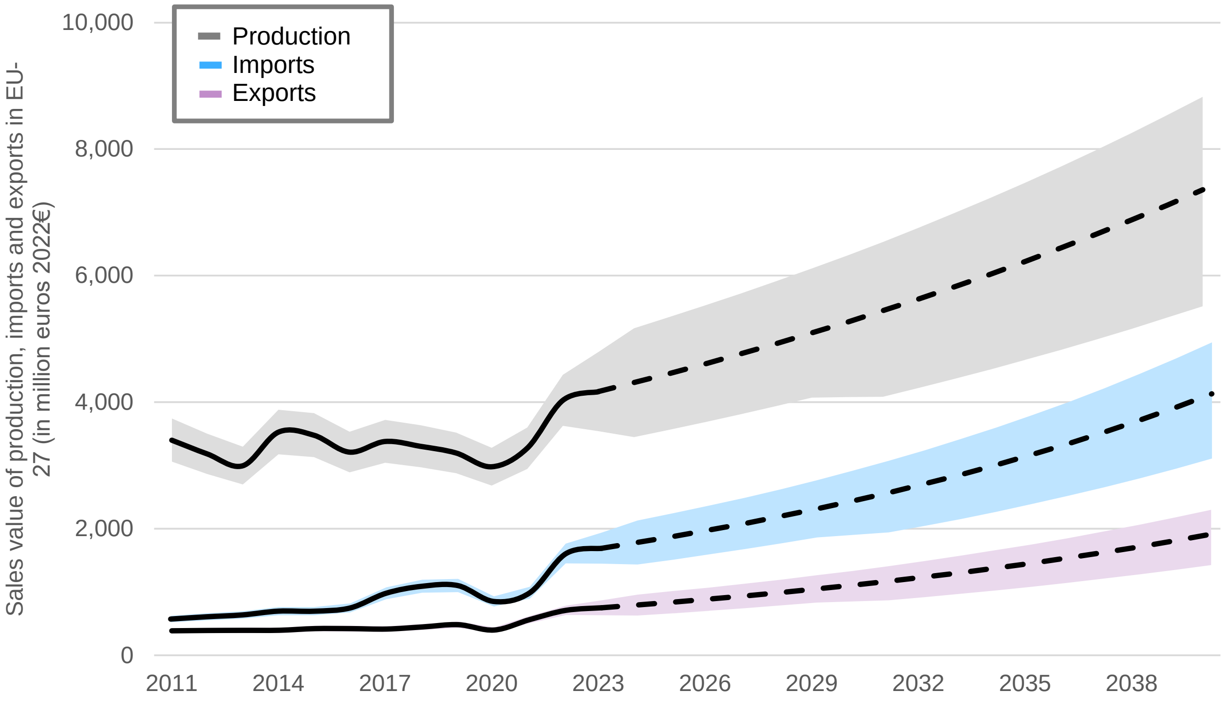
The EU-27 chemicals industry has faced rising costs of production, including labour costs, raw materials and other inputs. Despite continued investment in R&D, product development, innovation and product differentiation, these developments have put pressure on domestic manufacturing activities, their competitive position, and future prospects. In particular, the D4, D5, D6 and silicone polymer manufacturing activity in the EU-27 has grown over the last decade. However, domestic production and exports have grown (2-6% p.a.) slower than imports (~11% p.a.). This might reflect, in part, the pressures faced by the EU industry overall and a relative loss in international competitiveness. In terms of scale, for comparison, 2022 production sales value has been estimated at around €4 billion, whereas imports surpassed €1.5 billion, and exports reached a sales value of €0.7 billion.

Available evidence also suggests that this 'upstream' industry will increasingly rely on imports, which will result in further dependency on third countries. On the one hand, this allows European manufacturers and/or consumers to access raw materials, intermediate and/or final products of similar or equivalent quality and performance at lower prices. On the other, **critical European supply chains could face greater exposure to additional and/or potentially more severe risks, such as for example, healthcare and defence, or transport and low-carbon energy which play essential roles in the EU's green and digital transition. This reliance on import may also weaken the EU strategic autonomy.**

The Figure below presents illustrative estimates of the sales value of production, imports and exports of these upstream industries in the EU-27 and their potential evolution to 2040.

[278] Input-Output methodologies were employed to produce these estimates. Please see the Annexes for more details on the methodology employed.

Figure 3-4 Baseline sales value of production, imports and exports of the D4, D5, D6 and silicone polymers in the EU-27 (€ million)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

The international trade dynamics and the increasing EU dependency on D4, D5, D6 and silicone polymers manufactured in third countries could also have complex implications in the 'downstream user' sectors. They too will become increasingly more dependent on third countries and exposed to additional risks associated with global supply chains.

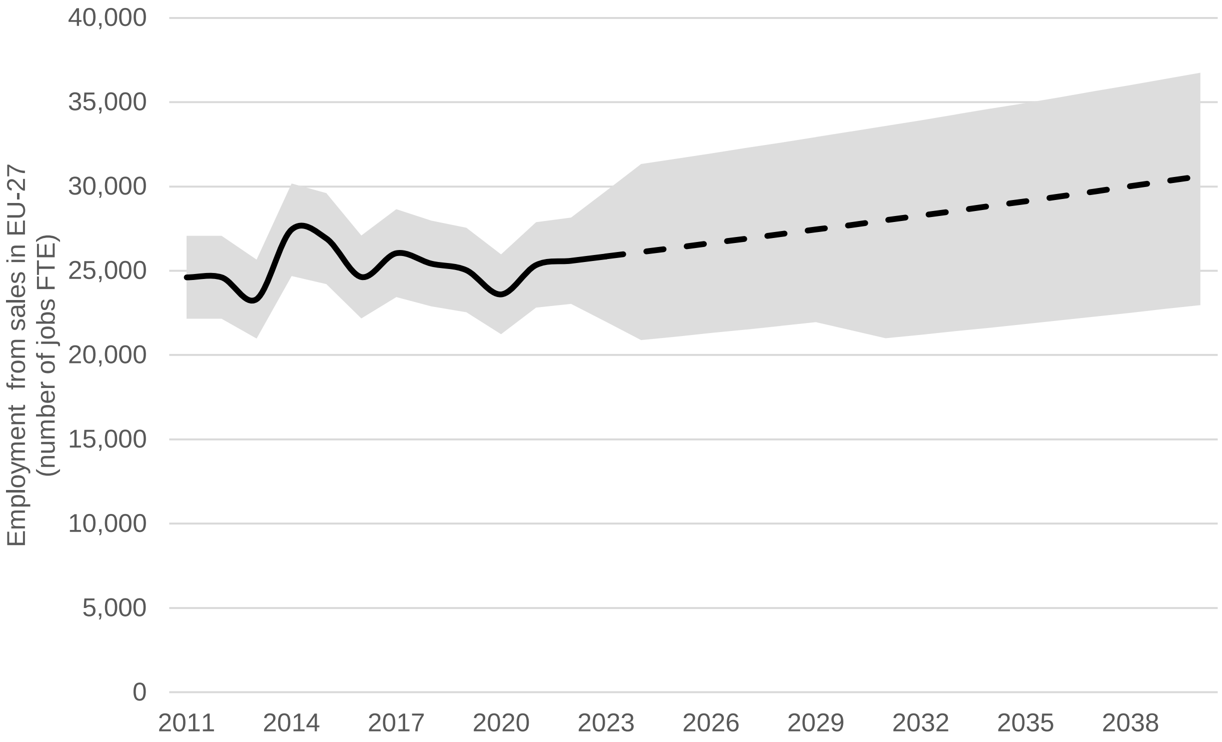
In fact, the evidence points to an EU-27 'downstream user' manufacturing industry that is increasingly more challenged by international competition as well as more reliant on third country imports. At present, estimates of 'downstream user' imports and exports in 2022 suggest that they are of a similar scale, €345 billion and €390 billion respectively. However, whilst the evolution of international trade differs across 'downstream user' sectors, the evidence available suggests that, overall, imports might also grow relatively faster than exports in the future. Most recently, in the post-pandemic period, exports have faced significant downward pressures, especially in some of the downstream sectors in scope or when compared to imports, which have generally continued to grow.

These estimates and conclusions remain uncertain. There are multiple, exogenous economic, geopolitical and regulatory dynamics that will continue to affect international trade. **This said, overall, it is considered that: 1) the EU-27's industry appears to be losing competitiveness in the global context; and 2) the estimated scale and potential evolution of international trade offer a reasonable counterfactual against which to consider the effects of the policy scenarios under assessment.**

3.1.2.4 Employment supported by these industries

The D4, D5, D6 and silicone polymer industry as well as the 'downstream user' sectors employ more than 3.4 million people directly in the EU-27. In detail, the manufacturing and complementary activities associated with the D4, D5, D6 and silicone industries involves more than 25,000 people employed across the EU-27. These professionals are involved in research and development, manufacturing, logistics and a range of other activities required to produce and sell high-quality products to their customers in the EU-27 or abroad. Historically, employment has grown positively but at a slower rate than the industrial activity. This could be partly driven by continued technological advancement and transformation within the industry. It is also estimated that employment will continue to grow in the baseline, at a real CAGR of around 1%, to enable the forecast growth in industrial activity. As a result, the number of jobs that could be directly supported by these upstream industries could reach 30,000 jobs in 2040, as presented in Figure 3-5 below.

Figure 3-5 Baseline direct employment supported by the D4, D5, D6 and silicone polymers industry in the EU-27 (Number of jobs)

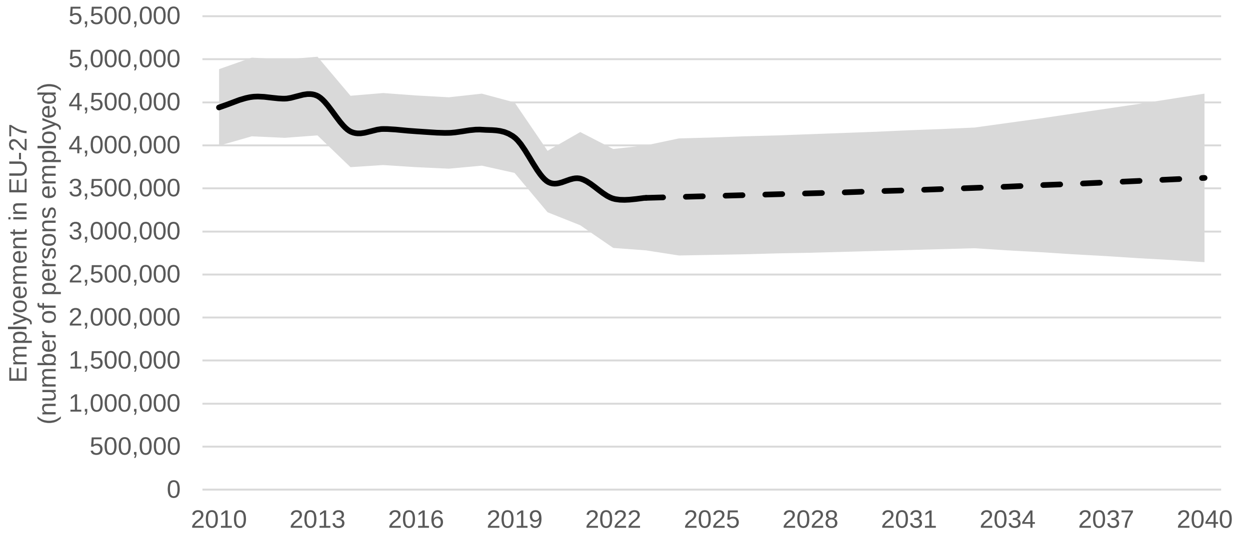


Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

As noted above, D4, D5, D6 and silicone polymers play critical roles in a range of ‘downstream user’ sectors. **Significant parts of this sectoral activity in the EU-27 rely, in some way, on these substances and materials within their manufacturing processes and/or as critical components to intermediate and final products (such as cars, motors, airplanes, semi-conductors, medical devices, etc).** Employment supported across these ‘downstream user’ sectors has thus also been analysed and estimated for establishing a baseline that might be potentially affected by any of the policy scenarios under consideration.

The available evidence suggests that, in 2022, **‘downstream user’ industries directly employed more than 3.4 million people in the EU-27.** Employment across these industries appeared to suffer from a downward trend over the past decade, potentially driven by sectoral transformation, technological advancement and/or international competitiveness. Some of this decline is particularly pronounced in recent years, which might not be representative of the medium-term trend. Based on input from companies and experts, it was considered that a relatively flat baseline might be most appropriate for this assessment, given the uncertainty that surrounds the necessary transformation that the EU-27 manufacturing industry has embarked on and which will accelerate over the coming decade. The forecast is presented in Figure 3-6 below.

Figure 3-6 Baseline direct employment supported by the 'downstream user' industry in the EU-27 (Number of jobs)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

This estimated, direct employment supported across the D4, D5, D6 and silicone polymer industry and its downstream users (the 'value chain') will be amplified by intermediate purchases of goods and services (the indirect effect) and the economic contribution of expenditures and consumption by these very same employees (the induced effect). **This means that the estimated employment footprint of this 'value chain' in the EU-27, including the direct, indirect and induced effects, could surpass 9 million jobs[279].**

3.1.2.5 Consumption and use of D4, D5, D6 and silicone polymers

The D4, D5, D6 and silicone polymers industries play critical roles across a range of essential 'downstream user' sectors in the EU-27 that affect the lives of millions of households. This could include the use of cars, the availability and effectiveness of medical devices, the availability of semiconductors and the knock-on implications on the availability and performance of a wide range of electronics, the generation of low carbon energy, and the ability to effectively heat and cool buildings, etc.

In more detail, silicone polymers are known for their versatility and are employed in a wide range of applications including transport, aerospace and defence, electronics, construction, low-carbon energy, healthcare and more. In construction, they serve as sealants, adhesives, and waterproofing agents, enhancing the longevity and performance of structures; in electronics, silicone polymers provide insulation and protection, ensuring the reliability of electronic devices, and are key in the manufacture of semiconductors and glass fibres; in paper product manufacturing silicones help de-airing or drainage in the pulp washing and paper-making processes. Furthermore, their heat resistance and flexibility make them indispensable in automotive manufacturing for gaskets, hoses, and seals.

The availability and performance of these substances and materials in the baseline, thus, affects the availability, quality and performance, and costs of the final products they supply to consumers and households across the EU-27. For example, applications in electronics, especially semiconductors, play a key role in technological development and the digital economy that is pivotal to achieve the EU's green and digital transitions.

[279] Input-Output methodologies were employed to produce these estimates. Please see the Annexes for more details on the methodology employed.

In addition, regulatory actions under consideration to achieve a range of EU Green Deal objectives, such as the Net Zero Industry Act[280], and the zero-pollution ambition, including the potential restriction of per- and polyfluoroalkyl substances (PFAS), would result in additional demand for silicone polymers as a reasonable alternative in the baseline. As an illustration, silicone polymers can serve as substitutes for certain fluoropolymers, offering a means to mitigate the potential economic implications of any further restriction on the manufacture and placing on the market of PFAS.

Key net-zero technologies which currently require the use of D4, D5 and D6 and silicone polymers include:

- Solar technologies, including solar photovoltaic, solar thermal electric and solar thermal technologies;
- Onshore wind and offshore renewable technologies;
- Battery and energy storage technologies;
- Heat pumps and geothermal energy technologies;
- Hydrogen technologies, including electrolysers and fuel cells
- Electricity grid technologies, including electric charging technologies for transportation and technologies to digitalise the grid
    - Nuclear fission energy technologies, including nuclear fuel cycle technologies;
    - Renewable energy technologies, not covered under the previous categories;
- Energy system-related energy efficiency technologies, including heat grid technologies;
    - Transformative industrial technologies for decarbonisation not covered under the previous categories;
    - CO2 transport and utilization technologies;
- Wind propulsion and electric propulsion technologies for transportation;
- Nuclear technologies not covered under previous categories.[281]

This underscores the **additional relevance that silicone polymers could gain in the baseline scenario, given the evolving regulatory landscape** that will likely affect a range of chemical substances that have been, to date, ubiquitous in consumer applications across the EU-27 and globally.

3.1.3 Environmental baseline

As outlined in Section 2.2, the REACH Annex XV restriction proposal on the use of D4, D5 and D6 in consumer and professional products, including cosmetics, is estimated to result in a reduction of approximately 90% of the emissions to the environment. However, this restriction excludes certain uses, such as industrial uses for the formulation of mixtures, production of silicone polymers or production of articles (see Section 1.2), meaning that around 10% of emissions are expected to remain[282,65]. These are termed the "baseline emissions" in this Study and are the basis against which emission reductions in the policy scenarios shall be measured.

[280] Council of the European Union (2024) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act)

[281] Council of the European Union (2024) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act)

[282] Ibid footnote 49

Table 3-2 Overview of baseline environmental emissions

Indicator	Remaining emissions of impurities from silicone polymers (tpa)	Remaining emissions from other use (tpa)	Steady-state environmental stock (t)
Baseline emissions	597-708	841-901	36-41

3.2 POLICY SCENARIOS UNDER CONSIDERATION

In this assessment three policy scenarios have been developed based on indications of considerations by the Commission, as well as previous examples of nominations to the Stockholm Convention. These three scenarios are described in detail below, with an overview of the initiative provided in Figure 3-7. These policy scenarios are compared to a business-as-usual baseline scenario to understand the impacts in Section 0. The policy scenarios (1-3) provide an increase in the scope of prohibitions, from broad exemptions (PS1) to total prohibition (PS3).

Although the EU's draft nomination suggests a proposal to list the siloxanes in Annex B, there is no guarantee that this will be agreed. **Nominating parties do not have inherent legal authority to dictate the final deposition of a nomination listing and conditional nominations cannot be made, such that the Annex, derogations or end control measures they deem appropriate cannot be specified. Instead, the nomination of D4, D5 and D6 to the Stockholm Convention would trigger a multilateral procedure that would determine both the placement of the listing and the content of the associated control measures.**

Figure 3-7 Overview of the problem tree, specific objectives and the proposed initiative

Policy context

Stockholm Convention

European Green Deal

Circular Economy action plan

Zero-Pollution Action Plan

REACH Regulation
- restriction D4/ D5/ D6 in professional and consumer products

Cosmetic Products Regulation

Drivers

Widely used in upstream and downstream products
D4, D5 and D6 may be used directly as substances within mixtures, as a monomer in the production of silicone polymers, and in the production of certain components.

Environmental Fate and Behaviour
D4, D5 and D6 meet the criteria for PBT/ vPvB under REACH, with some evidence for long-range environmental transport, thus potentially qualifying as a POP under the Stockholm Convention.

Uncertainty in real-world environmental risk
Conflicting evidence creates difficulties in identifying the real-world environmental risk of D4, D5 and D6

Problems

Regulation of D4, D5 and D6 under REACH in the EU does not result in regulation at a global level

The high persistence in the environment and possible long-range transport, bioaccumulation potential and potential toxicity to sediment and terrestrial organisms means that regional regulatory action does not offer sufficient protection. Broader international action is required.

Specific objectives

1. Limit the potential for transboundary exposure to D4, D5 and/or D6 from non-EU cosmetic and other consumer sources

2. Avoid (or mitigate) international trade and competition distortions, which would otherwise negatively affect the EU's industry

3. Contribute to the transition towards the use of safer chemicals, improved resource efficiency and the circular economy

Overview of the policy scenarios

Three policy scenarios have been identified to address these shortcomings and problems, and meet the defined specific objectives.

PS1: Stockholm Convention Annex B listing

Acceptable purpose granted for:
- production of silicone polymers with the use of D4, D5 and D6 as intermediates;
- transport of D4, D5 and D6 for the sole purpose of the production of silicone polymers, with a threshold for D4, D5 and D6 of ≤0.1% w/w each for the placing on the market of polymers and formulations of polymers.

PS2: Stockholm Convention Annex B listing
Global exemptions for:
- acceptable purpose granted for the manufacture of D4, D5 and D6;
- transportation of D4, D5 and D6 only allowed for exempted uses;
- use as intermediate for the production of polymers used in specific applications.

The acceptable purpose exemptions include for use as an intermediate in the production of silicone polymers used in the following applications:
- as a silicone encapsulant in solar panels used in space satellites;
- as an encapsulant in LED lighting;
- as a liquid silicone rubber to manufacture seals for aircraft windows;
- as a liquid silicone rubber to manufacture medical tubing;
- as a surfactant or stabiliser in polyurethane foams used in construction insulation;
- as a sealant used to bond glass to steel in building facades; and
- use of D4 in the manufacture of semi-conductor wafers.

PS3: Stockholm Convention Annex A listing

Prohibition on the manufacture and use of D4/5/6

3.2.1 Policy Scenario 1

This policy scenario includes the listing of D4, D5 and D6 under Annex B of the Stockholm Convention with broad exemptions for the production of silicone polymers.

Box 3-1 Policy Scenario 1 description

Stockholm Convention Annex B listing

Exemptions granted for

- production of silicone polymers with the use of D4, D5 and D6 as intermediates;
    - transport of D4, D5 and D6 for the sole purpose of the production of silicone polymers, with a threshold for D4, D5 and D6 of ≤0.1% w/w each for the placing on the market of polymers and formulations of polymers.

Further implications include:

- the transportation of D4, D5 and D6 only allowed for exempted uses i.e., to produce silicone polymers and polymer mixtures and the components containing them;
- the manufacturing process for D4, D5, D6, silicone polymers and mixtures containing them are required to take place under strictly controlled conditions;
- all silicone polymers, mixtures, and the components containing them placed on the relevant markets (including for industrial uses) must contain residues below 0.1% of D4, D5 and D6;
- the recycling of materials containing and derived from D4, D5 and D6 is prohibited;
- polymers, mixtures and the components containing them cannot be exported, to any non-Party to Stockholm Convention;
- the import and export from or to Parties to the Convention would be permitted for exempted purposes only if the receiving or sending country has implemented the specific exemption into National law; and
- the Stockholm Convention overrules any derogation provided in EU Legislation, unless these derogations are stricter in existing EU legislation.

3.2.2 Policy Scenario 2

This policy scenario also includes the listing of D4, D5 and D6 under Annex B of the Stockholm Convention, with specific exemptions for the production of silicone polymers against acceptable purposes. The acceptable purposes below were chosen by Cefic to illustrate the impact if policy scenario 1 could not be achieved and a narrow scope of exemption was used.

Box 3-2 Policy Scenario 2 description

Stockholm Convention Annex B listing

Global exemptions for:

- acceptable purpose granted for the manufacture of D4, D5 and D6;
- transportation of D4, D5 and D6 only allowed for exempted uses;
    - use as intermediate for the production of polymers for specific applications.

The acceptable purposes include for use as an intermediate in the production of silicone polymers for the following applications:

- as a silicone encapsulant in solar panels used in space satellites;

- as an encapsulant in LED lighting;
    - as a liquid silicone rubber to manufacture seals for aircraft windows;
- as a liquid silicone rubber to manufacture medical tubing;
- as a surfactant or stabiliser in polyurethane foams used in construction insulation;
- as a sealant used to bond glass to steel in building facades; and
- use of D4 in the manufacture of semi-conductor wafers.

The further implications stated under Policy Scenario 1 are also relevant to this scenario.

3.2.3 Policy Scenario 3

This policy scenario includes the listing of D4, D5 and D6 under Annex A of the Stockholm Convention.

Box 3-3 Policy Scenario 3 description

Stockholm Convention Annex A listing
Prohibition on the manufacture and use of D4, D5 and D6.

This policy scenario includes a prohibition on the manufacture, import, export, placing on the market, use and transportation of D4, D5 and D6. This prohibition also encompasses polymers, mixtures and articles that contain D4, D5 and/or D6. Transport of these substances, mixtures or articles is only permitted for waste disposal and recycling is not allowed.

4. IMPACTS OF THE POLICY SCENARIOS

This section contains a presentation of the economic, social, and environmental impacts across specific impact categories and concludes on the overall costs and benefits associated with each of the three policy scenarios under consideration related to a potential nomination of D4, D5 and D6 to the Stockholm Convention.

The section summarises the assessment approach (Subsection 4.1), and the *ex-ante* assessment of impacts, costs and benefits pertaining to economic (Subsection 4.2), social (Subsection 1.1), and environmental (Subsection 4.4) dimensions. A horizontal summary of the uncertainties and sensitivity analysis is also included (Subsection 4.5).

A more detailed description of the assessment methodology and other analytical methods employed in this report can be found in the Annexes.

4.1 SUMMARY OF THE APPROACH

A **five-step approach** has been employed to assess the impacts of each policy scenario, following the latest Commission's **Better Regulation Guidelines and Toolbox** (BRG, BRT)[283], [284]. These steps are:

- Step 1: Mapping and longlisting all potential impacts of the policy scenarios.
- Step 2: Screening this longlist based on the estimated absolute and relative magnitude of these impacts and their likelihood, based on the available evidence.
- Step 3: Shortlisting the potentially most significant impacts (costs and benefits).
- Step 4: Assessing these impacts, qualitatively and/or quantitatively.
- Step 5: Reviewing key uncertainties and conducting sensitivity analysis.

All key economic, environmental, and social impacts of the policy scenarios across stakeholder groups – public authorities, industry (larger and smaller businesses), citizens and workers, third countries – were identified and mapped onto a longlist of 34 potential impacts (**Step 1**). This longlist of impacts was screened, by considering their absolute and relative magnitude and likelihood of occurrence based on the available evidence (**Step 2**), so that a selection of the significant impacts could be developed. This exercise was conducted following the Tool # 18 (identification of impacts) of the Commission's Better Regulation Guidelines, and the details are summarised in Annex 2. Health impacts have been reviewed and screened out of the social impacts due to the evidence of toxic effect in laboratory animals not being relevant to humans (See Annex 2). Following communication with the Commission, it has been established that the Public Authority impacts related to the administrative burden of implementation and enforcement would not be significant as a result of this Stockholm Convention nomination for D4, D5, D6 and so Public Authority impacts have been screened out of the assessment (see Annex 2). The output of this exercise is a shortlist of the most significant categories of impact for in-depth assessment as part of this Study (**Step 3**).

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[283] European Commission (2021) Better Regulation Guidelines and Toolbox. Available: Better regulation: guidelines and toolbox (europa.eu)

[284] European Commission (2023) Better Regulation Toolbox. Available: 9c8d2189-8abd-4f29-84e9-abc843cc68e0_en (europa.eu)

Table 4-1 presents this list, coupled with a brief description of the impacts and proxy indicators that are employed in the *ex-ante* assessment of their direction and scale over time.

Table 4-1 Significant categories of impact for in-depth assessment

Broad and specific categories		Description
Economic impacts	Conduct of businesses, functioning of the internal market, and sustainable production	Substantive adjustment costs, which refer to any changes to capital and/or operating expenditure that would be required under the policy scenarios, excluding administrative burden. These costs might include adjustment or reformulation and substitution of products and the economic and other implications, which might include the opportunity costs of market withdrawal of substances and products that would no longer be compliant with the new regulatory environment under each Policy Scenario, impacts on consumer choice, and any impacts on sustainability. (Tools #21-25 and #36 BRT)
	Administrative burden on businesses	Any administrative costs and/or direct regulatory charges, especially pertaining to the administrative approval processes required to trade with third countries. (Tool #58 BRT)
	Position of SMEs	The costs of the policy scenarios on the industry, organised by organisational size will also be considered to understand the extent to which SMEs may or may not be disproportionately affected by the PS. Average administrative and adjustment 'costs per employee' (following the SME test) will be estimated to consider any difference in industry impacts by organisational size. (Tool #23 BRT)
	Innovation and research	The extent to which additional investment and expenditures in Research and Development may lead to innovation outcomes and/or new market opportunities under each of the policy scenarios.
	Sectoral competitiveness, trade and investment flows; and third countries	The extent to which the policy scenarios may affect the costs of doing business in the EU-27, especially in comparison to competitors within and outside of the Stockholm Convention; and the any implications that this might have on the geographical distribution of manufacturing activity. (Tool #21, #24, #25, #27 and #35 BRT)
Social impacts	Employment	Employment (or jobs) supported by the industry and value chain in the EU-27. (Tool #30 BRT)
	Consumers and households	The extent to which the policy scenarios might affect consumers' access to good and services from within and outside of the EU-27, including availability and choice, quality and price. (Tool #33 BRT)
	Technological development and the digital economy	The extent to which the policy scenarios might affect the possibilities and pace of the EU's digital transformation. (Tool #28 BRT)
Environmental impacts	Quality of natural resources (water, soil, air)	The effects of the policy scenarios on the concentration of harmful chemicals in air, water and soil, affecting the quality of air, soil and the quality and/or quantity of freshwater, groundwater, coastal and marine areas, drinking resources, etc. (Tool #36 BRT)
	Biodiversity, including flora, fauna, ecosystems and landscapes	Potential effects on the quality of natural resources, the population of organisms and biodiversity (linked to quality of natural resources). (Tool #36 BRT)
	Waste production, generation, and recycling	Potential changes in waste production and treatment options resulting from the Policy Scenarios. (Tool #36 BRT)
	Climate, efficient use of resources; transport and the use of energy	The extent to which this might affect the use of non-renewable sources of energy and ability to use renewable sources, as well as the shift towards greener modes of transport (Tools #21, #22, #36 of the BRT)

The impacts, costs and benefits of each policy scenario will be assessed in-depth along these shortlisted categories or dimensions (**Step 4**), so they can be compared and conclusions on the overall and relative merits can be developed. Some of the impact categories have been grouped as they are interrelated.

Qualitative and quantitative methods aligned with the Better Regulation Guidelines and Toolbox are proposed to characterise impacts, costs and benefits over the period of 2023-2040 (see the Annexes for methodological details). In summary, where evidence was available, impacts were quantified. For example, quantitative analysis was performed to estimate the impacts on: manufacturing activity and economic contributions in the EU-27, in terms of adjustment costs, administrative burden and Gross Value Added impacts, as well as employment supported in the EU-27; and environmental emissions of D4, D5 and D6 under each policy scenario.

Other impacts were not quantifiable. Thus, qualitative methods were employed to bring together all of the evidence conclusively, as much as it was possible. A scoring approach, on a scale of -5 to +5, was applied to rate each policy scenario across the selected impact categories. The scoring reflects the direction (positive or negative) and magnitude (weakly to strongly, limited or unclear) of impacts, which is also represented using the colour codes set out below. Please note that this approach is also consistent with the Better Regulation Tools sign-posted on the previous Table.

Table 4-2 Scoring and colour coding used to present the assessment conclusions

Strongly negative	Negative	Weakly negative	No or limited impact	Weakly positive	Positive	Strongly positive	Unclear
-5	-3	-1	0	+1	+3	+5	N/A

The assessment outputs, both qualitative and quantitative, have been used as a basis to establish a set of internally coherent, comparable and evidence-based ‘scores’. This has required an iterative and multidisciplinary approach that is described in detail in the Annexes.

Finally, the evidence and analytical outputs generated for this Study are uncertain (**Step 5**). There are uncertainties that are inherent to *ex-ante* assessments, but these are exacerbated, in this case, by limitations to the availability of evidence.

4.2 ECONOMIC IMPACTS

This section presents the assessment of impacts of the three policy scenarios on industrial activity in the EU-27, including effects on production, the conduct of business and the administrative burden faced by EU-based businesses; the position of SMEs; innovation and research; sectoral competitiveness, trade and investment flows and the functioning of the internal market; and the overall contribution to economic value-added in the EU-27.

The section is structured in five subsections as follows:

- **Industrial activity:** estimated impacts on the size, functioning and sustainability of the industry following different scenarios of the listing of D4, D5 and D6 under the Stockholm Convention.
- **Innovation and research:** investigation of the potential alternatives to the use of D4, D5 and D6 and silicone polymers, including availability, technical feasibility, and performance of alternatives.

- **Competitiveness, trade and functioning of the internal market:** estimated impacts on industry's competitiveness and a discussion of the implications of the Stockholm Convention nomination might have on international trade dynamics.
- **Overall economic impacts in the EU-27:** estimated impacts on the overall EU-27 economy, quantitatively via potential implications on the Gross Domestic Product of the EU-27 and qualitatively across the shortlisted impact categories.
- **Sectoral deep dives:** Exploration of the effects of the policy scenarios across specific downstream sectors.

The analysis and results presented in this Section are based on publicly available evidence and literature, including Eurostat datasets such as PRODCOM and SBS and multiple external sources such as, e.g., socio-economic analysis reports from the Global Silicone Council and overall industry and market studies[285,286,287]; and the online survey and follow-up interviews of companies manufacturing or importing D4, D5, D6 and silicone polymers and 'downstream user' businesses across sectors in scope of this Study. A detailed consultation synopsis is summarised in the Annexes. The evidence presented in this the following sections is thus based on analysis of the evidence from these sources. Please note that when ranges are presented, the 'medium' estimate is generally based on the weighted or simple averages of the evidence collected, and the 25% and 75% percentile usually provide the basis for the 'low' and 'high' estimates.

4.2.1 Industrial activity (size, functioning and sustainability)

In 2022, the scale of manufacturing activity in the EU-27 across the upstream and downstream industries in scope has been estimated to surpass €1 trillion (see Section 3.1), which comprises around €4 billion of sales from upstream manufacturing activity and just above €1 trillion of sales from 'downstream user' manufacturing activity in the EU-27. This section summarises the assessment of impacts of adopting the three policy scenarios in three key steps.

- **Step 1: 'the affected portfolio of products' is estimated across the policy scenarios.** Conceptually, under PS1, any D4, D5 or D6 which are not used as a monomer in the production of silicone polymers, silicone polymers that contain more than 0.1% w/w of impurities of D4, D5, D6 and/or any 'downstream user' companies that rely on these products would be affected. Under PS2, any manufacture of D4, D5 or D6 as well as silicone polymers containing impurities would be affected unless they are classified as 'uses for acceptable purposes', in which case they would follow the requirements set out under this policy scenario. Finally, under PS3, all of D4, D5 and D6 manufacturing and uses would be prohibited, having knock-on implications on the manufacture and use of silicone polymers and their downstream supply chains.
- **Step 2: the business response through the introduction of potential alternatives and substitutes and the additional costs that could be incurred.** Illustratively, alternative processes to produce silicone polymers might include technologies that can reduce the presence of impurities of D4, D5 and D6 to at least below 0.1% w/w. Moreover, applications of silicone polymers across 'downstream user' could be substituted by other substances and/or materials that do not contain

[285] Ibid footnote 54

[286] Amec Foster Wheeler (2017). Global Silicones Council. Impact Assessment of D4 POP Listing.

[287] Global Silicones Council (2020) Silicone Research. An Industry Commitment. Available: https://globalsilicones.org/wp-content/uploads/2020/10/Silicone-Monitoring-initiatives.pdf

any impurities of D4, D5 and D6. A literature review was conducted, and companies were consulted to estimate the potential scale and capital and operating costs of 'substitution'.

- **Step 3: impacts on industrial activity in the EU-27 were estimated.** Having identified the proportion of upstream and downstream activity that could be affected under each of the policy scenarios (step 1) and characterised the potential business response to reduce these impacts (step 2), the potential effects on the scale of industrial activity in the EU-27 were considered. This could include shifts in manufacturing of upstream activity to other regions in which substitution may be economically viable and/or withdrawing products and even complete supply chains from the market. The scale of these impacts has also been estimated by considering the available literature and input from companies within the D4, D5, D6 and silicone polymer industry as well as 'downstream user' sectors.

The analysis across each of these steps and, thus, the assessment of impact on the size, functioning and sustainability of the EU-27 industry are considered in the following subsections.

4.2.1.1 The portfolio of products that could be affected by the policy scenarios (step 1)

Businesses were consulted (N[288]=124) about the products they manufactured, imported and/or distributed in the EU-27 across the D4, D5, D6 and silicone polymer industries (N=27) as well as a diverse selection of 'downstream user' sectors (N=97), including transport, aerospace and defence, construction (materials and machinery), healthcare (medical devices and pharmaceuticals), low-carbon energy (manufacture), electronics, paper products and component manufacturers and/or importers of sealants, lubricants, insulation, adhesives, coatings and paints.

The policy scenarios under consideration pose a significant challenge to the EU-27 manufacturers, importers and/or distributors of D4, D5, D6 and silicone polymers. All (100%) manufacturing and importing activity pertaining to the D4, D5, D6 and silicone polymer markets could be potentially affected, although there are different levels of exemptions built into some of the policy scenarios (as described in Section 3.2). It has thus been key to estimate the scale of these exemptions in terms of sales turnover to understand the size of the potentially affected portfolio. The analysis of evidence collected through the industry consultation suggests that under PS1, 80% (65-95%) of the sales from manufacturers and importers of D4, D5, D6 and silicone polymers could be exempted, down to 15% (5-25%) under PS2 or 0% under PS3, as no exemptions are considered in this scenario. The rest of the product portfolio (that is, that which is not exempted) would represent the scale of products that could be affected under each policy scenario. These estimates are summarised in the Table below.

[288] N is short for the sample size of the businesses that participated in the online survey and follow-up interviews conducted as part of this Study. A total of 124 businesses submitted evidence to this Study. More organisations participated; however, their submissions were insufficiently complete to include as part of the assessment. Of these 124, 27 were businesses or organisations which belonged to the D4, D5, D6 and silicone polymer industries and 97 were 'downstream users'. A more detailed consultation synopsis can be found in the Annex.

Table 4-3 Percentage of sales turnover of the D4, D5, D6 and silicone polymer industries in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the sales turnover of D4, D5, D6 and silicone polymers industries which could be **potentially exempted**	80% (65%-95%)	15% (5%-25%)	0%
Percentage of the sales turnover of D4, D5, D6 and silicone polymers industries which could be **potentially affected**	**20% (5%-35%)**	**85% (75%-95%)**	**100%**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=26).

The 'downstream user' companies that rely, in some way, on D4, D5, D6 and/or silicone polymers in their manufacturing processes and/or for their product components would necessarily be affected in some way. It is, however, uncertain the extent to which companies across the 'downstream user' sectors in scope do indeed rely on these substances and materials. Thus, 'downstream user' companies were also consulted.

Firstly, the survey participants were asked about the proportion of the intermediate and/or final products they manufacture and/or import that could contain and/or depend (in the manufacturing process) on D4, D5, D6 and silicone polymers or silicone polymer formulations. Based on their submissions, it is estimated that **around 75% (25-100%)[289] of the sales value of these 'downstream user' industries would likely rely, in some way, on D4, D5, D6 and silicone polymers**.

'Downstream user' companies were asked whether they were aware of the D4, D5 and D6 presence, w/w, in the materials and/or products used within their processes and/or specific components of their products. This evidence is less readily available to 'downstream user' firms, and thus fewer participants were able to provide this information in their submissions. A sample of ~30 companies across sectors supplied information, which provides interesting insights that add to further understanding, albeit by no means statistically representative. Moreover, it is harder to collect this information robustly and in a comparable way, thus it is summarised on the Table below as an illustration with caveats and limitations.

Table 4-4 Proportion of the sales in the EU-27 that rely, in some way, on D4, D5, D6 and/or silicone polymers by w/w content of D4, D5, D6

Proportion of sales that relies on D4, D5, D6 and/or silicone polymers (i.e., ~75% of all sales by 'downstream users'), which contains…	Estimate (%)
More than 0 but less than 0.01% w/w of D4, D5, D6	~20%
More than 0.01 but less than 0.05% w/w D4, D5, D6	~15%
More than 0.05 but less than 0.1% w/w D4, D5, D6	~40%
More than 0.1 but less than 0.5% w/w D4, D5, D6	~15%
More than 0.5 but less than 1% w/w D4, D5, D6	~5%
More than 1% w/w D4, D5, D6	~5%
Total	100%

Source: Ricardo analysis based on evidence collected from business stakeholders (N=30).

289 Please note that whilst there are wide variations across the survey respondent; the central estimate of this indicator appears reasonable and potentially conservative, given that of survey submissions representing more than 70% of the turnover of all respondents reported more than 75% of their portfolio potentially relying in some way on D4, D5, D6 and silicone polymers.

Stakeholders were asked more directly about the extent to which they believed the products they manufactured and/or sold in the EU-27 would be covered by the exemptions specified under each of the policy scenarios. As found in the upstream markets, companies estimated the exemptions under PS1 to cover a larger proportion of their activity than under PS2. No exemptions are available under PS3. The activity that relies on D4, D5, D6 and silicone polymers that is not exempted would, therefore, be potentially affected by the policy scenarios. These estimates are presented in the Table below.

Table 4-5 Percentage of sales turnover of the selected 'downstream user' industries in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of 'downstream user' **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers**…('reliant sales') –(1)	75% (60%-99%)		
Of these 'reliant' sales, the percentage that could be **potentially exempted** –(2)	70% (20%-99%)	40% (10%-80%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** –(3)	30% (1%-80%)	60% (20%-90%)	100%
Or, equivalently, the **proportion of all 'downstream user' sales that could be potentially affected** –(4)[290]	**20% (1%-80%)**	**45% (15%-95%)**	**75% (60%-99%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N>80).

This means that 20% (1-80%) of all 'downstream user' sales in the EU-27 could be potentially affected under PS1; 45% (15-95%) under PS2 and 75% (25-100%) under PS3. As mentioned previously, there are a range of applications of D4, D5, D6 and silicone polymers across 'downstream user' sectors that are critical and on which these industries rely, either as part of the manufacturing processes and/or components within the design of their intermediate and final products. The policy scenarios could, therefore, have sizeable ramifications throughout downstream markets across Europe, the functioning of the internal market, the costs of doing business in the EU and global competitiveness, and the availability of high-quality products and consumer choice.

Business will undoubtedly take any action they can to mitigate any potential disruptions of their activity in the EU-27. These are considered in the following subsection.

4.2.1.2 The business response through the introduction of alternatives and/or substitutes and associated costs (step 2)

Upon the introduction of any of the policy scenarios under consideration, **companies manufacturing, importing, distributing and/or using D4, D5, D6 and/or silicone polymers will respond by making adjustments to their products and/or operations in the EU-27 if these are technically and economically viable,** or withdraw from the EU-27 market (see Section 4.2.1.3). A literature review was conducted, and business were asked to explore any viable adjustments they could make to the baseline substances, materials and products along the supply chain and/or introduce any viable alternatives or substitutes they have identified and/or developed so far.

[290] Please note that these estimates (4) = (1) × (3). (1), (2), and (3) are estimates directly sourced from the analysis of the evidence submitted by the participants of the online survey.

The findings suggest that viable adjustments, alternatives and substitutes exist, especially under PS1 and, to a much lower extent, under more restrictive scenarios PS2 and PS3, albeit this is uncertain. Cyclic siloxanes play a crucial role in silicone polymer production resulting in the presence of D4, D5 and/or D6 as impurities. Removal or 'stripping' technologies that are available could, at a cost (e.g., CAPEX on technological assets, higher energy requirements, loss of productivity due to longer cycle times, etc.), reduce these impurities below 0.1% w/w, albeit they cannot remove the impurities completely. Alternative processes could also be introduced that would lower the presence of these impurities. However, the resulting materials and products, both up and downstream, can fall short on performance when compared to the baseline and have other implications that are considered in subsequent sections of this assessment, such as the short useful product/asset lives and the need for more frequent component or product replacements, lower levels of energy efficiency and thus increases in energy use and potentially additional greenhouse gas emissions. Section 4.2.2 provides additional insights and depth on the opportunities that innovation and research might offer companies if the policy scenarios were adopted, covering the availability, viability and performance of potential 'alternative' or 'substitute' options.

The scale of these viable adjustments, alternatives and substitutes also remains uncertain. It is difficult to estimate the proportion of the affected portfolio of baseline products under each policy scenario that could be adjusted and/or replaced with viable alternatives, especially given the wide range of applications with different technical and economic requirements. Upstream and 'downstream user' companies consulted as part of this Study were tasked with reviewing all of their product portfolios and establishing which would viably be adjustable and/or replaceable under each of the policy scenarios.

Businesses manufacturing D4, D5, D6 and silicone polymers in the EU-27 could be able to transform part of their production under PS1 and PS2, whilst these production activities would be technically unviable under PS3. Some survey participants reported they would be able to replace at least part of their operations in the EU-27 under PS1 and PS2, and address challenges with the economic viability, especially of removal technologies, by increasing their production activity in third countries where costs of production would be relatively lower, e.g., China[291]. This would enable them to increase imports into the EU-27 and remain competitive in the global market of silicones despite the additional costs incurred as a result of the policy scenarios (e.g., through the investment in the technologies to reduce impurities of D4, D5 and/or D6 in silicone polymers, etc). Under PS3, there are no financially[292] viable technologies or processes that would lead to the production of silicone polymers without detectable, residual levels of D4, D5 and/or D6, and thus, no alternative options were identified. The Table below presents the estimated proportion of the affected operations that could be adjusted and/or replaced by alternatives or substitutes upstream under each policy scenario.

Table 4-6 Estimated level of upstream 'substitution' in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of D4, D5, D6 and silicone polymer products that could be **adjusted and/or replaced by alternatives/substitutes** (including silicone	50% (10%-80%)	35% (10%-60%)	0%

[291] Countries Party to the Stockholm Convention e.g., China

[292] The evidence gathered through the consultation conducted for this Study suggested that it is not technically viable now to remove impurities of D4, D5, D6 to undetectable levels within silicone polymers. However, it could not be confirmed whether this was driven by financial and/or technological barriers.

Indicator	PS1	PS2	PS3
polymers with lower residue levels), in sales turnover.			

Source: Ricardo analysis based on evidence collected from stakeholders (N=27).

These changes to manufacturing in the EU-27 could be complemented by a shift towards production in third countries for import, further developed in the subsequent Section 3.1.2.3. In summary, and especially under PS1, this could mean that **whilst adjusting or replacing domestic production of D4, D5, D6 and silicone polymers is not necessarily economically viable, it could be complemented by an increase in imports that could meet the policy scenario requirements.** Fewer exemptions and more restrictive requirements under PS2 and PS3 could affect sectors in which silicone polymer applications are critical and no technically and economically viable alternatives have been identified.

The evidence collected in an online survey highlighted a lack of knowledge in 'downstream user' markets of potential alternatives to the silicone polymers they rely on in the baseline (N=82). In fact, these companies were asked whether they were aware of alternative substances, polymers and/or mixtures; product components; and/or overall 'substitute' products that they could draw on to adjust and/or replace their baseline production and/or importing activities in the EU-27. The majority of the company respondents (94% or 77 companies) submitted that "there are no alternatives that we are aware of". This lack of awareness could affect any transitional period if any of the policy scenarios were adopted.

Nevertheless, the potential level of 'substitution' overall in the downstream user markets in scope of this Study was estimated under each Scenario, by drawing on expert input, in-depth follow-up interviews with selected 'downstream user' companies, and the evidence collected from companies operating across upstream markets. These estimates are presented on the Table below.

Table 4-7 Estimated level of downstream user 'substitution' in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of 'downstream user' companies in scope that could be **adjusted or replaced by alternatives/substitutes**, (including silicone polymers with lower residue levels), in sales turnover.	90% (65%-95%)	50% (20%-90%)	10% (5%-20%)

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Under PS1, it is estimated that around 50% (10-80%) of the baseline affected D4, D5, D6 and silicone polymer activities in the EU-27 could be retained with adjustments. In addition, it was concluded that imports of silicone polymers could increase to complement the resulting deficit in domestic production. Overall supply of silicone polymers could thus meet the baseline demand of 'downstream users', except in cases where it is not technically viable to reduce the level of D4, D5 and/or D6 impurities in silicone polymers without affecting the functionality (e.g., viscosity requirements linked to higher concentrations of impurities). Thus, 'downstream user' companies might be able to reach an estimated level of overall 'substitution' equivalent to 90% (65-95%) of their affected portfolios of baseline products (in sales turnover terms).

Under PS2, a reduction in exemptions across critical applications of silicone polymers mean that the level of overall 'substitution' declines notably even across 'downstream user' markets;

potentially, this could reach 50% (20-90%) of the baseline sales turnover. Under PS3, silicone polymers would not be manufactured and/or imported into the EU-27. The only option for the 'downstream user' companies that currently rely, in some way, on silicone polymers would be to: 1) find non-regrettable alternatives outside of the silicone industry; and/or 2) replace their products with similar performing 'versions' that can function without silicone polymers. The evidence suggests that, whilst this might be possible for a few 'downstream user' applications, the scale of this is likely to be low, estimated at 10% (5-20%) of the baseline operations in terms of sales turnover.

Businesses would thus transform, which requires both one-off capital investments and adjustments to their operations that could lead to annual, recurring costs, especially under PS1 and PS2. These adjustment costs would include, illustratively: 1) one-off investments in removal technologies and/or new machinery and equipment necessary to adjust their manufacturing processes; and 2) additional recurring costs from more energy intensive production processes or a reduction in the productivity of existing processes, additional administrative activities to facilitate trade under each of the policy scenarios, etc. Online survey participants were asked to provide an aggregated estimate of the one-off and recurring, annual costs they would incur to achieve the scale of reported transformation (i.e., adjusted, alternative and/or substitute operations). These responses were reviewed and validated through follow-up interviews to confirm a medium scenario and possible lower and upper bounds. These estimates were transformed into a percentage of baseline turnover to facilitate the estimation of the scale of total costs that might be incurred in the upstream and 'downstream user' markets in scope. The results of this analysis are presented in the Table 4-8 below.

Table 4-8 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	Segment of the industry	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	Manufacturers and importers of D4, D5, D6 and silicone polymers	3% (0.1%-12.5%)	10% (0.4%-30%)	-
	Downstream users of D4, D5, D6 and silicone polymers	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	Manufacturers and importers of D4, D5, D6 and silicone polymers	1% (0.0%-6%)	1% (0.0%-6%)	-
	Downstream users of D4, D5, D6 and silicone polymers	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~20 upstream and N~40 downstream).

As noted, companies could undergo large-scale transformation across the sectors in scope, which could lead to significant adjustment costs under PS1 and PS2, especially by temporarily doubling or more baseline capital expenditures. In addition, these costs could be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section. No transformative actions would be technically viable and thus no additional costs would be incurred under PS3 across upstream industries (except those associated with factory closures). Under PS3, fewer yet costly adjustments are estimated across 'downstream user' companies for which 'alternative' or 'substitute' options are technically viable.

Based on this evidence, the Net Present Value of the estimated one-off and recurring costs over the period 2023-2040 as well as the annualised or annual-equivalent costs were estimated. The results are presented in the Table below. The Annexes set out the methodologies employed in more detail[293].

Table 4-9 Total 'adjustment costs' estimated over 2023-2040 across industry segments and policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	Industry segment	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	Manufacturers and importers of D4, D5, D6 and silicone polymers	€0.75 bn (€0-3.0 bn)	€0.90 bn (€0-4.0 bn)	-
	Downstream users of D4, D5, D6 and silicone polymers	€220bn (€55-360 bn)	€255 bn (€65-345 bn)	€300 bn (€130-350 bn)
Annualised or annual-equivalent 'adjustment costs'	Manufacturers and importers of D4, D5, D6 and silicone polymers	€0.05 bn/year (€0-0.25 bn/y)	€0.07 bn/year (€0-0.30 bn/y)	-
	Downstream users of D4, D5, D6 and silicone polymers	€16 bn/year (€4-25 bn/y)	€19 bn/year (€5-26 bn/y)	€22 bn/year (€10-27 bn/y)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Adjustment costs in the upstream D4, D5, D6 and silicone polymer industries up to 2040 could be large and likely to surpass €750 million in Net Present Value under PS1 and PS2, equivalent to over €50 million each year over the period of assessment. These costs reflect the transformation that would be required across these manufacturing and importing companies in the EU-27 and abroad, to meet the requirements under the policy scenarios.

These costs are low compared to the expenditures that would be required further downstream, in sectors where silicone polymers play a critical role for large proportions of their portfolio of products and/or manufacturing processes. Costs downstream have been estimated at around €220 billion in Net Present Value, equivalent to around €16 billion each year over 2023-2040.

Even if the volume of silicone polymers and potential for emissions of D4, D5, and/or D6 is relatively low across these applications, the critical role these substances and materials play across these industries and the scale of transformation required demonstrate the difficulties that around 100,000 companies in the EU-27 may face upon the introduction of policy scenarios under considerations.

Finally, despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

4.2.1.3 Estimated impacts on industrial activity in the EU-27

The D4, D5, D6 and silicone polymer manufacturing activity in the EU-27 would be reduced, partially or completely, under the policy scenarios. In cases where baseline products do not comply with the requirements set out under the policy scenarios (i.e., "affected portfolio") nor can be adjusted and/or replaced for alternatives or substitutes (i.e., levels of possible substitution), these would need to be withdrawn from the EU-27 market. Thus, bringing together the evidence presented in earlier subsections results in estimates of the potential reductions that domestic production of D4, D5, D6 and silicone polymers may face

[293] Please note that a 3% real discount rate has been employed in line with the latest Better Regulation Guidelines (Tool #64).

across scenarios. These estimates and the quantified uncertainties are presented in the Table below.

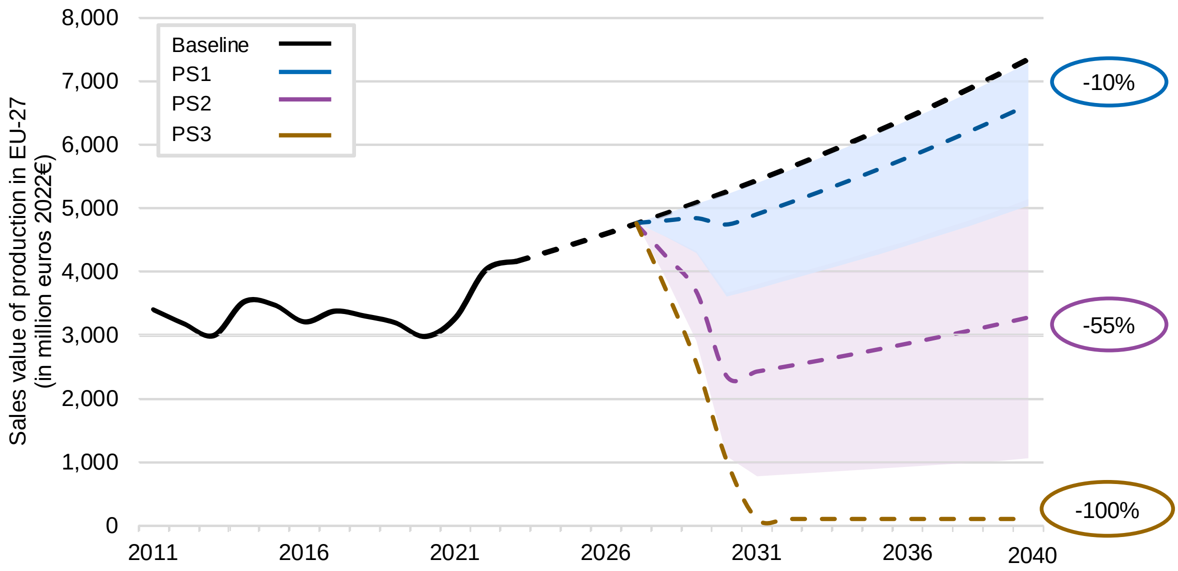
Table 4-10 Estimated reduction in the production of D4, D5, D6 and silicone polymers in the EU-27 against the 2040 baseline (medium (low-high)%[294])

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of manufacturing of D4, D5, D6 and silicone polymers in the EU-27, against the baseline**	-10% (-30% – -1%)	-55% (-85% – -30%)	-100% -

Source: Ricardo analysis based on evidence collected from stakeholders (N=27).

Based on the evidence collected, billions of euros in production activity across the EU-27 could be lost, when compared to the baseline. Production ‘losses’ under PS1 would be notable yet relatively limited, especially in comparison with the more pronounced and transformational effects that these upstream manufacturers could face under PS2 and PS3. The figure below represents these estimated impacts against baseline production levels across the policy scenarios.

Figure 4-1 Sales value of the production of D4, D5, D6 and silicone polymers in the EU-27 across the baseline and Policy Scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Trade could be affected as well (see Section 4.2.3). **It is considered that, especially under PS1 and PS2, an increase in import dependency, whilst with drawbacks, would reduce (or mitigate) the negative impacts on the availability of silicone polymer alternatives in the EU-27 market and mitigate the knock-on negative effects that this would have on ‘downstream user’ companies**. That is, the effects in ‘downstream users’ could be relatively less pronounced than the impacts faced by upstream manufacturers in the EU-27. The Table

[294] Please note that in this case, a “low” estimate refers to the high impact scenario, as these are negative numbers representing estimated reductions against the baseline. This applies to any other table with negative figures.

below presents the estimated reductions in industrial activity across the 'downstream user' markets in scope of the Study.

Table 4-11 Estimated reduction in 'downstream user' manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

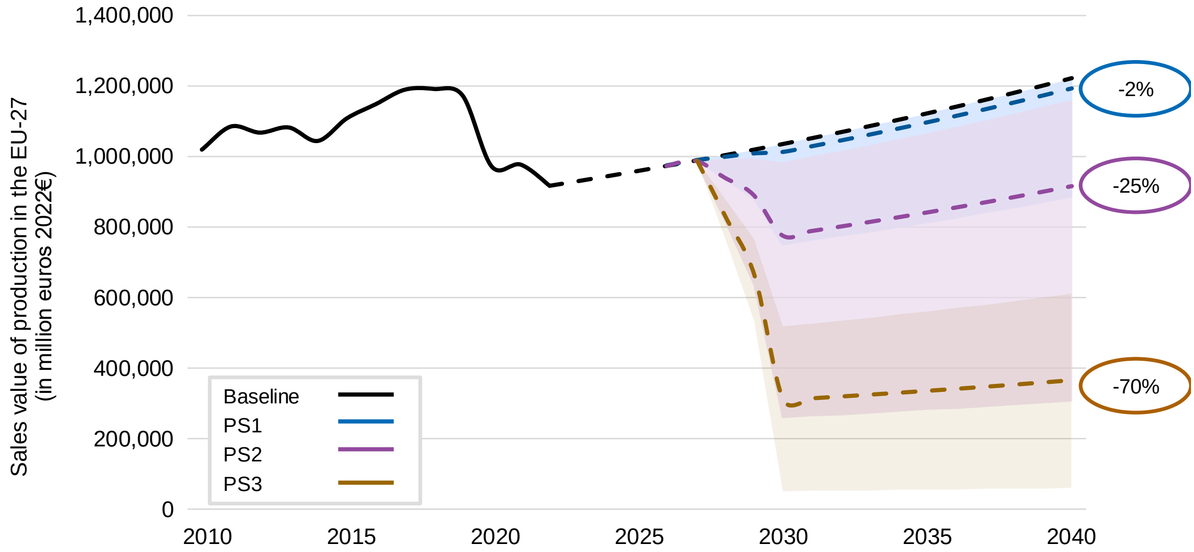
Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of 'downstream users' in the EU-27, against the baseline**	-2% (-25% – 0%[295])	-25% (-75% – -5%)	-70% (-95% – -50%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €15 bn/year of downstream production activity could be lost under PS1, which could be 10 or 30 times worse under PS2 and PS3 respectively. These estimates suggest the potential for pronounced and negative impacts on industrial activity not just within upstream but also 'downstream user' markets in the EU-27. They depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. Focussing on the lower estimates of the impacts on 'downstream user' companies, the impact could range from no losses under PS1 to €30 bn/year under PS2 and surpassing €130 bn/year under PS3. These impacts are presented in Figure 4-6 below.

[295] Please note that this rounded to, but slightly over 0%.

Figure 4-2 Sales value of the production of selected 'downstream user' sectors in the EU-27 across the baseline and Policy Scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

In conclusion, both upstream and downstream companies could face significant challenges under each policy scenario, incurring billions of additional 'adjustment costs' each year and reducing their production activity and thus economic footprint in the EU-27 when compared against the baseline. These impacts could be sizeable under PS1 and many times more severe under PS2 and PS3.

4.2.1.4 Position of SMEs

Not all businesses would be affected in the same way, and it is likely that SMEs could be more severely burdened by the transformation that is required for companies to continue to operate in the EU-27 under each of the following scenarios. It is considered that, based on the available evidence, a large proportion of the more than 100,000 firms operating in the upstream and downstream industries are likely to be SMEs. The sample of participants in the survey and follow-up interviews included a small number of SMEs (see the Annexes for a survey synopsis). It has not been possible to estimate the differences in unit costs that might be incurred by businesses as a result of adopting any of the policy scenarios in a robust, quantitative way. Nevertheless, the analysis conducted for this Study presented some indications that '**unit one-off costs' faced by SMEs, defined as total costs divided by the number of employees of the organisation[296], could be larger and potentially more than double the 'unit one-off costs' faced by larger businesses.** Albeit aligned with findings from other available studies[297,298] of other chemicals policy interventions, these

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[296] In line with Tool #23 of the Commission's Better Regulation Guidelines, we sought to compare the "overall costs identified to the number of persons employed to get the average cost per employee", as a proxy for unit costs. This allows for an exploration of the extent the burden might be disproportionately affecting SMEs or not.

[297] CSES et al (2015). Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs. Available: monitoring-the-impacts-of-reach.pdf

[298] European Commission (2020) Commission Staff Working Document Evaluation of Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys. SWD(2020) 287 final. Available: DocsRoom - European Commission (europa.eu)

indications remain inconclusive due to an insufficient sample of SME participants on the online survey and follow-up interviews conducted for this Study.

4.2.2 Innovation and research

In the face of increasing regulation and growing environmental concerns surrounding the emissions of D4, D5 and D6, **industries manufacturing or reliant on D4, D5, and D6 and silicone polymers have been compelled to invest in research and development (R&D) of alternatives to the baseline manufacturing processes and/or product design.** The majority of companies consulted for this Study suggested that they perform R&D activities in the EU-27: 70% of the manufacturers of D4, D5, D6 and silicone polymers (N=27) and over 90% of the 'downstream user' companies (N=87). These company participants also reported that more than 20% of their investments were devoted to identifying and developing product alternatives.

Upstream and 'downstream user' companies have also provided evidence suggesting there are potential alternatives already available or that could be brought to the market in response to the policy scenarios. The findings from a rapid review of this evidence, complemented by the outputs of a literature review, are summarised in the Box 4-1 below.

Box 4-1 Alternatives to D4, D5 and D6 and/or silicone polymers across the supply chain

Cyclic siloxanes include an inorganic silicon-oxygen alternating backbone (Si-O-Si), which, in combination with the methyl groups on each silicon atom, provide D4, D5 and D6 with a useful combination of inorganic and organic properties such as dielectric behaviour and hydrophobicity (see Section 2.1). D4, D5 and D6 are thus used as monomers in the production of silicone polymers, which have useful properties such as thermal stability; resistance to oxidation and UV exposure; good wetting, spreading and flow; electrical conductivity; water repellence; and biocompatibility. **These useful properties make silicone polymers critical or important in a large number of applications.**

A literature review and consultation of relevant businesses were conducted to explore potential alternatives to D4, D5, D6 and/or silicone polymers across the supply chain. The evidence collected suggests there is no single alternative that could replace silicone polymers in all applications. **Alternatives do exist across a range of applications.** The three main types of alternatives to silicone polymers as used in the baseline are: 1) silicone polymers which contain impurities of D4, D5 and D6 in concentrations ≤0.1% w/w; 2) alternative chemicals/ materials; and/or 3) alternative intermediate and/or final products across downstream markets. The viability of these alternatives varies across policy scenario, there being fewer to no alternatives under PS3 (as Type 1 is not viable); additional alternatives under PS2, as type 1 is a viable option for some sectors for which exemptions are granted, and even more so under PS1. **Moreover, whilst alternatives exist and may be viable across these policy scenarios, these can have inferior properties with knock-on implications across other impact dimensions, e.g., shorter service lives, the need for more frequent replacement and higher energy and GHG intensity**.

The evidence available suggests that, for a large number of silicone polymer applications, it could be possible to reduce the concentration of D4, D5 and D6 impurities to ≤0.1% w/w through the use of stripping technologies such as vacuum distillation or stripping, or thin film evaporation, which would be viable under PS1 especially. This may involve heat and/ or vacuum. Heat may be applied to the product during the final stage of the manufacturing process to drive off the volatile cyclics. Where products are heat sensitive or there is a need to reduce heat input, a vacuum is applied to the system to achieve the stripping effect at lower temperatures. Reduction of D4, D5 and D6 to considerably lower than 0.1% in silicone polymers is deemed unlikely due to the thermodynamic equilibrium of the condensation-polymerisation process[299].

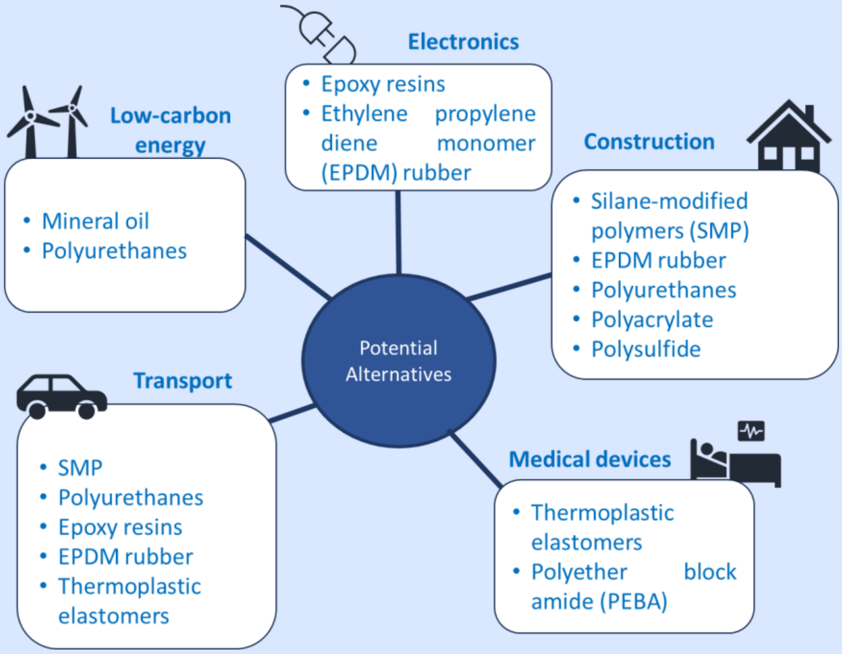
However, reducing the impurity concentration to <0.1% w/w is an energy intensive process. Companies consulted have highlighted that, due to high energy costs in the EU-27, they might move parts or all of their manufacturing operations to third countries that are Party to the Stockholm Convention where energy costs are cheaper, e.g., China, and subsequently import silicone polymer alternatives into the EU-27.

This stripping process is not possible for all silicone polymer products as it does have implications on some of the functionalities due to partial curing of the polymer, for example, for uncured sealants in construction. This means that certain applications will require silicone polymers with higher impurity concentrations, such as specific medical devices and construction sealants. Such products would, therefore, have to be removed from the market or replaced with product alternatives which do not require silicone polymers. This is of particular concern for medical devices where biocompatibility and ability to withstand sterilisation are key drivers for the use of silicones properties not displayed by the alternatives.

Consultation participants that manufacture D4, D5, D6 and/or silicone polymers in the EU-27 and available literature provided insight into the types of materials that could potentially be alternatives to silicone polymers for specific applications. The findings are presented in Figure 4-3 below. As noted previously, 'downstream user' companies consulted for this Study reported a general lack of awareness of alternatives to their baseline silicone polymer uses and would rely on their suppliers to indicate materials that would be suitable. An interview with representatives of manufacturers within the transport sector highlighted that **when seeking alternative products, they do not specify the chemical to their suppliers, but the properties that are required**. This means that it is their suppliers who are performing the R&D to identify suitable chemicals/ materials to meet the specifications. Silicone polymers were selected as their properties are deemed to be highest performing and despite their higher cost, leads to them being critical components of vehicles. As such, interviewees suggested that on the whole, substitution of silicone polymers in transport applications would not be possible and would likely be limited to select applications only e.g. a specific sealing device used in one part of the vehicle, rather than all sealing devices.

[299] Ibid footnote 269

Figure 4-3 Potential alternatives to silicone polymers across a selection of 'downstream user' sectors and applications



There are a number of common potential alternatives across the sectors highlighted above, such as: SMP, polyurethanes, epoxy resins, and EPDM rubber. This is due to the type of components for which they can be used e.g. epoxy resins as encapsulants, or polyurethane sealants. **Fluoropolymers and other PFAS have also been suggested as alternatives for certain applications,** but they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

There is a cross-cutting silicone polymer application that could be particularly affected by all three policy scenarios – optic (glass) fibres, which use D4 in the production of silicon dioxide (SiO_2). A potential alternative to D4 is silicone tetrachloride ($SiCl_4$). However, as outlined by consultation participants, using $SiCl_4$ would significantly increase the costs that would be incurred by manufacturers of telecommunication cables in ways that could make this activity unviable in the EU-27. In addition, there are also environmental concerns related to the use of $SiCl_4$. Based on this, evidence suggests that any of the policy scenarios could cause the total disruption on the telecommunication cable manufacturing sector, i.e., bringing the sector to a halt.

Finally, although some potential alternatives have been identified for a wide range of applications especially under PS1, there are questions over their potential performance and their use, which would have knock-on implications on manufacturing activity across the supply chain and final consumers, as well as other impact categories such as the environment. The lower performance and functionality of the potential alternatives may result in negative environmental impacts from lower service lives and thus increased replacement, as well as an increase in energy intensity and thus overall energy consumption and GHG emissions. These specific environmental impacts are considered in more depth in Section 4.4.6.

Additional evidence gathered through stakeholder engagement suggests that companies have the capacity and skills to transform at least parts of their industry if the policy scenarios were adopted, albeit this would not be without challenges. On the one hand, more than 80% of the business survey participants have experience in developing new products related to the use of D4, D5, D6 and silicone polymers (N=96). On the other, more than 90% of the business participants reported facing some hurdle during the launch of alternative products (N=93). Companies upstream reported regulatory compliance costs, capital investment requirements, and the navigation of complex legal frameworks as the most significant hurdles to bringing new products into the market; whilst companies downstream found worsened product performance, complex and difficult-to-meet legal requirements and upfront capital requirements as the main hurdles they face. As an example, representatives of manufacturers in the transport sector highlighted that should silicone polymer-based components become unavailable, there would need to be investment in redesign of vehicles to adapt to the lower performance of alternatives which could impact durability and environmental and passenger safety.

Despite this, business survey participants demonstrated, especially in their open text and qualitative responses, generalised pessimism about the performance and cost of these potential alternatives (N>90[300]). In particular, companies highlighted uncertainty and lack of awareness of the extent to which at least some of the baseline applications could be replaceable with the alternatives identified so far and how these might perform. Company respondents also considered that it is very likely costs of production would, at least in the short-term, increase, potentially significantly. These have been estimated previously based on their input (see Section 4.2.1.2).

In conclusion, whilst additional investment in R&D could have positive impacts in the EU-27 across economic, social and environmental dimensions; the regulatory push could also result in the misallocation of resources towards lower yield or less productive investments, reducing innovation when compared to the baseline.

4.2.3 Competitiveness, trade and the functioning of the internal market

The cost of doing business in the EU-27 could increase across all policy scenarios, especially in relation to other countries within the Stockholm Convention, which could deter the global competitiveness of the European manufacturing industry, both upstream and downstream. Companies that participated in the online survey agree and report, on average, weakly negative[301] (-1), negative (-2) or strongly negative (-3) impacts on global competitiveness, under PS1, PS2 and PS3 respectively (N=101), especially driven by increases in relative costs of production when compared to third countries.

The estimated EU-27 industry’s loss in global competitiveness could also be exacerbated by second order effects, such as the reduction in economies of scale, which could even make these activities relatively costlier and less efficient especially when compared to third countries. A reduction in the size of domestic manufacturing could also negatively affect R&D capacity within the EU-27 and reduce the adaptability of companies to changes in market demand, further hindering the global competitive position and the functioning of the EU-27 internal market.

In addition to this, some companies participating in the online survey reported that they would **relocate some or all of their operations in EU-27 to a third country(ies) such as China, to improve the economic viability of alternatives to the baseline that would comply with the policy scenarios** (N~100), under PS1 (>15%) and more so under PS2 (>30%). As a

[300] Please recall that “>” is used because the sample sizes do vary depending on the question and, in this case, always superior to 90 observations.

[301] Company participants were asked to report whether a range of dimensions, such as global competitiveness, would be positively or negatively affected on a scale of -5 (strongly negative) to +5 (strongly positive) impacts. See Annexes for the consultation synopsis.

result, production output (or manufacturing activity) and exports out of the EU-27 could be reduced proportionately more than imports from Stockholm Convention countries, which could in some cases be less affected and potentially even increase when compared to the baseline in some cases, such as under PS1.

The Table below sets out the estimated impacts on imports and exports of D4, D5, D6 and silicone polymers, into and out of the EU-27 in 2040, against the baseline and by policy scenario.

Table 4-12 Estimated impacts on imports/exports of D4, D5, D6 and silicone polymers into/out of the EU-27 by policy scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Exports of D4, D5, D6 and silicone polymers out of the EU-27 in 2040	-10% (-30%, -1%)	-55% (-80%, -30%)	-100% -
Imports of D4, D5, D6 and silicone polymers into of the EU-27 in 2040	+8% (-20%, +8%)	-33% (-80%, +20%)	-100% -

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Overall, the EU-27 import dependency on silicone polymers could increase and the EU's share of the global silicone market would decrease. Whilst this would be the most cost-efficient outcome under the policy scenarios, this would necessarily **introduce supply chain risk for many critical downstream sectors in the EU-27, such as transport, construction, defence, healthcare and pharmaceuticals and others. At the economy level, the EU's current account balance would be negatively affected.**

Further downstream, the EU's manufacturing activity could decline (see Section 4.2.1.3), and it is assumed that both exports and imports would decline proportionately, maintaining the sectors' baseline current account balance. It is possible that the increasing costs of production also for 'downstream user' companies lead to a partial relocation of downstream manufacturing activities to third countries and an increase in import dependency within the EU-27. However, the scale of this is very uncertain and conclusive evidence has not been identified that would support a quantitative characterisation of this hypothesis.

Illicit imports are unlikely to be a challenge, especially under PS2 and PS3, based on the opinion of companies participating on the online survey (N=102). Most of them consider it unlikely that businesses would resort to importing products that contain and/or required the use of D4, D5 and D6 in concentrations above the legal limit during their manufacturing process (including as an intermediate in semiconductor and glass fibre production, silicone polymers and silicone polymer formulations).

4.2.4 Overall economic impacts in the EU-27

In summary, the EU's economy overall could be negatively affected by the policy scenarios, with a reduction in the D4, D5, D6, silicone polymer and downstream user industries' production activity and contribution to the EU's GDP against the baseline. The EU industry's total GVA contribution could be lower by an estimated €8 billion/year, €60 billion/year or €240 billion/year under PS1, PS2 or PS3 respectively from 2023-2040. The estimated effects on domestic production activity as well as GVA contributions, against the baseline, are summarised in the Table below.

Table 4-13 Annualised or annual average impacts on selected indicators for the D4, D5, D6, silicone polymer and 'downstream user' industries from 2023-2040 (medium (low-high))

Indicators	PS1	PS2	PS3
Direct impacts on total **production activity** in the EU-27, against the baseline	- € 15 billion/year (-180 – -0.20 bn/y)	- € 165 billion/year (-500 – -35 bn/y)	- € 460 billion/year (-630 – -330 bn/y)
Impacts on the **direct GVA contributions** of the industries in scope, against the baseline	- € 4 billion/year (-50 – -0.05 bn/y)	- € 40 billion/year (-140 – -10 bn/y)	- € 130 billion/year (-170 – -90 bn/y)
Impacts on the **total GVA contributions** of the industries in scope, against the baseline (including *direct, indirect, induced effects*)	- € 8 billion/year (-95 – -0.10 bn/y)	- € 60 billion/year (-175 – -10 bn/y)	- € 240 billion/year (-325 – -170 bn/y)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Albeit uncertain, it is considered that innovation could be positively affected even if the scale of these benefits is smaller than the scale of the overall and negative economic effects of each of the policy scenarios. In fact, the estimated, overall negative impacts on the EU economy already take into account the mitigating effects achieved through research and development efforts to replace baseline products and manufacturing processes with alternatives that comply with the policy scenarios.

The increased costs of doing business in the EU, especially relative to third countries also party to the Stockholm Convention, could further deter the EU industry's global competitiveness position. The EU would further lose its share of the global silicone market, and its import dependency would continue to grow, faster than in the baseline.

More broadly, it is likely that designation of siloxanes as a global POP would indirectly trigger more expansive controls that would damage the global silicones market overall[302]. These controls could arise under list-based secondary standards, such as those used by various retailers and eco-labels, which are automatically triggered by a POPs listing decision. Moreover, many of these automatic consequences may not differentiate based on the exemptions or nuances in listing decisions. They lie outside of the Convention's control, and there is no legal mechanism by which the Stockholm Convention listing could mitigate these impacts.

The economic impact conclusions are summarised qualitatively in the Table below, using the scoring framework described in Section 4.1 and, in more detail, in the Annexes.

Table 4-14 Qualitative, economic impact ratings

Broad category	PS1	PS2	PS3
Conduct of businesses and administrative burden, functioning of the internal market, sustainable production, and position of SMEs	-2.0	-3.0	-5.0
Innovation and research	+1.0	+1.5	+1.0

[302] Beveridge & Diamond (2023) Potential Consequences of Siloxane Nominations to Stockholm Convention.

Broad category	PS1	PS2	PS3
Sectoral competitiveness, trade and investment flows and third countries	-1.0	-1.5	-2.0

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this assessment, it is concluded that all policy scenarios could have an increasingly negative, overall economic impact on the EU. The ratings have been reviewed and recalibrated against the -5/+5 scoring framework, for a comparison of the balance of impacts across impact categories, costs and benefits. The Table below presents the qualitative ratings given to the overall economic impacts of each of the policy scenario for these comparisons. The methodological Annexes explain the recalibration exercise.

Table 4-15 Overall economic impact ratings

Broad category	PS1	PS2	PS3
Overall economic impacts	-0.5	-1.0	-2.0

Source: Ricardo analysis based on the evidence presented in this Study.

4.2.5 Sectoral Deep Dives

This section explores how a selection[303] downstream sectors in scope of this study might be affected differently by the policy scenarios. Together, the selected sectors account for around 45% of the 'downstream user' sectors in scope in terms of sales turnover. The selected sectors comprise (parts of) healthcare and pharmaceuticals (5.5%), sealants (0.3%), lubricants (0.6%), adhesives (1.1%), coatings (0.2%), electronics (10.7%), aerospace and defence (19.4%) and paper products (7.1%).

It is acknowledged that there might be overlaps across the sectors included in the 'downstream market' in this study, especially given that some 'final product' and 'component' sectors have been brought together. We have, however, checked that their definitions are as mutually exclusive as possible; and, upon review, concluded that whilst there could be some overlaps (e.g. a proportion of some component sectors might sell and thus be captured as part of the final product sectors in scope), these are unlikely to affect the scale and order of magnitude of the overall estimates for manufacturing footprint of the downstream user industry in scope (especially given that the final product sectors in scope account for more than 90% of the baseline production activity).

[303] Selection based on the level of responses to the consultation activities.

4.2.5.1 Healthcare and Pharmaceuticals

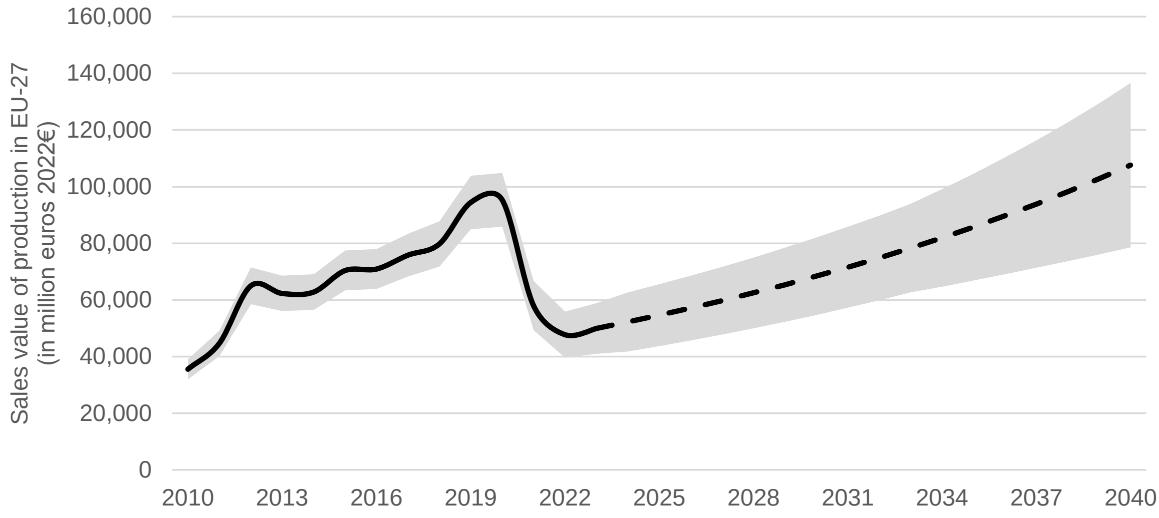
Baseline

The healthcare and pharmaceuticals industry, especially medical devices incl. prosthetics, vaccines, and wound prevention and care, rely, to some extent, on D5, D6 and/or silicone polymers. For example, silicone polymers are valued for their biocompatibility, flexibility, and durability and are used in various medical devices such as components of medical implant devices, catheters, and prosthetics, where their inert nature minimises the risk of adverse reactions and ensures compatibility with biological tissues. The pharmaceutical industry also uses silicone polymer in applications such as antifoam for drug manufacturing, skin disease treatment, and transdermal drug delivery systems.

The **sales value of such production in the healthcare and pharmaceuticals sector[304] in scope in the EU-27 has been estimated at around €48 billion in 2022**, which accounts for 5.5% of the total production value of the downstream user sectors in scope. This sector generated an estimated €15 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 30% of its production value.

Between 2010-2022, the sector's sales turnover has grown at a real CAGR of 2%, although prior to the pandemic the sector had grown more rapidly, at a real CAGR of 11% between 2010-2019. Looking ahead, this industry might grow at a real CAGR between 4-5% in the EU-27 and could reach a production sales value of around €108 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-4 below.

Figure 4-4 Baseline sales value of the production of healthcare and pharmaceuticals sector in the EU-27 (€ million)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 3% of their production value in capital within the EU-27, surpassing €1 billion in 2022. They also purchased goods

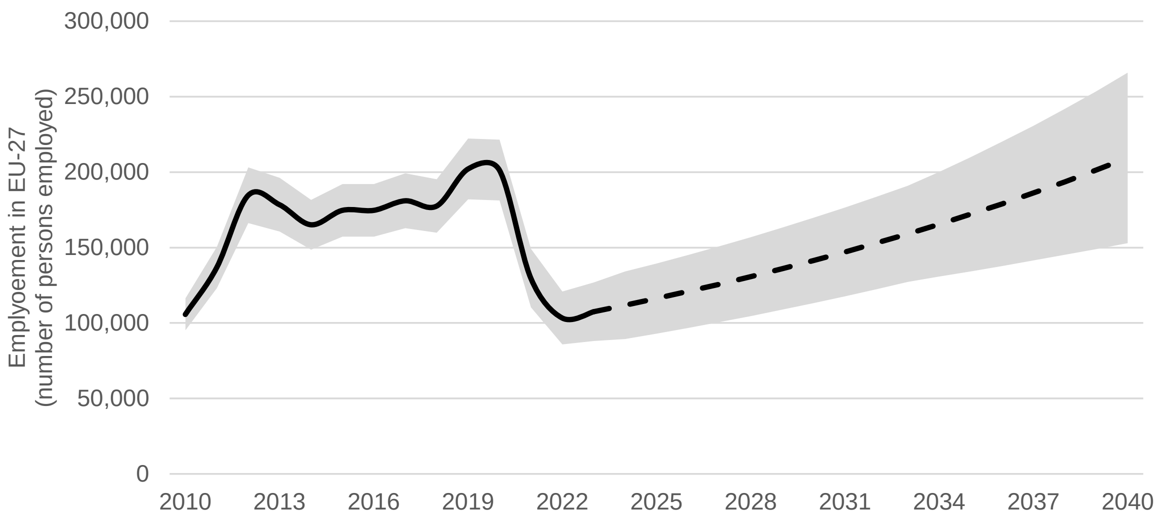
[304] Sector related to products regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency; and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; and related Directives and Regulations.

and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were equivalent to 60-80% of the production sales value, estimated to be between €30-35 billion in 2022. These expenditures also include investments in Research and Development (R&D) within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of medical devices and other healthcare products in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €35 billion, with imports not surpassing €25 billion. Potential growth (in real terms) is likely to be similar for both exports and imports, around 4% per annum.

Finally, the healthcare and pharmaceuticals industry in scope supported more than 100,000 jobs (in FTE) in 2022. It is estimated that sectoral jobs could grow notably over the period of assessment in the baseline scenario, at a real CAGR of 4%, surpassing 200,000 FTE in 2040. This is presented in Figure 4-5 below.

Figure 4-5 Baseline direct employment supported by the healthcare and pharmaceuticals sector in the EU-27 (Number of persons employed)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers ('reliant products') across the healthcare and pharmaceuticals sectors in scope is estimated to be 70% (40%-90%) of sales turnover, similar to average downstream sector estimates. Ten organisations participated in the survey, covering around 25% of 2022 baseline estimated sales value and 10% of 2022 baseline estimated employment for the healthcare and pharmaceuticals sector, reporting a variety of experiences yet suggesting a high likelihood of notable reliance on silicone polymers.

Companies also considered that their activities could well be exempted in higher proportions than other downstream user respondents: under PS1, estimated at 90% (80-100%) of their portfolio of 'reliant products' and, under PS2, estimated at around 70% (65-100%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 10% (0-20%) and 20% (0-35%) under PS2, which are relatively lower than averages across other sectors. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 70% (40-90%). These estimates are presented in the Table 4-16 below.

Table 4-16 Percentage of sales turnover of the healthcare and pharmaceuticals sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of healthcare and pharmaceuticals sector **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers**… ('reliant sales') – (1)		70% (40%-90%)	
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	90% (80%-100%)	70% (65%-100%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	10% (0%-20%)	30% (0%-35%)	100%
Or, equivalently, the **proportion of <u>healthcare and pharmaceuticals sector</u> sales that could be potentially affected** – (4)[305]	**10% (0%-20%)**	**20% (0%-35%)**	**70% (40%-90%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=10).

The ability of organisations within the healthcare and pharmaceuticals sector to find substitutes will be notably higher under PS1, than PS2, and virtually non-existent under PS3, given the present state of technology and innovation. The evidence collected, however, has limitations. For example, there are products within this sector with viscosity requirements that are linked to higher concentrations of impurities of D4, D5 and D6 in silicone polymers. This implies there are complexities with understanding the extent to which it is possible to use removal technologies, such as stripping, to reduce the concentration of impurities of D4, D5 and D6 within silicone polymers, whilst maintaining the key characteristics of the products. Further, alternative materials with potentially similar performance might not always be available.

Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 75% (50-85%) of their affected portfolio; under PS2, this would decline to 40% (10-70%), and it is likely that barely any adjustments and/or substitutions are possible under PS3, with an estimated level of 5% (0-10%) due to the material requirements within this sector. These are presented in Table 4-17 below.

Table 4-17 Estimated level of 'substitution' in the healthcare and pharmaceuticals sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the healthcare and pharmaceuticals sector that could be **<u>adjusted or replaced by alternatives/substitutes</u>**, in sales turnover.	**75% (50%-85%)**	**40% (10%-70%)**	**5% (0%-10%)**

[305] Ibid footnote 290

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-2 Alternatives to D4, D5 and D6 and/or silicone polymers in healthcare and pharmaceuticals

Silicone polymers (also known as medical grade silicone) are ubiquitous in the healthcare sector due to their flexibility, thermal and chemical resistance, and biocompatibility. Two potential alternatives to silicone polymers for healthcare applications were identified from the literature and consultation: 1) thermoplastic elastomers (TPE), 2) polyether block amide (PEBA).

Thermoplastic elastomers have been identified as potential alternatives for silicones in healthcare applications. Although they have good thermal resistance, the temperature range does not extend as far as the silicone polymers (-100°C - 200°C). TPE also does not have as strong chemical resistance and can degrade with prolonged exposure to oils, solvents or fuels. TPE is biocompatible but is not used in as many medical devices as silicones, with key applications being IV components, tubing and grips.[306] TPE tends to be less costly than silicone polymers but due to the lower resistance, this cost may be increased through more frequent replacement. TPE can be recycled.

Polyether block amides are a specific form of TPEs which also exhibit good biocompatibility, flexibility and temperature and chemical resistance. They too can be used for medical tubing, catheters and other medical devices. PEBA is more costly than other TPEs but offers the same advantage of recyclability, although recycling of PEBA requires the use of solvents.[307]

It should be noted that none of the alternatives are suitable substitutes for all silicone polymer applications within the healthcare and pharmaceutical sector, and for some products there will be no alternative available. The authorisation of pharmaceuticals and medical devices is also a complex and time intensive process, which places high standards on the performance and safety of products. Substitution of D5, D6 and/ or silicone polymers could also require a re-qualification and registration/ authorisation of the affected product. This means that it is unlikely to be possible to bring new products to the market quickly.

Fluoropolymers and other PFAS have also been suggested as alternatives for certain applications, but they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

This means that companies might need to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the healthcare and pharmaceuticals sector were assumed to be proportionately similar to the average downstream users sector in scope. These are presented in Table 4-18 below.

[306] LSR Guide (2023) TPE vs Silicone: Which is better for your application. Available: TPE vs Silicone: Which Is Better for Your Application? - LSR Guide

[307] Material-Properties (2024) Polyether Block Amide (PEBA). Available: Polyether Block Amide (PEBA) | Formula, Properties & Application (material-properties.org)

Table 4-18 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-19 below.

Table 4-19 Total 'adjustment costs' for the healthcare and pharmaceuticals sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€22bn (€5-34 bn)	€28 bn (€10-74 bn)	€29 bn (€21-27* bn)
Annualised or annual-equivalent 'adjustment costs'	€1.6 bn/year (€0.3-2.5 bn/y)	€2 bn/year (€0.8-5.4 bn/y)	€2.1 bn/year (€1.5-2* bn/y)

*Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets. * Under PS3, despite the higher costs of industrial transformation, the 'high'* ***adjustment cost*** *estimate might be similar or even lower than the 'medium'* ***estimate*** *due to the neutralising effect of the reduction in manufacturing activity.*

That is, the costs of industrial transformation for the healthcare and pharmaceutical sector could surpass €22 billion in Net Present Value, equivalent to over €1.6 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The healthcare and pharmaceuticals sector in scope would likely be affected especially under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -2% (-9% – 0%) under PS1, rising to -15% (-30% – 0%) under PS2 and a large -65% (-90% – -35%) under PS3. These are presented in Table 4-20 below.

Table 4-20 Estimated reduction in the healthcare and pharmaceuticals sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

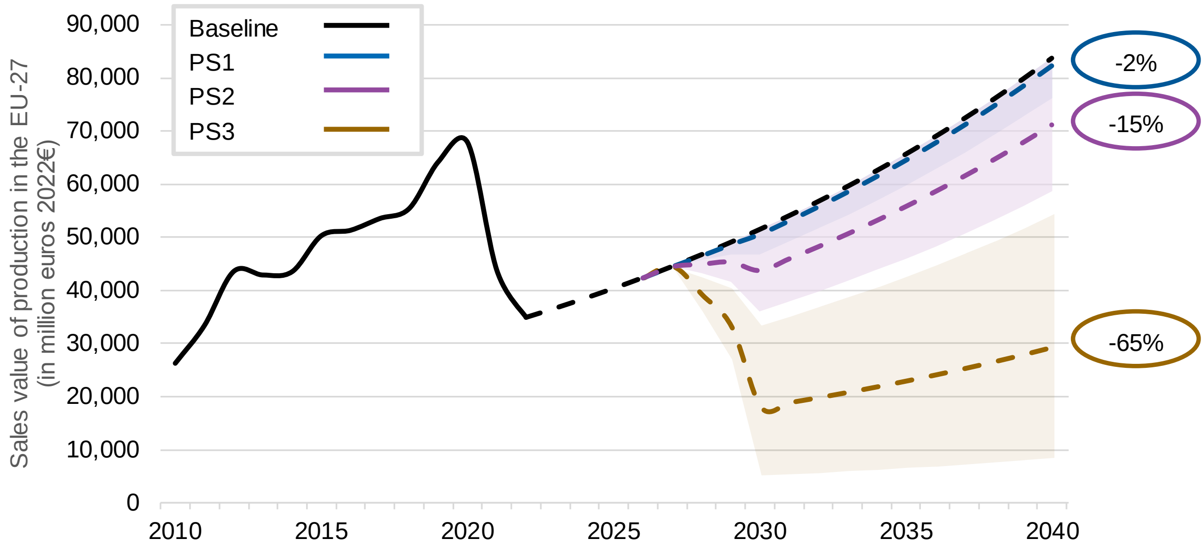
Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the healthcare and pharmaceuticals sector in the EU-27, against the baseline**	-2% (-9% – 0%)	-15% (-30% – 0%)	-65% (-90% – -35%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €0.6 bn/year of sectoral production activity could be lost under PS1, which could be 10 or 40 times worse under PS2 and

PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from no losses under PS1, €0.4 bn/year of losses under PS2 to €14 bn/year under PS3. These impacts are presented in Figure 4-6 below.

Figure 4-6 Sales value of the production of the healthcare and pharmaceuticals sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment, the quality of care and, of course, consumers and patients who currently benefit from quality medical devices or pharmaceuticals that might contain D4, D5 or D6 and/ or silicone polymers.

Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by healthcare and pharmaceuticals sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-21 below.

Table 4-21 Average impacts on annual employment supported, in FTE, by the healthcare and pharmaceuticals sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by healthcare and pharmaceuticals sector	-900 jobs (-4,000 – 0)	- 7,000 jobs (-15,000 – 0)	- 32,000 jobs (-45,000 – -17,000)

Indicator	PS1	PS2	PS3
in scope against the baseline (FTE)			

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the healthcare and pharmaceuticals sector in the EU, even when broad exemptions are taken into account.

All policy scenarios are likely to result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the healthcare and pharmaceuticals sector within the EU-27 could decrease by 2% under PS1, 15% under PS2, and 65% under PS3,
- The average impact on annual employment, measured in FTE, in the healthcare and pharmaceuticals sector from 2023 to 2040 could range from a decrease of 900 jobs under PS1, 7,000 jobs under PS2, to 32,000 jobs under PS3.

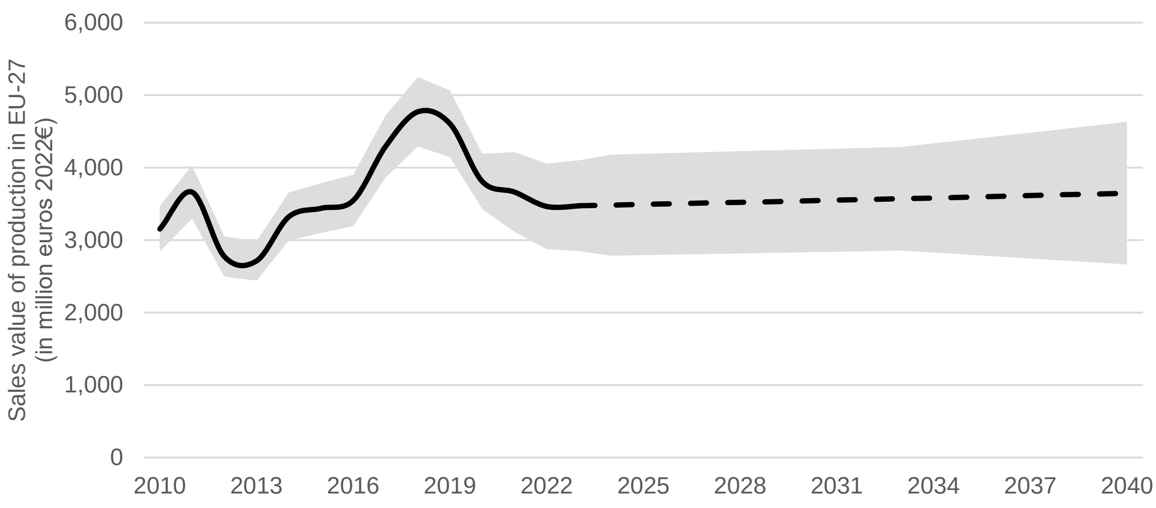
4.2.5.2 Sealants

Baseline

In the sealant sector, D4, D5, D6 and silicone polymers are essential due to their unique properties, in particular their flexibility, durability and excellent bonding properties. They are used in a wide range of applications, from construction and automotive to electronics and household products. Their resistance to extreme temperatures, UV radiation and moisture makes them ideal for sealing joints, gaps and seams in buildings, vehicles and electronic devices. In addition, the chemical stability and durability of silicone-based sealants ensure long-lasting performance and protection against environmental factors, making them indispensable in both industrial and consumer applications. The **sales value of such production in the sealants sector in scope in the EU-27 has been estimated at around €3.5 billion in 2022**, which accounts for 0.3% of the total production value of the downstream user sectors in scope. This sector generated an estimated €1 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 35% of its production value.

Between 2010-2022, the sector's sales turnover has grown at a real CAGR of 0.8%, although prior to the pandemic the sector had grown more rapidly, at a real CAGR of around 4% between 2010-2019. Looking ahead, this industry is expected to grow at a similar rate and could reach a production sales value of around €3.6 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-7 below.

Figure 4-7 Baseline sales value of the production of sealants sector in the EU-27 (€ million)



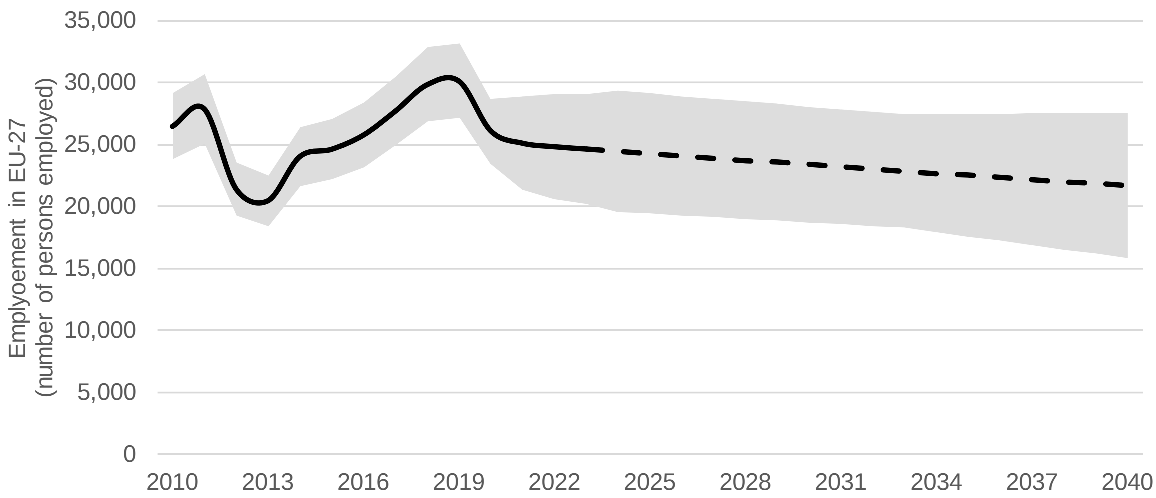
Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 4% of their production value in capital within the EU-27, around €150 million in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were equivalent to 70-80% of the production sales value, around €2.5-3 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of sealants products in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €1.5 billion, with imports not surpassing €800 million. Potential growth (in real terms) is likely to be similar for both exports and imports, also between 4-5% per annum.

Finally, the sealants industry in scope supported around 25,000 jobs (in FTE) in 2022. Based on historical fluctuations and the observed decline in employment supported by the sector in recent years, it is estimated that sectoral jobs could decrease slightly over the period of assessment in the baseline scenario, at a real CAGR of around -0.8%, reaching 22,000 FTE in 2040. This is presented in Figure 4-8 below, where the uncertainty bounds also include scenarios of potential growth in employment in the future.

Figure 4-8 Baseline direct employment supported by the sealants sector in the EU-27 (Number of persons employed)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers ('reliant products') across the sealants sectors in scope is 55% (15%-95%) of sales turnover, lower than the average downstream sector estimates. Thirteen organisations participated in the survey, covering around 75% of 2022 baseline estimated sales value and 35% of 2022 baseline estimated employment for the sealants sector, reporting a variety of experiences yet suggesting a high likelihood of notable reliance on silicone polymers.

Companies also considered that their activities could well be exempted in higher proportions than other downstream user respondents: under PS1, estimated at 90% (75-95%) of their portfolio of 'reliant products' and, under PS2, estimated at around 80% (15-95%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 5% (1-25%) and 10% (1-80%) under PS2, which are considerably lower than averages across other sectors. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 55% (15%-95%). These estimates are presented in the Table 4-22 below.

Table 4-22 Percentage of sales turnover of the sealants sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of sealants sector **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers**… ('reliant sales') – (1)		55% (15%-95%)	
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	90% (75-95%)	80% (15-95%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	10% (5%-25%)	20% (5%-85%)	100%
Or, equivalently, the **proportion of <u>sealants</u> sales that could be potentially affected** – (4)[308]	**5% (1-25%)**	**10% (1-80%)**	**55% (15%-95%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=13).

The ability of organisations within the sealants sector to find substitutes will be notably higher under PS1, than PS2, and virtually non-existent under PS3, given the present state of technology and innovation. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 75% (50-85%) of their affected portfolio; under PS2, this would decline to 40% (10-70%), and it is likely that minimal adjustments and/or substitutions of the affected portfolio are possible under PS3**, with an estimated level of 5% (0-10%) due to the material requirements within this sector. These are presented in Table 4-23 below.

Table 4-23 Estimated level of 'substitution' in the sealants sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the sealants sector that could be **<u>adjusted or replaced by alternatives/substitutes</u>** , in sales turnover.	**75% (50%-85%)**	**40% (10%-70%)**	**5% (0%-10%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-3 Alternatives to D4, D5 and D6 and/or silicone polymers in sealants sector

Silicone polymers are used as sealants in construction (e.g. glazing units) but also in a wide variety of other applications that require sealants (e.g. transport) or sealing devices, such as o-rings e.g. valves. Silicone sealants are used because of their high temperature resistance (standard silicone sealants -55°C - 200°C, high temperature silicone sealants up to 300°C), low viscosity, chemical and UV resistance, flexibility, low cost and high availability.

Responses to the consultation indicated two main potential alternatives to silicone sealants: MS sealants, and polyurethanes.

MS sealants are a mixture of silane modified polymer and polyether, combining the characteristics of silicone with polyurethanes. MS polymers have strong adhesion, unlike silicone sealants, and good flexibility. They are particularly suitable for joints and seams or

[308] Ibid footnote 290

bonding applications. These products can be considered “premium products” due to their higher cost and have longer curing times and cannot withstand temperatures >150°C, reducing their applications.[309]

Polyurethane sealants are also flexible and durable, which allows them to be used for joints or seams. As with the MS polymers, they have good adhesion and can bond to concrete, wood and metal. Although they offer chemical resistance, it is not comparable to silicones. Temperature resistance varies between standard polyurethanes (-62°C - 93°C) and high temperature polyurethanes (up to 149°C) and is lower than that of the silicone sealants.

EPDM rubber can be used as an alternative for sealing devices such as o-rings and washers for gaskets, plumbing applications or seals for doors or windows (particularly relevant for transport applications). As with the other alternatives, EPDM rubber has good UV, ozone and temperature resistance, although not comparable to silicones (e.g. temperature resistance -40°C - 120°C). As with the other sealant applications, EPDM is not suitable for all specialist applications in which silicones are currently used and cannot be used where there may be exposure to petroleum-based oils or fuels[310].

Fluoropolymers and other PFAS have also been suggested as alternatives for certain applications, but they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

Although alternatives to silicone sealants exist, they cannot be employed to replace all current applications, especially where there is exposure to UV radiation or extremes of temperature, and should silicone polymers no longer be available, there would need to be investment in the redesign of products to adapt to lower performance standards related to temperature and chemical resistance.

This means that companies might need to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the sealants sector were assumed to be the proportionately similar to the average downstream user sectors in scope. These are presented in Table 4-24 below.

Table 4-24 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

[309] Forgeway (2024) Silicones vs. MS Polymer Sealants; A guide to choosing the best sealant for your application. Available: Silicones vs. MS Polymer Sealants; A guide to choosing the best sealant for your application - Forgeway Ltd

[310] Seals Direct (2024) A complete guide to EPDM Rubber. Available: A Complete Guide to EPDM Rubber - Properties and Applications (sealsdirect.co.uk)

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-25 below.

Table 4-25 Total 'adjustment costs' for the sealants sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€0.9 bn (€0.2-1.4 bn)	€1.3 bn (€0.5-1.5 bn)	€1.7 bn (€1.1-0.8* bn)
Annualised or annual-equivalent 'adjustment costs'	€0.07 bn/year (€0.01-0.1 bn/y)	€0.1 bn/year (€0.03-0.11 bn/y)	€0.13 bn/year (€0.08-0.06* bn/y)

*Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets. * Under PS3, despite the higher costs of industrial transformation, the 'high' adjustment cost estimate might be similar or even lower than the 'medium' estimate due to the neutralising effect of the reduction in manufacturing activity.*

That is, the costs of industrial transformation for the sealants sector could surpass €0.9 billion in Net Present Value, equivalent to over €0.07 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The sealants sector in scope would likely be negatively affected, especially under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -1% (-12% – -0.1%) under PS1, rising to -5% (-70% – -0.5%) under PS2 and a large negative impact of -50% (-90% – -15%) under PS3. These are presented in Table 4-26 below.

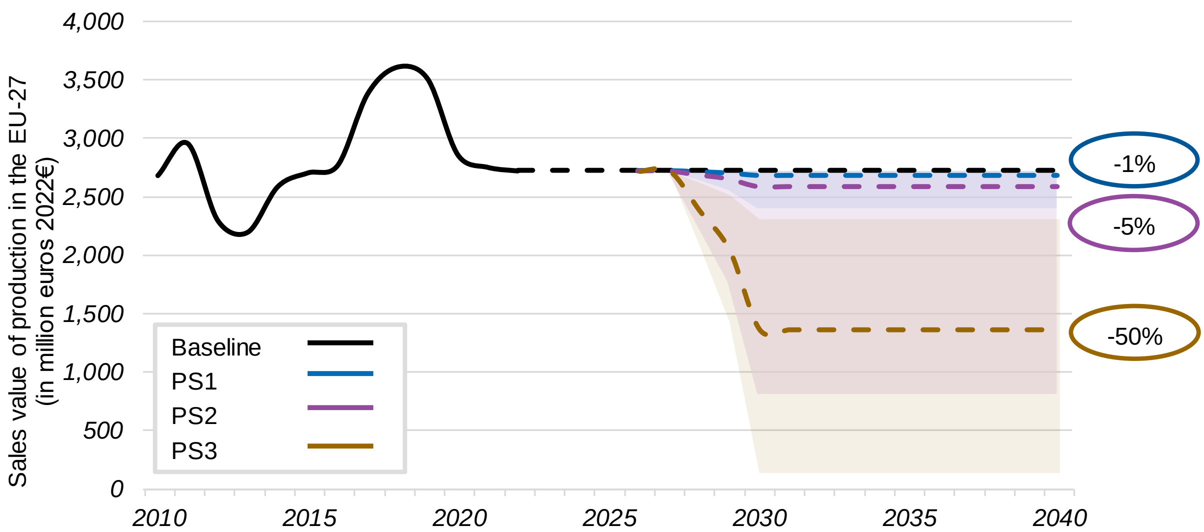
Table 4-26 Estimated reduction in the sealants sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the sealants sector in the EU-27, against the baseline**	-1% (-12% – -0.1%)	-5% (-70% – -0.5%)	-50% (-90% – -15%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €22 million/year of sectoral production activity could be lost under PS1, which could be 4 or 35 times worse under PS2 and PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from almost no losses under PS1 and PS2 to € 250 million/year under PS3. These impacts are presented in Figure 4-9 below.

Figure 4-9 Sales value of the production of the sealants sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by sealants sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-27 below.

Table 4-27 Average impacts on annual employment supported, in FTE, by the sealants sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by sealants sector in scope against the baseline (FTE)	-100 jobs (-800 – -10)	- 300 jobs (-5,000 – -30)	- 3,000 jobs (-6,000 – -1,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the sealants sector in the EU, even when broad exemptions are taken into account.

All policy scenarios are likely to result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the sealants sector within the EU-27 could decrease by 1% under PS1, 5% under PS2, and 50% under PS3,
- The average impact on annual employment, measured in FTE, in the sealants sector from 2023 to 2040 could range from a decrease of 100 jobs under PS1, 300 jobs under PS2, to 3,000 jobs under PS3.

4.2.5.3 Lubricants

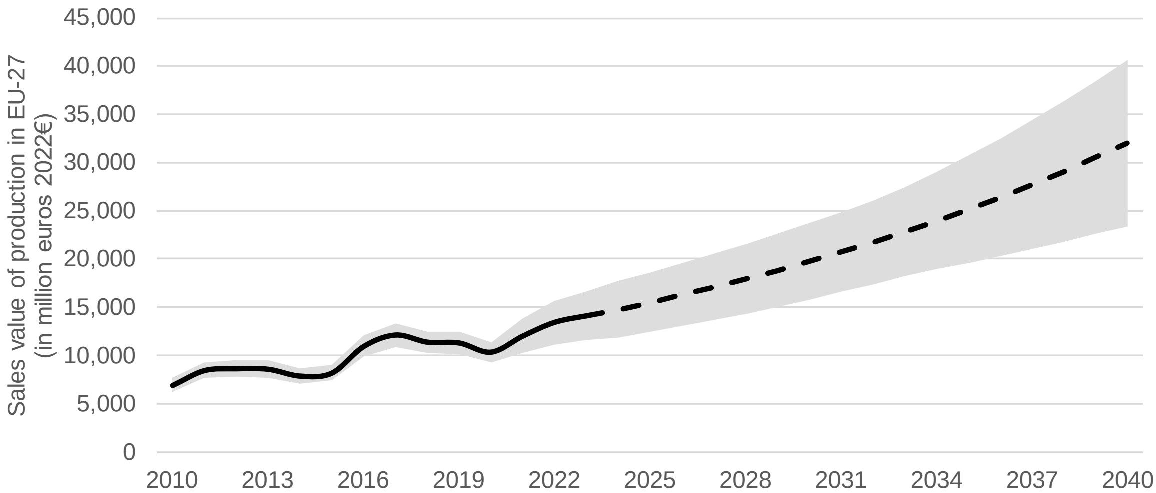
Baseline

The lubricants market relies on D4, D5, D6, and silicone polymers for various applications. Silicone polymers are particularly valued for their thermal stability, lack of flammability, lubricity, and resistance to oxidation and degradation. These properties make them ideal for use in high-performance lubricants, where they reduce friction and wear in machinery and automotive components. Additionally, their excellent temperature resistance ensures effective performance in both extreme heat and cold conditions, while their chemical inertness prevents reactions with other materials, enhancing the longevity and reliability of the lubricants.

The **sales value of such production in the lubricants sector in scope in the EU-27 has been estimated at surpassing €13 billion in 2022**, which accounts for 0.6% of the total production value of the downstream user sectors in scope. This sector generated an estimated €2.5 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 20% of its production value.

Between 2010-2022, the sector's sales turnover has grown at a real CAGR of 5.5%. Looking ahead, this industry might grow at a real CAGR of around 5% in the EU-27 and could reach a production sales value of €32 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-10 below.

Figure 4-10 Baseline sales value of the production of lubricants sector in the EU-27 (€ million)



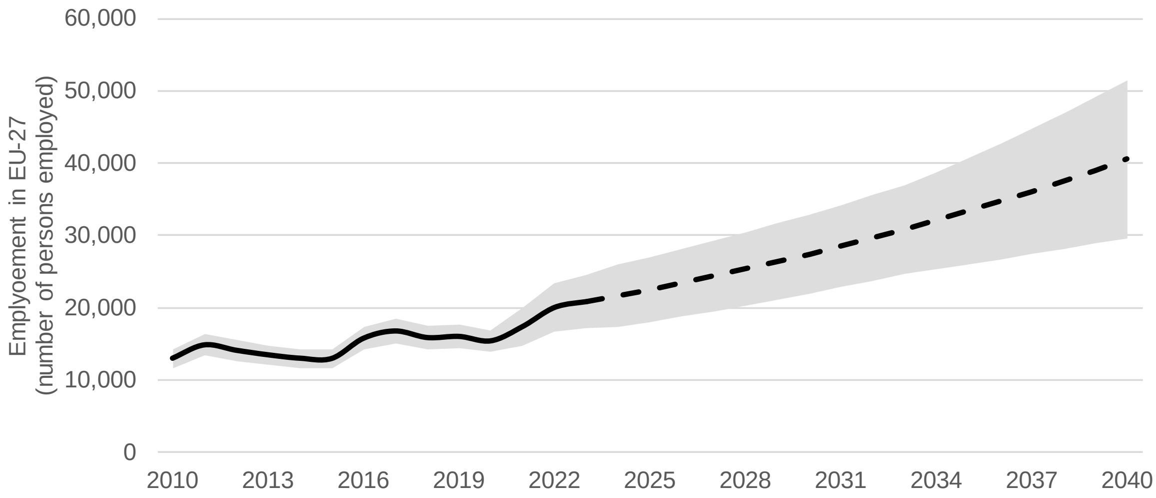
Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 3% of their production value in capital within the EU-27, surpassing €350 million in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were estimated to be between 70-90% of the production sales value, at around €9-12 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of lubricants products in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €5 billion, with imports not surpassing €1.5 billion. Potential growth (in real terms) is likely to be similar for both exports and imports, also between 5-6% per annum.

Finally, the lubricants industry in scope supported around 20,000 jobs (in FTE) in 2022. It is estimated that sectoral jobs could increase over the period of assessment in the baseline scenario, at a real CAGR of around 4%, reaching 40,000 FTE in 2040. This is presented in Figure 4-11 below.

Figure 4-11 Baseline direct employment supported by the lubricants sector in the EU-27 (Number of jobs)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers ('reliant products') across the lubricants sectors in scope is 25% (15%-35%) of sales turnover, considerably lower than the average downstream sector estimates. Six organisations participated in the survey, covering around 1.5% of the 2022 baseline estimated sales value and 4% of the 2022 baseline estimated employment for the lubricants sector.

Conversely, companies considered that their activities could be exempted in lower proportions than other downstream user respondents: under PS1, estimated at 25% (15-45%) of their portfolio of 'reliant products' and, under PS2, estimated at around 15% (0-45%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 20% (5-25%) and 20% (10-35%) under PS2. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 25% (15%-35%). These estimates are presented in the Table 4-28 below.

Table 4-28 Percentage of sales turnover of the lubricants sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of lubricants sector **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers**… ('reliant sales') – (1)		25% (15%-35%)	

Indicator	PS1	PS2	PS3
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	25% (15-45%)	15% (0-45%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	75% (55%-85%)	85% (55%-100%)	100%
Or, equivalently, the **proportion of lubricants sales that could be potentially affected** – (4)[311]	**20% (5-25%)**	**20% (10-35%)**	**25% (15%-35%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=6).

The ability of organisations within the lubricants sector to find substitutes will be notably higher under PS1, than PS2, and considerably lower under PS3, given the present state of technology and innovation. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 90% (70-95%) of their affected portfolio; under PS2, this would decline to 50% (20-90%), and under PS3, this would decline further to an estimated level of 10% (5-20%)** due to the material requirements within this sector. These are presented in Table 4-29 below.

Table 4-29 Estimated level of 'substitution' in the lubricants sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the lubricants sector that could be **adjusted or replaced by alternatives/substitutes**, in sales turnover.	**90% (70-95%)**	**50% (20-90%)**	**10% (5-20%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-4 Alternatives to D4, D5 and D6 and/or silicone polymers in the lubricants sector

There are three main types of lubricants: mineral oil, synthetic and vegetable. Silicone-based lubricants are synthetic and generally cost more than other lubricants. As such, they are used for specific applications, such as under extreme high temperatures, or where their chemical and radiation resistance is critical. Silicone-based lubricants are also used in cases where flammability is a concern, such as in transport applications.

Mineral-oil lubricants have been suggested as potential alternatives to silicone lubricants. Mineral oil lubricants, also known as hydrocarbon lubricants, are derived from crude oil. Mineral oil is comparatively cheaper than silicone lubricants and has good corrosion stability, however the temperature range is inferior and so would not be suitable for applications which require extremes of heat.[312] Mineral oil lubricants are also not suitable for applications where there are flammability concerns.

Other synthetic lubricants may be suitable alternatives to silicone-based lubricants although this was not confirmed by responses to the consultation. Such synthetic lubricants may include: diesters and polyesters, phosphate esters, polyalkylene glycols (PAGs). As with the

[311] Ibid footnote 290

[312] Understanding the Differences Between Base Oil Formulations (machinerylubrication.com)

mineral oils, there are advantages and disadvantages to their use, such as good thermal and oxidative stability (although lower than silicones).

Fluoropolymers and other PFAS have also been suggested as alternatives for certain applications, but they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

This means that companies might need to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the lubricants sector were assumed to be the proportionately similar to the average downstream users sector in scope. These are presented in Table 4-30 below.

Table 4-30 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-31 below.

Table 4-31 Total 'adjustment costs' for the lubricants sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€6 bn (€1-9 bn)	€8 bn (€3-20 bn)	€16 bn (€7-34 bn)
Annualised or annual-equivalent 'adjustment costs'	€0.4 bn/year (€0.1-0.7 bn/y)	€0.6 bn/year (€0.2-1.4 bn/y)	€1.2 bn/year (€0.5-2.4 bn/y)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

That is, the costs of industrial transformation for the lubricants sector could reach €6 billion in Net Present Value, equivalent to over €0.4 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The lubricants sector in scope would likely be negatively affected especially under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -2% (-9% – -0.4%) under PS1, rising to -10% (-25% – -1%) under PS2 and -25% (-35% – -15%) under PS3. These are presented in Table 4-32 below.

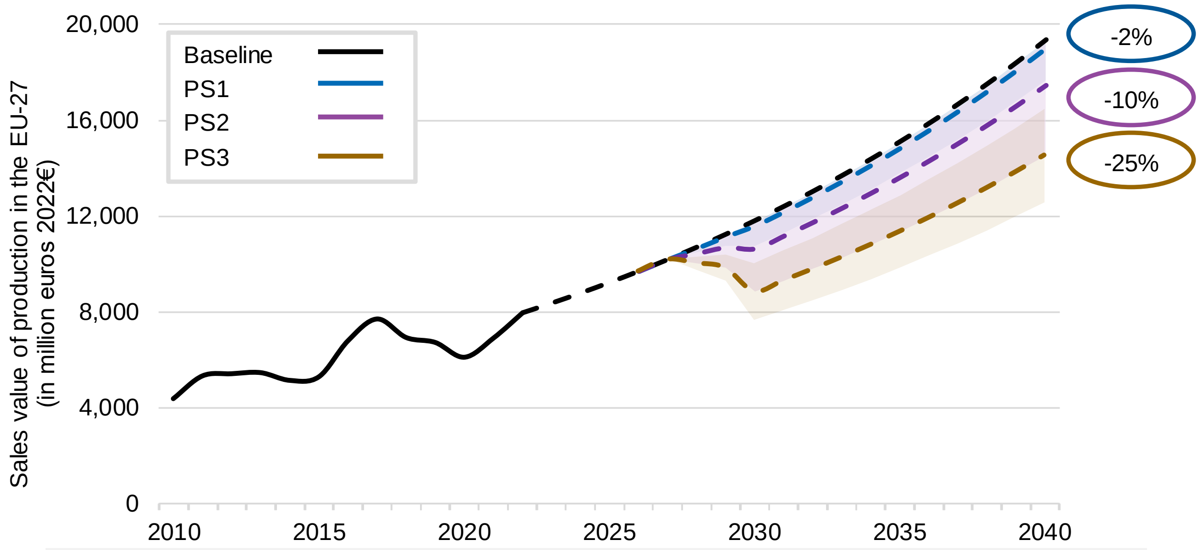
Table 4-32 Estimated reduction in the lubricants sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the lubricants sector in the EU-27, against the baseline**	-2% (-9% – -0.4%)	-10% (-25% – -1%)	-25% (-35% – -15%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €0.2 billion/year of sectoral production activity could be lost under PS1, which could be 5 or 15 times worse under PS2 and PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from a loss of € 0.04 billion/year under PS1, to € 0.09 billion/year under PS2 and € 1.3 billion/year under PS3. These impacts are presented in Figure 4-12 below.

Figure 4-12 Sales value of the production of the lubricants sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by lubricants sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-33 below.

Table 4-33 Average impacts on annual employment supported, in FTE, by the lubricants sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by lubricants sector in scope against the baseline (FTE)	-200 jobs (-900 – -40)	- 1000 jobs (-2,500 – 100)	- 2,000 jobs (-1,000 – -3,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the lubricants sector in the EU, even when broad exemptions are taken into account.

In the lubricants sector, despite a lower reliance on D4, D5, D6, and silicone polymers compared to the average estimates for downstream sectors, the lower exemption rate would result in a net decrease in production activity and job losses within the EU. This negative impact is expected to intensify progressively from PS1 to PS3 across all policy scenarios. Respectively**,**

- The sales value of production in the lubricants sector within the EU-27 could decrease by 2% under PS1, 10% under PS2, and 25% under PS3,
- The average impact on annual employment, measured in FTE, in the lubricants sector from 2023 to 2040 could range from a decrease of 200 jobs under PS1, 1,000 jobs under PS2, to 2,000 jobs under PS3.

4.2.5.4 Adhesives

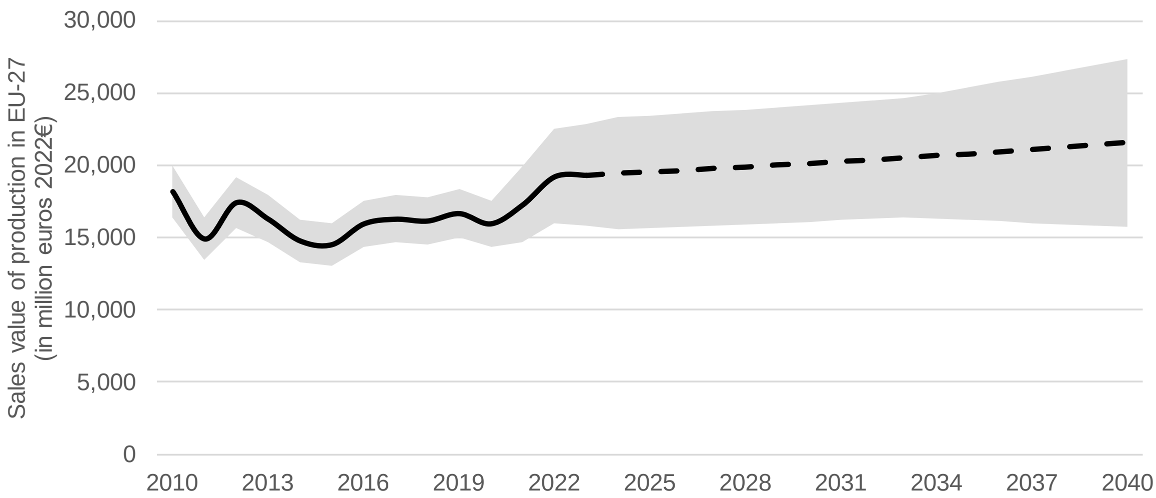
Baseline

In the adhesives sector, D4, D5, D6, and silicone polymers play a crucial role due to their unique properties. Silicone polymers, for instance, are highly valued for their excellent adhesion, flexibility, and durability. These polymers provide strong, long-lasting bonds and can withstand extreme temperatures, moisture, and chemical exposure. Their versatility and reliability make them indispensable in creating high-performance adhesives that meet the demanding requirements of different industries.

The **sales value of such production in the adhesives sector in scope in the EU-27 has been estimated at surpassing €19 billion in 2022**, which accounts for 1.1% of the total production value of the downstream user sectors in scope. This sector generated an estimated €6 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 40% of its production value.

Between 2010-2022, the sector's sales turnover has grown at a real CAGR of 0.5%, although prior to the pandemic the sector was decreasing, at a real CAGR of -1% between 2010-2019. Looking ahead, this industry might slightly continue to grow at a real CAGR between 0-1% in the EU-27 and would reach a production sales value of around €22 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-13 below.

Figure 4-13 Baseline sales value of the production of adhesives sector in the EU-27 (€ million)



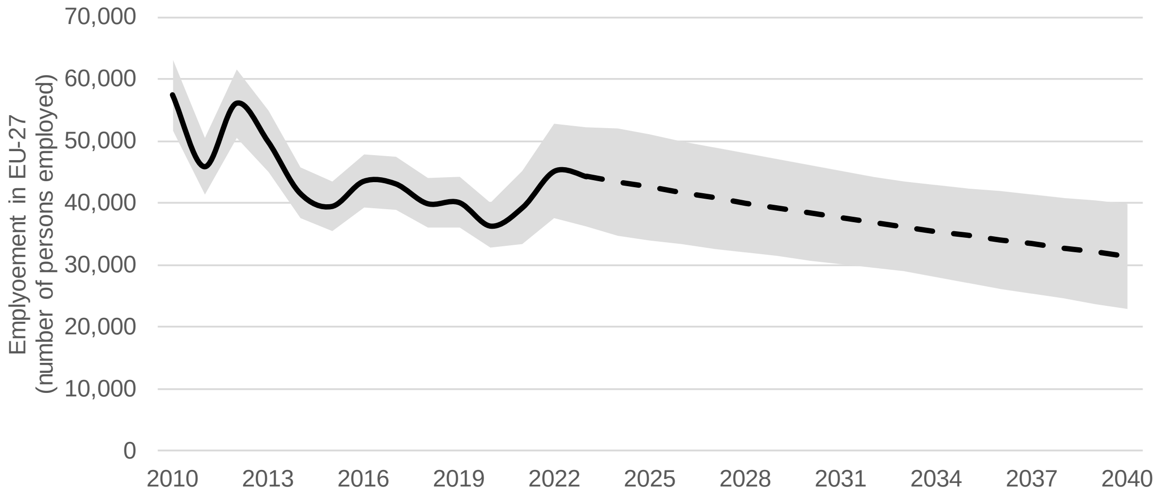
Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 3% of their production value in capital within the EU-27, surpassing €600 million in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were estimated at 70-80% of the production sales value, equivalent to €13-15 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of adhesives products (medical and non-medical) in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €5.5 billion, with imports amounting to €3 billion. Potential growth (in real terms) is likely to be similar for both exports and imports, also between 3-4% per annum.

Finally, the adhesives industry in scope supported more than 45,000 jobs (in FTE) in 2022, although the employment supported by the industry has shown a declining trend in recent years. It is estimated that sectoral jobs could decrease over the period of assessment in the baseline scenario, at a real CAGR of -2%, decreasing to 32,000 FTE in 2040. This is presented in Figure 4-14 below, noting that the uncertainty bounds presented in the Figure capture scenarios of employment remaining approximately stable in the future.

Figure 4-14 Baseline direct employment supported by the adhesives sector in the EU-27 (Number of persons employed)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers (‘reliant products’) across the adhesives sectors in scope is 45% (35-100%) of sales turnover, lower than average downstream sector estimates. Five organisations participated in the survey, covering around 1.5% of 2022 baseline estimated sales value and 2% of 2022 baseline estimated employment for the adhesives sector, reporting experiences which may suggest a high likelihood of reliance on silicone polymers.

Companies also considered that their activities could well be exempted in higher proportions than other downstream user respondents: under PS1, estimated at 98% (95-100%) of their portfolio of ‘reliant products’ and, under PS2, estimated at around 50% (5-95%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 1% (0-5%) and 20% (5-95%) under PS2, which are lower than averages across other sectors. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 45% (35-100%). These estimates are presented in the Table 4-34 below.

Table 4-34 Percentage of sales turnover of the adhesives sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of adhesives sector **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers**… (‘reliant sales’) – (1)		45% (35-100%)	

Indicator	PS1	PS2	PS3
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	98% (95-100%)	50% (5-95%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	2% (0%-5%)	50% (5%-95%)	100%
Or, equivalently, the **proportion of adhesives sector sales that could be potentially affected** – (4)[313]	**1% (0-5%)**	**20% (5-95%)**	**45% (35%-100%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=5).

The ability of organisations within the adhesives sector to find substitutes will be notably higher under PS1, than PS2, and virtually inexistent under PS3, given the present state of technology and innovation. The evidence collected, however, has limitations. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 90% (70-95%) of their affected portfolio; under PS2, this would decline to 50% (20-90%), and it is likely that limited adjustments and/or substitutions rates are possible under PS3**, with an estimated level of 10% (5-20%), due to the material requirements within this sector. These are presented in Table 4-35 below.

Table 4-35 Estimated level of 'substitution' in the adhesives sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the adhesives sector that could be **adjusted or replaced by alternatives/substitutes**, in sales turnover.	**90% (70%-95%)**	**50% (20%-90%)**	**10% (5%-20%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-5 Alternatives to D4, D5 and D6 and/or silicone polymers in the adhesives sector

The literature and available evidence reviewed for this study, especially upstream, suggests that there are potential alternatives to baseline silicone polymers within the adhesives industry under PS1 and PS2 especially, for example, by introducing silicone polymers with lower presence of D4, D5, D6 from the use of removal technologies (striping) upstream. Under PS3, non-regrettable alternatives are more difficult to identify. For example, although certain PFAS may be alternatives for certain applications, they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

The consultation identified a lack of awareness of alternatives across the survey respondents from this industry, as no responses were received. However, the evidence especially of alternative options upstream confirms that, at a cost, high rates of substitution might be possible under PS1, declining under PS2 and very limited under PS3.

Companies might thus be required to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated

[313] Ibid footnote 290

reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the adhesives sector were assumed to be proportionately similar to the average downstream users sector in scope. These are presented in Table 4-36 below.

Table 4-36 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-37 below.

Table 4-37 Total 'adjustment costs' for the adhesives sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€6bn (€1-9 bn)	€7 bn (€3-8 bn)	€12 bn (€6-5* bn)
Annualised or annual-equivalent 'adjustment costs'	€0.4 bn/year (€0.1-0.7 bn/y)	€0.5 bn/year (€0.2-0.6 bn/y)	€0.9 bn/year (€0.4-0.4* bn/y)

*Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets. * Under PS3, despite the higher costs of industrial transformation, the 'high' adjustment cost estimate might be similar or even lower than the 'medium' estimate due to the neutralising effect of the reduction in manufacturing activity.*

That is, the costs of industrial transformation for the adhesives sector could surpass €6 billion in Net Present Value, equivalent to over €0.4 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The adhesives sector in scope would likely be affected negatively under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -0.1% (-2% – 0%) under PS1, rising to -15% (-75% – -0.5%) under PS2 and -40% (-95% – -25%) under PS3. These are presented in Table 4-38 below.

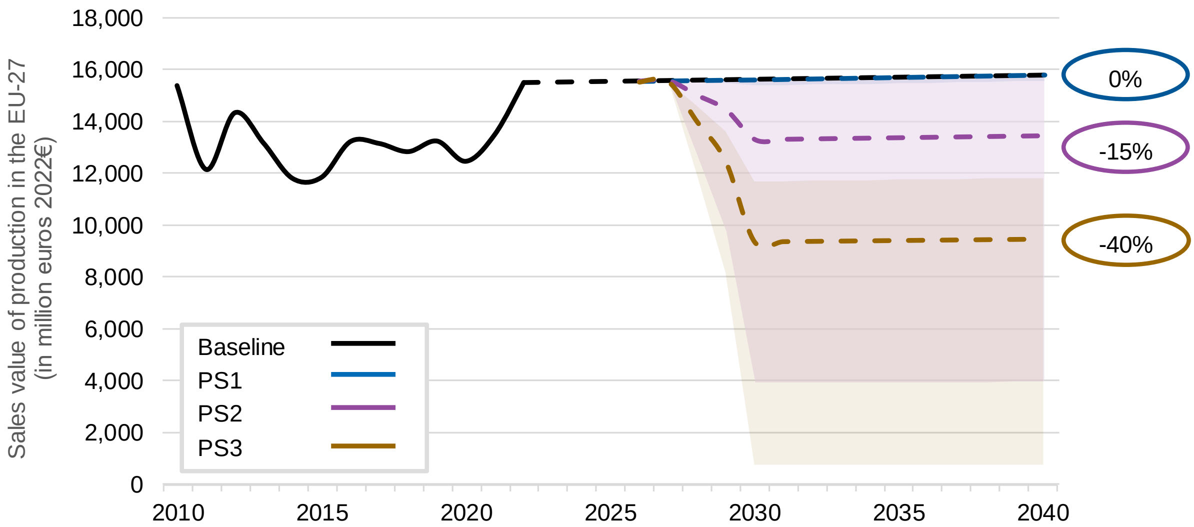
Table 4-38 Estimated reduction in the adhesives sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the adhesives sector in the EU-27, against the baseline**	-0.1% (-2% – 0%)	-15% (-75% – -0.5%)	-40% (-95% – -25%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €10 million/year of sectoral production activity could be lost under PS1, which could increase to around €1.5 bn/year under PS2 and around €4 bn/year under PS3 as a result of the decline in exemptions. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from no losses under PS1, €0.5 bn/year of losses under PS2 to €2.5 bn/year under PS3. These impacts are presented in Figure 4-15 below.

Figure 4-15 Sales value of the production of the adhesives sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by adhesives sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-39 below.

Table 4-39 Average impacts on annual employment supported, in FTE, by the adhesives sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by adhesives sector in scope against the baseline (FTE)	-10 jobs (-200 – 0)	- 2,000 jobs (-8,000 – -50)	- 4,000 jobs (-10,000 – -3,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under policy scenarios PS2 and PS3 there could be a negative impact on the adhesives sector in the EU, even when broad exemptions are taken into account.

Although policy scenario 1 is expected to have a limited to no impact, both PS2 and PS3 could result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the adhesives sector within the EU-27 is expected to have a limited decline if any under PS1, but could decrease by 2% under PS2 and by 15% under PS3,
- The average impact on annual employment, measured in FTE, in the adhesives sector from 2023 to 2040 could range from limited job losses under PS1, to 2,000 jobs under PS2, and 4,000 jobs under PS3.

4.2.5.5 Coatings

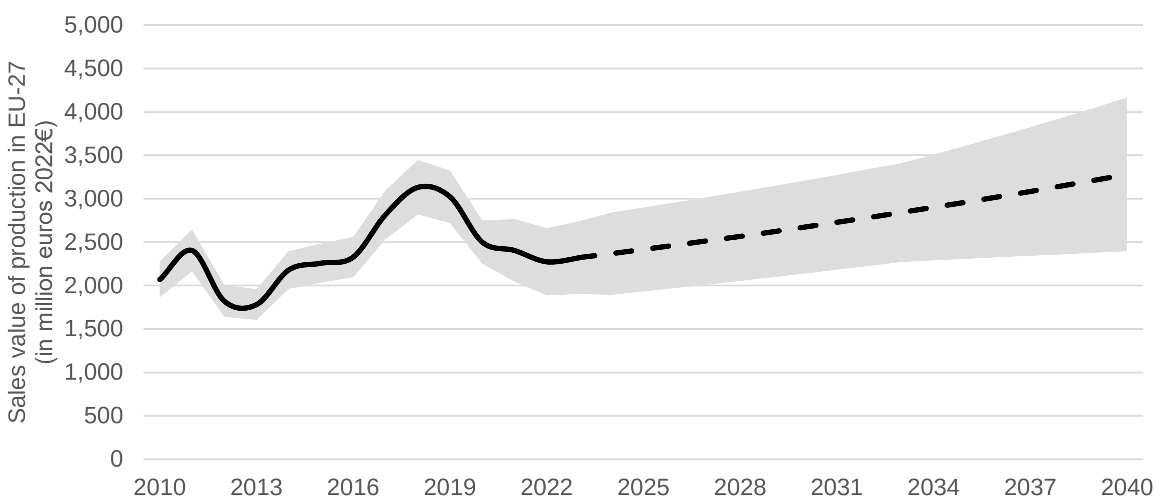
Baseline

In the coatings sector, D4, D5, D6, and silicone polymers are selected due to their distinct properties. Silicone polymers, particularly, are valued for their durability, flexibility, and resistance to extreme temperatures and harsh environmental conditions. They are widely used in various coating applications, such as protective and decorative finishes for automotive, construction, and industrial sectors. These polymers offer superior weather resistance, UV stability, and water repellence, ensuring surfaces remain protected and visually appealing over time. Their capacity to create flexible yet robust films make silicone-based coatings crucial for delivering high-performance solutions across a range of industries.

The **sales value of such production in the coating sector in scope in the EU-27 has been estimated at around €2.5 billion in 2022**, which accounts for 0.2% of the total production value of the downstream user sectors in scope. This sector generated around €0.8 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 35% of its production value.

Between 2010-2022, the sector's sales turnover has grown at a real CAGR of around 1%, although prior to the pandemic the sector had grown more rapidly, at a real CAGR of 4% between 2010-2019. Looking ahead, this industry might grow at a real CAGR of 2% in the EU-27 and could reach a production sales value surpassing €3 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-16 below.

Figure 4-16 Baseline sales value of the production of the coatings sector in the EU-27 (€ million)



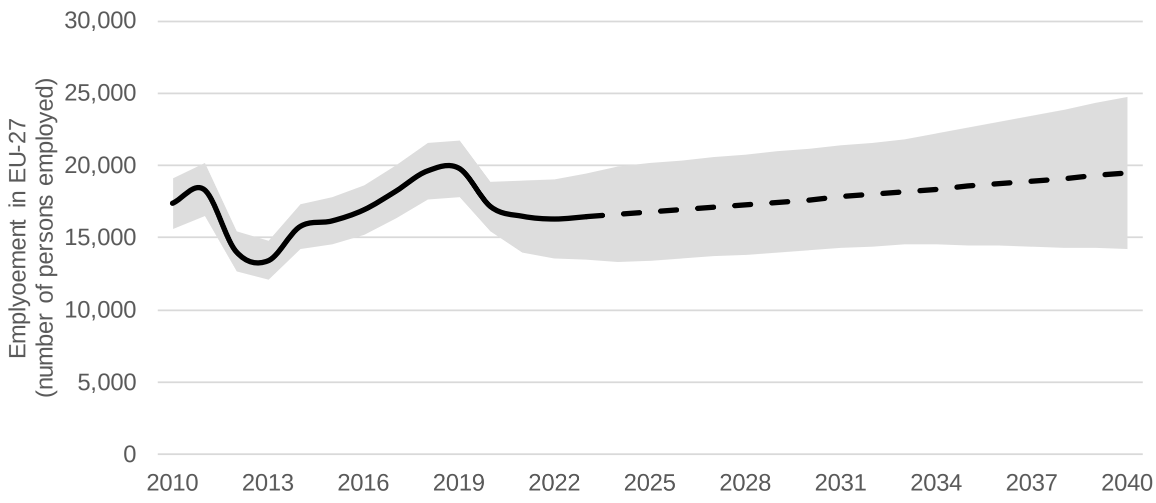
Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 5% of their production value in capital within the EU-27, around €100 million in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were equivalent to around 70-90% of the production sales value, estimated to be between €1.5-2 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of coated products (hard coatings, soft coatings, release coatings, external coatings, hard casings, internal coatings, textiles) in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €900 million, with imports just above €500 million. Potential growth (in real terms) is likely to be similar for both exports and imports, around 4% per annum.

Finally, the coating industry in scope supported more than 16,000 jobs (in FTE) in 2022. It is estimated that sectoral jobs could grow over the period of assessment in the baseline scenario, at a real CAGR of 1%, reaching around 20,000 FTE in 2040. This is presented in Figure 4-17 below.

Figure 4-17 Baseline direct employment supported by the coatings sector in the EU-27 (Number of persons employed)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers (‘reliant products’) across the coating sectors in scope is 55% (45%-100%) of sales turnover, lower than average downstream sector estimates. Eight organisations participated in the survey, covering around 50% of 2022 baseline estimated sales value and 80% of 2022 baseline estimated employment for the coating sector, reporting a variety of experiences yet suggesting a high likelihood of reliance on silicone polymers.

Companies also considered that their activities could well be exempted in higher proportions than other downstream user respondents under PS1, estimated at 85% (65-95%) of their portfolio of ‘reliant products’ and, under PS2, estimated at around 35% (0-80%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 10% (5-35%) and 35% (10-100%) under PS2. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 55% (45-100%). These estimates are presented in the Table 4-40 below.

Table 4-40 Percentage of sales turnover of the coatings sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

<table>
<tr><th>Indicator</th><th>PS1</th><th>PS2</th><th>PS3</th></tr>
<tr><td>Proportion of coating sector sales that rely, in some way, on D4, D5, D6</td><td colspan="3">55%
(45%-100%)</td></tr>
</table>

Indicator	PS1	PS2	PS3
and/or silicone polymers… ('reliant sales') – (1)			
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	85% (65-95%)	35% (0-80%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	15% (5%-35%)	65% (20%-100%)	100%
Or, equivalently, the **proportion of coating sector sales that could be potentially affected** – (4)[314]	**10% (5-35%)**	**35% (10-100%)**	**55% (45%-100%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=8).

The ability of organisations within the coating sector to find substitutes will be notably higher under PS1, than PS2, and virtually non-existent under PS3, given the present state of technology and innovation. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 90% (70-95%) of their affected portfolio; under PS2, this would decline to 50% (20-90%), and it is likely that lower adjustments and/or substitutions are possible under PS3**, **at an estimated level of 10% (5-20%)** due to the material requirements within this sector. These are presented in Table 4-41 below.

Table 4-41 Estimated level of 'substitution' in the coatings sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the coating sector that could be **adjusted or replaced by alternatives/ substitutes**, in sales turnover.	**90% (70%-95%)**	**50% (20%-90%)**	**10% (5%-20%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-6 Alternatives to D4, D5 and D6 and/or silicone polymers in the coatings sector

The literature and available evidence reviewed for this study, especially upstream, suggests that there are potential alternatives to baseline silicone polymers within the coatings industry under PS1 and PS2 especially, for example, by introducing silicone polymers with lower presence of D4, D5, D6 from the use of removal technologies (stripping) upstream. Under PS3, non-regrettable alternatives are more difficult to identify. For example, although certain PFAS may be alternatives for certain applications, they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

The consultation identified a lack of awareness of alternatives across the survey respondents from this industry, as no responses were received. However, the evidence especially of alternative options upstream confirms that, at a cost, high rates of substitution might be possible under PS1, declining under PS2 and very limited under PS3.

[314] Ibid footnote 290

Companies might thus be required to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the coating sector were assumed to be the proportionately similar to the average downstream users sector in scope. These are presented in Table 4-42 below.

Table 4-42 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-43 below.

Table 4-43 Total 'adjustment costs' for the coatings sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€0.8 bn (€0.2-1.1 bn)	€0.9 bn (€0.4-0.9* bn)	€1.4 bn (€0.7-0.7* bn)
Annualised or annual-equivalent 'adjustment costs'	€0.06 bn/year (€0.01-0.08 bn/y)	€0.07 bn/year (€0.03-0.06* bn/y)	€0.1 bn/year (€0.05-0.05* bn/y)

*Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets. * Under PS2 and PS3, despite the higher costs of industrial transformation, the 'high' adjustment cost estimate might be similar or even lower than the 'medium' estimate due to the neutralising effect of the reduction in manufacturing activity.*

That is, the costs of industrial transformation for the coating sector could surpass €800 million in Net Present Value, equivalent to over €60 million each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The coating sector in scope would likely be negatively affected especially under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -1% (-11% – -0.1%) under PS1, rising to -20% (-80% – -1%) under PS2 and -50% (-95% – -35%) under PS3. These are presented in Table 4-44 below.

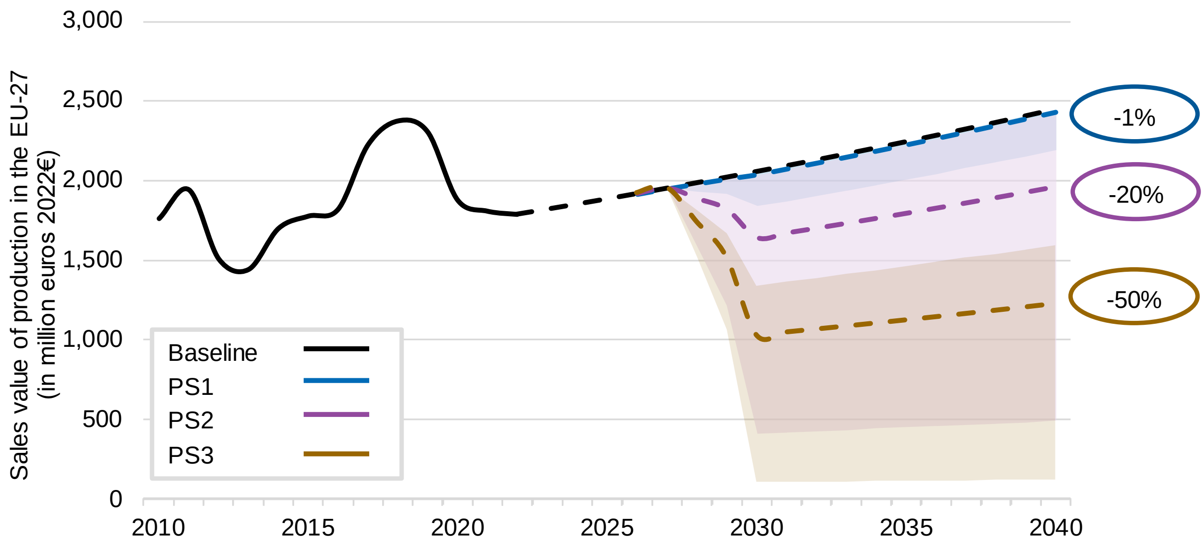
Table 4-44 Estimated reduction in the coating sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the coating sector in the EU-27, against the baseline**	-1% (-11% – -0.1%)	-20% (-80% – -1%)	-50% (-95% – -35%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €10 million/year of sectoral production activity could be lost under PS1, which could be 25 or 60 times worse under PS2 and PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from almost no losses under PS1, €10 million/year of losses under PS2 to €500 million/year under PS3. These impacts are presented in Figure 4-18 below.

Figure 4-18 Sales value of the production of the coating sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by coating sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-45 below.

Table 4-45 Average impacts on annual employment supported, in FTE, by the coating sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by coating sector in scope against the baseline (FTE)	-50 jobs (-500 – -5)	- 1,000 jobs (-4,000 – -50)	- 3,000 jobs (-5,000 – -2,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the coating sector in the EU, even when broad exemptions are taken into account.

While PS1 is expected to have a minor impact, all policy scenarios are likely to result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the coatings sector within the EU-27 could decrease by 1% under PS1, 20% under PS2, and 50% under PS3,
- The average impact on annual employment, measured in FTE, in the coatings sector from 2023 to 2040 could range from a decrease of 50 jobs under PS1, 1,000 jobs under PS2, to 3,000 jobs under PS3.

4.2.5.6 Electronics

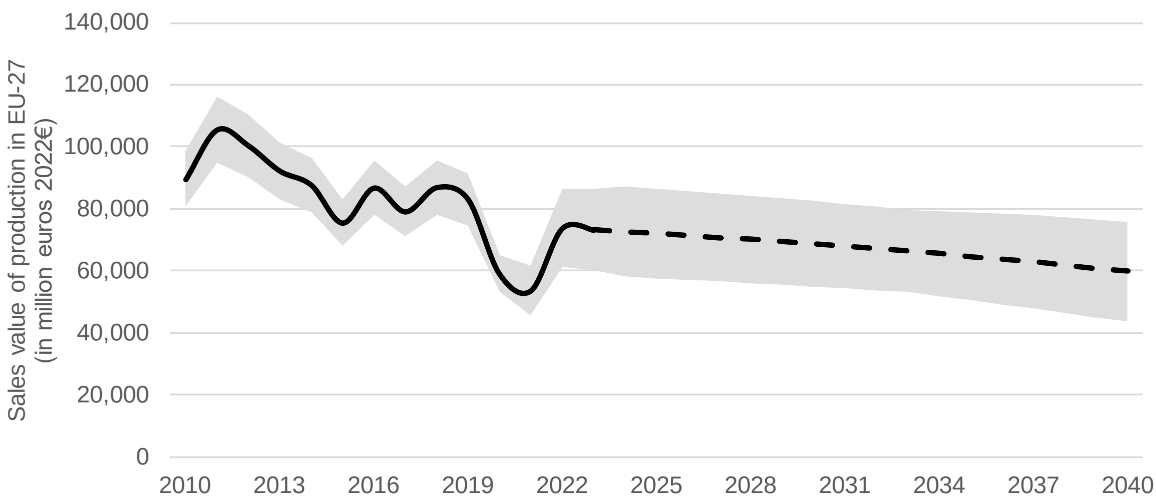
Baseline

In the electronics sector, D4, D5, D6, and silicone polymers are crucial for both components and final products. Silicone polymers are highly valued for their excellent thermal stability, electrical insulation properties, and durability. They are used in various electronic applications, such as insulating materials for wiring and cables, coatings for circuit boards, and as adhesives and sealants for electronic assemblies. Their ability to withstand high temperatures and resist environmental stress ensures the reliability and longevity of electronic devices, making them indispensable in the manufacturing of advanced electronics.

The **sales value of such production in the electronics sector in scope in the EU-27 has been estimated at around €75 billion in 2022**, which accounts for 10.7% of the total production value of the downstream user sectors in scope. This sector generated an estimated €40 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 55% of its production value.

Between 2010-2022, the sector's sales turnover has decreased at a real CAGR of -1.5%. Looking ahead, this industry might continue to decrease at a real CAGR in line with past CAGR, between -1 to -2%, in the EU-27 and could reach a production sales value of around €60 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-19 below.

Figure 4-19 Baseline sales value of the production of the electronics sector in the EU-27 (€ million)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

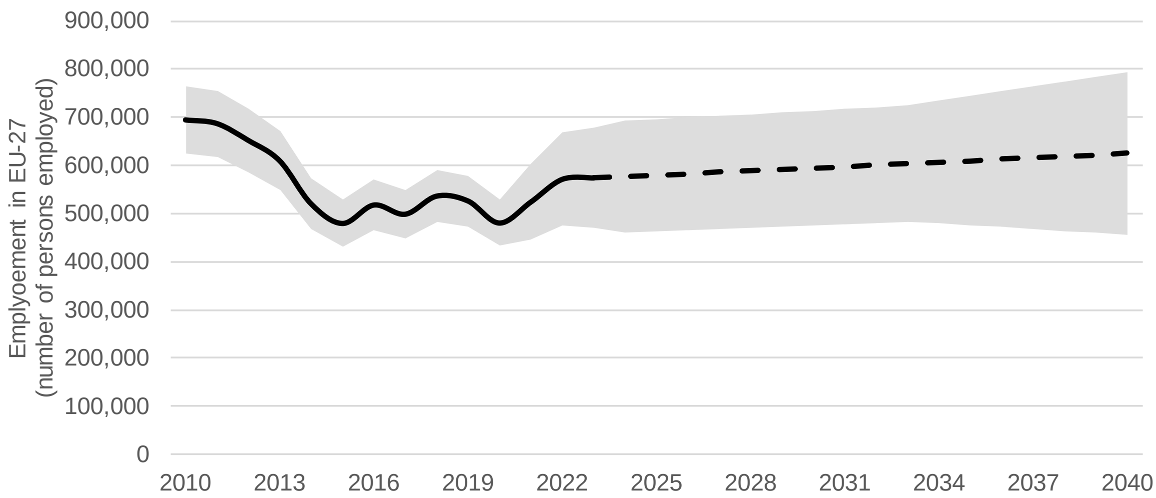
In addition, it is estimated that companies in this sector **invested** around 5% of their production value in capital within the EU-27, around €4 billion in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were around 90-95% of the production sales value in the EU equivalent to €65-70 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net importer of electronics products in scope of this Study; and, based on historical evidence, this appears to be a position that could remain over time, in the baseline scenario. In 2022, extra-EU exports reached around €105 billion, with imports not surpassing

€180 billion. Potential growth (in real terms) is likely to be similar for both exports and imports, around 2% per annum.

Finally, the electronics industry in scope supported more than 570,000 jobs (in FTE) in 2022. It is estimated that sectoral jobs could remain stable over the period of assessment in the baseline scenario, growing slightly at a real CAGR of 0.5%, surpassing 625,000 FTE in 2040. This is presented in Figure 4-20 below, wherein the uncertainty bounds also cover scenarios of any possible decline in the employment supported by the sector.

Figure 4-20 Baseline direct employment supported by the electronics sector in the EU-27 (Number of persons employed)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers (‘reliant products’) across the electronics sectors in scope is 80% (65%-100%) of sales turnover, similar to average downstream sector estimates. Thirteen organisations participated in the survey, covering around 5% of 2022 baseline estimated sales value and 2% of 2022 baseline estimated employment for electronics sectors, reporting a variety of experiences yet suggesting a high likelihood of notable reliance on silicone polymers.

Companies also considered that their activities could well be exempted: under PS1, estimated at 80% (5-100%) of their portfolio of ‘reliant products’ and, under PS2, estimated at around 25% (0-60%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 15% (0-95%) and 60% (25-100%) under PS2, which are relatively lower than averages across other sectors. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 80% (65-100%). These estimates are presented in the Table 4-46 below.

Table 4-46 Percentage of sales turnover of the electronics sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of electronics sector **sales that rely, in some way, on D4, D5, D6**		80% (65%-100%)	

Indicator	PS1	PS2	PS3
and/or silicone polymers… ('reliant sales') – (1)			
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	80% (5-100%)	25% (0-60%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	20% (0%-95%)	75% (40%-100%)	100%
Or, equivalently, the **proportion of electronics sector sales that could be potentially affected** – (4)[315]	**15% (0-95%)**	**60% (25-100%)**	**80% (65-100%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=13).

The ability of organisations within the electronics sector to find substitutes will be notably higher under PS1, than PS2, and virtually non-existent under PS3, given the present state of technology and innovation. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 90% (70-95%) of their affected portfolio; under PS2, this would decline to 50% (20-90%), and it is likely that lower adjustments and/or substitutions are possible under PS3**, at an estimated level of 10% (5-20%), due to the material requirements within this sector. These are presented in Table 4-47 below.

Table 4-47 Estimated level of 'substitution' in the electronics sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the electronics sector that could be **adjusted or replaced by alternatives/ substitutes**, in sales turnover.	**90% (70%-95%)**	**50% (20%-90%)**	**10% (5%-20%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-7 Alternatives to D4, D5 and D6 and/or silicone polymers in the electronics sector

Silicone polymers are used in a wide range of applications within the electronics sector including protection of displays from vibration/ shock absorption and temperature fluctuations, sealing, and thermal insulation.

EPDM rubber was suggested by respondents to the consultation as a potential alternative to silicone polymers for electrical and cable insulation. It has high dielectric strength and resistance to electrical current, as well as flexibility, making it a suitable insulator for wires, cables and electrical components.

Epoxy resin was suggested as a potential alternative to silicone polymers for encapsulation of electronic components, insultation of integrated circuits, transistors and PCBs, and coatings of components. Epoxy resin has high mechanical strength, thermal and chemical resistance, and insulating properties. It does not offer the flexibility of silicone polymers, the same extremes of temperature or UV resistance, meaning it is not suitable for all silicone polymer applications within the electronics sector.

[315] Ibid footnote 290

Fluoropolymers and other PFAS have also been suggested as alternatives for certain applications, but they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

This means that companies might need to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the electronics sector were assumed to be the proportionately similar to the average downstream users sector in scope. These are presented in Table 4-48 below.

Table 4-48 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-49 below.

Table 4-49 Total ‘adjustment costs’ for the electronics sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total ‘adjustment’ costs over the period (2023-2040)	€54 bn (€11-65 bn)	€56 bn (€24-58 bn)	€63 bn (€40-63 bn)
Annualised or annual-equivalent ‘adjustment costs’	€3.9 bn/year (€0.8-4.7 bn/y)	€4.1 bn/year (€1.8-4.3 bn/y)	€4.6 bn/year (€2.9-4.6 bn/y)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

That is, the costs of industrial transformation for the electronics sector could surpass €54 billion in Net Present Value, equivalent to over €3.9 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The electronics sector in scope would likely be affected to a larger extent under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -2% (-30% – 0%) under PS1, rising to -30% (-80% – -5%) under PS2 and a large -70% (-95% – -50%) under PS3. These are presented in Table 4-50 below.

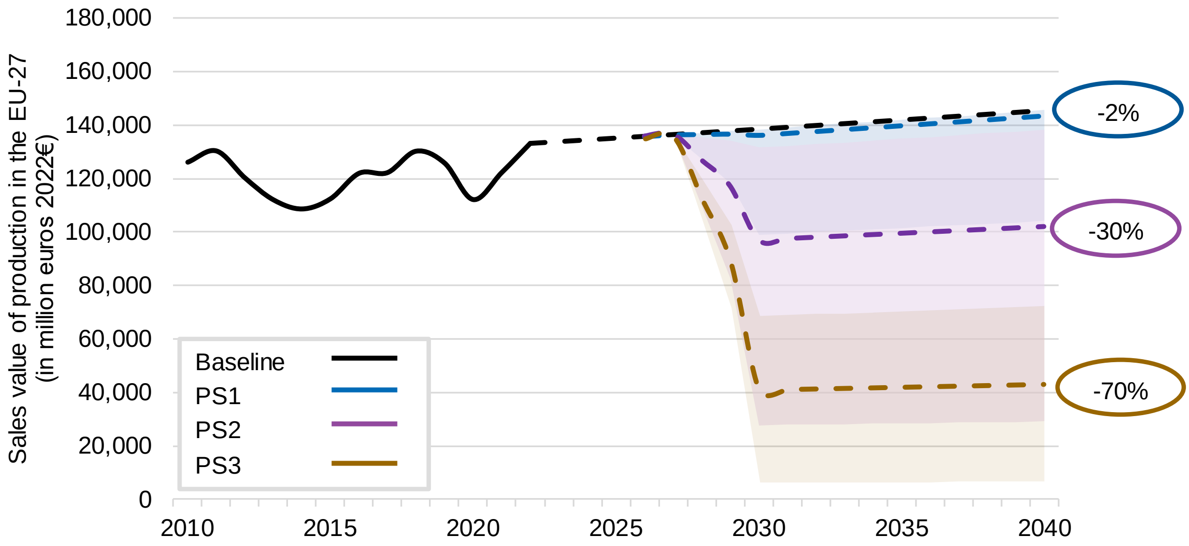
Table 4-50 Estimated reduction in the electronics sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the electronics sector in the EU-27, against the baseline**	-2% (-30% – 0%)	-30% (-80% – -5%)	-70% (-95% – -50%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €1.3 bn/year of sectoral production activity could be lost under PS1, which could be 20 or 45 times worse under PS2 and PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from no losses under PS1, €4 bn/year of losses under PS2 to €42 bn/year under PS3. These impacts are presented in Figure 4-21 below.

Figure 4-21 Sales value of the production of the electronics sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by electronics sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-51 below.

Table 4-51 Average impacts on annual employment supported, in FTE, by the electronics sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by electronics sector in scope against the baseline (FTE)	-3,000 jobs (-51,000 – 0)	- 54,000 jobs (-143,000 – -9,000)	- 126,000 jobs (-170,000 – -90,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the electronics sector in the EU, even when broad exemptions are taken into account.

All policy scenarios are likely to result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the electronics sector within the EU-27 could decrease by 2% under PS1, 30% under PS2, and 70% under PS3,
- The average impact on annual employment, measured in FTE, in the electronics sector from 2023 to 2040 could range from a decrease of 3,000 jobs under PS1, 54,000 jobs under PS2, to 126,000 jobs under PS3.

4.2.5.7 Aerospace and Defence

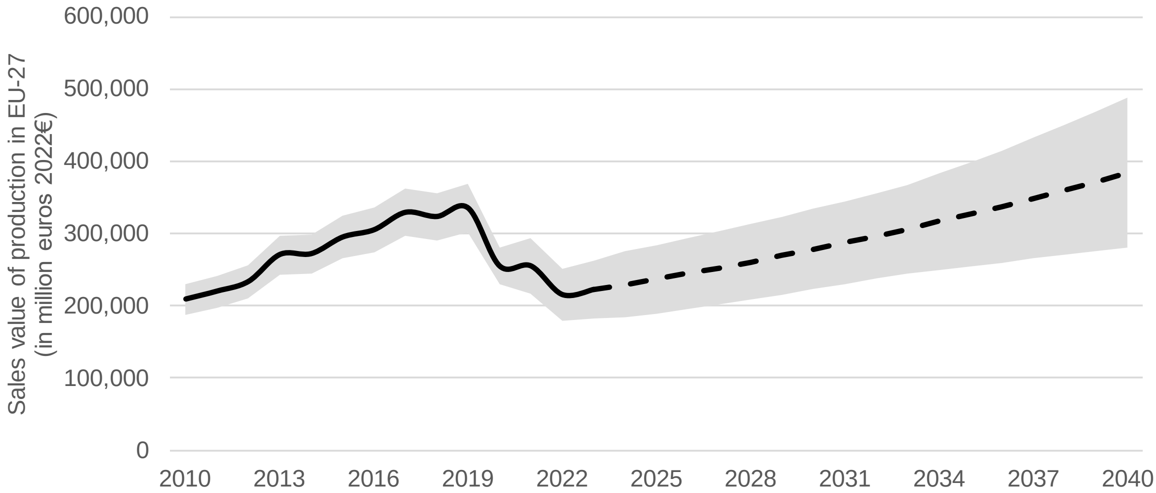
Baseline

In the Aerospace and Defence sectors, D4, D5, D6, and silicone polymers are essential due to their exceptional properties. Silicone polymers are used in a variety of applications, including lubricants, coatings, sealants, adhesives, and insulation materials. Their high thermal stability, flexibility, and resistance to harsh environmental conditions make them ideal for protecting and enhancing the performance of aircraft components, missiles, and other defence equipment. Silicone-based materials provide reliable sealing and bonding solutions that can withstand extreme temperatures and mechanical stresses, ensuring the safety and efficiency of aerospace and defence systems.

The **sales value of such production in the aerospace and defence sector in scope in the EU-27 has been estimated at around €215 billion in 2022**, which accounts for 19.4% of the total production value of the downstream user sectors in scope. This sector generated an estimated €40 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 20% of its production value.

Between 2010-2022, the sector's sales turnover had a real CAGR of 0.2%, although prior to the pandemic the sector had grown more rapidly, at a real CAGR of 5% between 2010-2019. Looking ahead, this industry might grow at a real CAGR between 3-4% in the EU-27 and could reach a production sales value surpassing €380 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-22 below.

Figure 4-22 Baseline sales value of the production of aerospace and defence sector in the EU-27 (€ million)



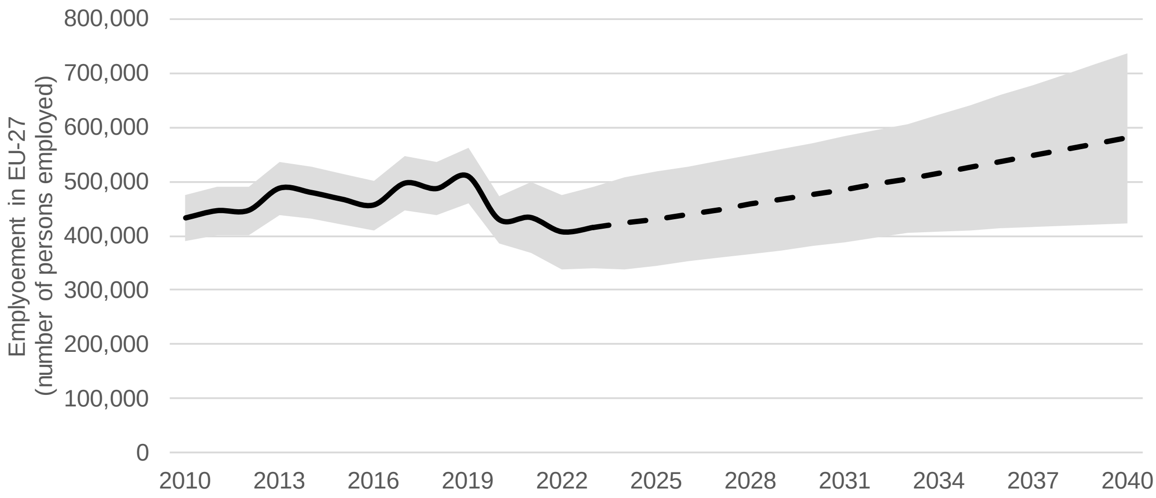
Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 3% of their production value in capital within the EU-27, around €7 billion in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were equivalent to 95% of the production sales value, surpassing €200 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of aerospace and defence products in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €35 billion, with imports not surpassing €30 billion. Potential growth (in real terms) is likely to be similar for both exports and imports, also around 3% per annum.

Finally, the aerospace and defence industry in scope supported more than 400,000 jobs (in FTE) in 2022. It is estimated that sectoral jobs could grow notably over the period of assessment in the baseline scenario, at a real CAGR of 2%, surpassing 580,000 FTE in 2040. This is presented in Figure 4-23 below.

Figure 4-23 Baseline direct employment supported by the aerospace and defence sector in the EU-27 (Number of jobs)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers ('reliant products') across the aerospace and defence sectors in scope is 80% (50%-100%) of sales turnover, similar to average downstream sector estimates. Seven organisations participated in the survey, covering around 35% of 2022 baseline estimated sales value and around 15% of 2022 baseline estimated employment for aerospace and defence sectors, reporting a variety of experiences yet suggesting a high likelihood of notable reliance on silicone polymers.

Companies also considered that their activities could well be exempted: under PS1 and PS2, estimated at 50% (1-100%), in terms of sales turnover, of their portfolio of 'reliant products' for both the policy scenario.

As a result, the potentially affected market under PS1 and PS2 is estimated at 40% (0-100%), which is relatively higher than averages across other sectors in PS1 and similar in PS2. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 80% (50-100%). These estimates are presented in the Table 4-52 below.

Table 4-52 Percentage of sales turnover of the aerospace and defence sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of aerospace and defence sector **sales that rely, in some way, on**		80% (50%-100%)	

Indicator	PS1	PS2	PS3
D4, D5, D6 and/or silicone polymers… ('reliant sales') – (1)			
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	50% (1-100%)	50% (0-100%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	50% (0%-99%)	50% (0%-100%)	100%
Or, equivalently, the **proportion of aerospace and defence sector sales that could be potentially affected** – (4)[316]	**40% (0-100%)**	**40% (0-100%)**	**80% (50%-100%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=7).

The ability of organisations within the aerospace and defence sector to find substitutes will be notably higher under PS1, than PS2, and virtually non-existent under PS3, given the present state of technology and innovation. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 75% (50-85%) of their affected portfolio; under PS2, this would decline to 40% (10-70%), and it is likely that minimal adjustments and/or substitutions are possible under PS3**, **at an estimated level of 5% (0-10%)**, due to the material requirements within this sector. These are presented in Table 4-53 below.

Table 4-53 Estimated level of 'substitution' in the aerospace and defence sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the aerospace and defence sector that could be **adjusted or replaced by alternatives/ substitutes**, in sales turnover.	**75% (50%-85%)**	**40% (10%-70%)**	**5% (0%-10%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-8 Alternatives to D4, D5 and D6 and/or silicone polymers in the aerospace and defence sector

The literature and available evidence reviewed for this study, especially upstream, suggests that there are potential alternatives to baseline silicone polymers within the aerospace and defence industry under PS1 and PS2 especially. Under PS3, non-regrettable alternatives are more difficult to identify.

For example, when considering individual applications there may be alternatives such as MS polymer or polyurethane sealants, EPDM rubber in seals or electronics, epoxy resin in electronics, etc. However, the strict certification, performance and safety requirements of the sector make substitution a lengthy and more difficult process. Certain PFAS may also be alternatives for certain applications; however, they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

The consultation identified a lack of awareness of alternatives across the survey respondents from this industry, as no responses were received. However, the evidence especially of

[316] Ibid footnote 290

alternative options upstream confirms that, at a cost, high rates of substitution might be possible under PS1, declining under PS2 and very limited under PS3.

This means that companies might need to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the aerospace and defence sector were assumed to be the proportionately similar to the average downstream users sector in scope. These are presented in Table 4-54 below.

Table 4-54 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-55 below.

Table 4-55 Total 'adjustment costs' for the aerospace and defence sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€95 bn (€20-95 bn)	€115 bn (€50-115 bn)	€100 bn* (€40-100 bn)
Annualised or annual-equivalent 'adjustment costs'	€7 bn/year (€2-7 bn/y)	€8 bn/year (€4-8 bn/y)	€7 bn/year* (€3-7 bn/y)

*Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets. *Please note that adjustment costs do not only depend on unit costs but also on the scale of transformation that is viable. In this case, despite there being higher unit costs of transformation under PS3, the scale is more limited due to a lack of viability, so total, absolute costs are lower than those under PS2.*

That is, the costs of industrial transformation for the aerospace and defence sector could surpass €95 billion in Net Present Value, equivalent to over €7 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The aerospace and defence sector in scope would likely be affected under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -10% (-50% – 0%) under PS1, rising to -25% (-90% – 0%) under PS2 and a large -75% (-100% – -45%) under PS3. These are presented in Table 4-56 below.

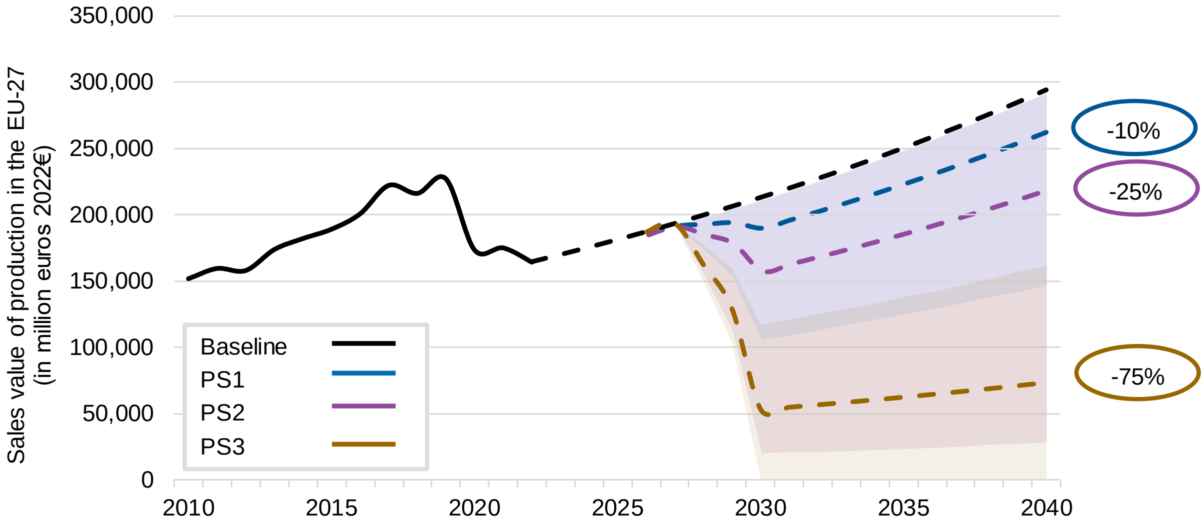
Table 4-56 Estimated reduction in the aerospace and defence sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the aerospace and defence sector in the EU-27, against the baseline**	-10% (-50% – 0%)	-25% (-90% – 0%)	-75% (-100% – -45%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of around €15 bn/year of sectoral production activity could be lost under PS1, which could be 3 or 8 times worse under PS2 and PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from no losses under PS1 and PS2 to €65 bn/year under PS3. These impacts are presented in Figure 4-24 below.

Figure 4-24 Sales value of the production of the aerospace and defence sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by aerospace and defence sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-57 below.

Table 4-57 Average impacts on annual employment supported, in FTE, by the aerospace and defence sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by aerospace and defence sector in scope against the baseline (FTE)	-15,000 jobs (-76,000 – -0)	- 38,000 jobs (-138,000 – -0)	- 115,000 jobs (-154,000 – -70,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the aerospace and defence sector in the EU, even when broad exemptions are taken into account.

All policy scenarios are likely to result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the aerospace and defence sector within the EU-27 could decrease by 10% under PS1, 25% under PS2, and 75% under PS3,
- The average impact on annual employment, measured in FTE, in the aerospace and defence sector from 2023 to 2040 could range from a decrease of 15,000 jobs under PS1, 38,000 jobs loss under PS2, and 115,000 jobs under PS3.

4.2.5.8 Paper Products

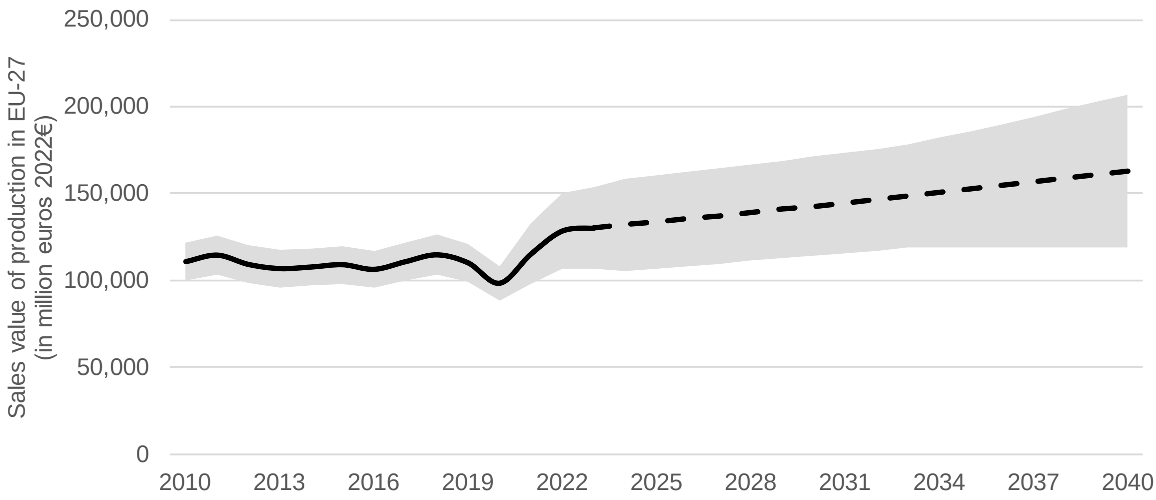
Baseline

In the paper products industry, D4, D5, D6, and silicone polymers play a significant role in enhancing the performance and quality of paper. Silicone polymers are utilized as release agents, coatings, and additives to improve the smoothness, water resistance, and durability of paper products, and as anti-foaming agents in the production of paper and pulp. For example, silicone-based coatings are applied to paper to create non-stick surfaces for labels and release liners. Additionally, these polymers help reduce friction during the printing process and enhance overall print quality, making them essential for high-performance paper products.

The sales value of such production in the paper products sector in scope in the EU-27 has been estimated at around €130 billion in 2022, which accounts for 7.1% of the total production value of the downstream user sectors in scope. This sector surpassed an estimated €25 billion of direct Gross Value Added (GVA) in 2022, equivalent to around 20% of its production value.

Between 2010-2022, the sector's sales turnover has grown at a real CAGR of 1%. Looking ahead, this industry might grow at a real CAGR between 1-1.5% in the EU-27 and could reach a production sales value of around €165 billion by 2040 (in constant 2022 euros). This is presented in Figure 4-25 below.

Figure 4-25 Baseline sales value of the production of paper products sector in the EU-27 (€ million)



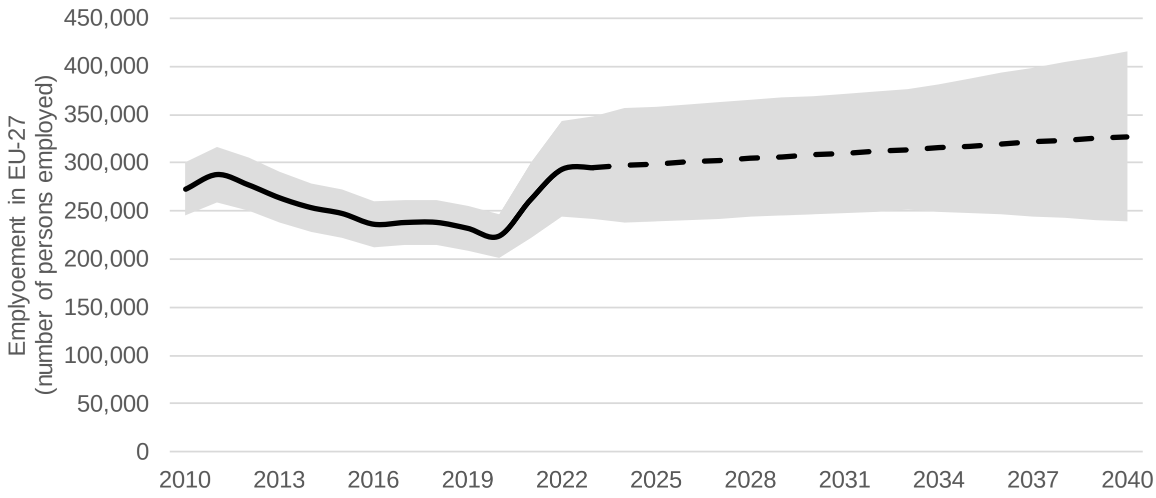
Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and expert input and validation by the CEFIC. Values are provided in 2022 prices.

In addition, it is estimated that companies in this sector **invested** around 4% of their production value in capital within the EU-27, surpassing €5 billion in 2022. They also purchased goods and services within the EU-27 and abroad to perform their manufacturing activities effectively. Their **operating expenditures** were around 80-90% of the production sales value, estimated at around €100-115 billion in 2022. These expenditures also include investments in R&D within the EU-27, playing a pivotal role in the sector's continued progress and innovation globally.

The EU-27 is a net exporter of paper products in scope of this Study; and, based on historical evidence, this appears to be a position that could be retained over time, in the baseline scenario. In 2022, extra-EU exports reached around €25 billion, with imports not surpassing €7 billion. Potential growth (in real terms) is likely to be similar for both exports and imports, also between 0-1% per annum.

Finally, the paper products industry in scope supported around 295,000 jobs (in FTE) in 2022. It is estimated that sectoral jobs could grow slightly over the period of assessment in the baseline scenario, at a real CAGR of 0.5%, reaching around 325,000 FTE in 2040. This is presented in Figure 4-26 below.

Figure 4-26 Baseline direct employment supported by the paper products sector in the EU-27 (Number of persons employed)



Source: Ricardo analysis based on Eurostat data (PRODCOM and SBS) and check and validation from external sources.

Socio-economic impacts of policy scenarios under consideration

The proportion of sales that rely, in some way, on D4, D5, D6 and/or silicone polymers ('reliant products') across the paper products sectors in scope is 80% (65%-95%) of sales turnover, similar to average downstream sector estimates. Five organisations participated in the survey, covering around 0.5% of both 2022 baseline estimated sales value and estimated employment, reporting experiences suggesting the potential for notable reliance on silicone polymers.

Companies also considered that their activities could well be exempted in higher proportions than other downstream user respondents: under PS1, estimated at 80% (80-100%) of their portfolio of 'reliant products' and, under PS2, estimated at around 75% (75-100%), in terms of sales turnover.

As a result, the potentially affected market under PS1 is estimated at 15% (0-20%) and 20% (0-25%) under PS2, which are relatively lower than averages across other sectors. Under PS3, all products reliant, in some way, on D4, D5, D6 and/or silicone polymers would be potentially affected, thus estimated at 80% (65%-95%). These estimates are presented in the Table 4-58 below.

Table 4-58 Percentage of sales turnover of the paper products sector in the EU-27 which could be exempted or otherwise affected under each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Proportion of paper products sector **sales that rely, in some way, on D4, D5, D6 and/or silicone polymers…** ('reliant sales') – (1)		80% (65%-95%)	

Indicator	PS1	PS2	PS3
Of these 'reliant' sales, the percentage that could be **potentially exempted** – (2)	80% (80-100%)	75% (75-100%)	0%
Otherwise, the **percentage of the 'reliant' sales that could be potentially affected** – (3)	20% (0%-20%)	25% (0%-25%)	100%
Or, equivalently, the **proportion of paper products sector sales that could be potentially affected** – (4)[317]	**15% (0-20%)**	**20% (0-25%)**	**80% (65-95%)**

Source: Ricardo analysis based on evidence collected from business stakeholders (N=5).

The ability of organisations within the paper products sector to find substitutes will be notably higher under PS1, than PS2, and virtually non-existent under PS3, given the present state of technology and innovation. **Under PS1, it is estimated that organisations might be able to adjust and/or substitute around 90% (70-95%) of their affected portfolio; under PS2, this would decline to 50% (20-90%), and it is likely that lower adjustments and/or substitutions are possible under PS3**, **at an estimated level of 10% (5-20%)**, due to the material requirements within this sector. These are presented in Table 4-59 below.

Table 4-59 Estimated level of 'substitution' in the paper products sector in each Policy Scenario (medium (low-high) %)

Indicator	PS1	PS2	PS3
Percentage of the affected portfolio of the coating sector that could be **adjusted or replaced by alternatives/ substitutes**, in sales turnover.	**90% (70%-95%)**	**50% (20%-90%)**	**10% (5%-20%)**

Source: Assumptions developed based on Ricardo analysis of the evidence collected through the survey, follow-up interviews and expert input.

Box 4-9 Alternatives to D4, D5 and D6 and/or silicone polymers in the paper products sector

The literature and available evidence reviewed for this study, especially upstream, suggests that there are potential alternatives to baseline silicone polymers within the paper products industry under PS1 and PS2 especially, for example, by introducing silicone polymers with lower presence of D4, D5, D6 from the use of removal technologies (stripping) upstream. Under PS3, non-regrettable alternatives are more difficult to identify. For example, although certain PFAS may be alternatives for certain applications, they may be considered regrettable due to ongoing regulatory scrutiny and potential human and environmental hazards.

The consultation identified a lack of awareness of alternatives across the survey respondents from this industry, as no responses were received. However, the evidence especially of alternative options upstream confirms that, at a cost, high rates of substitution might be possible under PS1, declining under PS2 and very limited under PS3.

This means that companies might need to undergo large-scale transformation, which would result in adjustment costs. These costs might also be incurred in the context of an estimated reduction in domestic manufacturing activity, which is assessed in more depth in the following section.

[317] Ibid footnote 290

The scale of costs reported in the consultation were of a similar scale for all downstream user sectors in scope. Thus, one-off and recurring annual costs for the paper products sector were assumed to be the proportionately similar to the average downstream users sector in scope. These are presented in Table 4-60 below.

Table 4-60 Estimated additional one-off and recurring annual costs as a percentage of baseline turnover across policy scenarios (medium (low-high) %)

Additional costs	PS1	PS2	PS3
One-off costs (as a % of sales turnover)	3% (0.5%-4%)	4% (2%-13%)	11% (5%-30%)
Annual costs (as a % of sales turnover)	2% (0.5%-4%)	3% (0.5%-9%)	6% (2%-15%)

Source: Ricardo analysis based on evidence collected from stakeholders (N~40 downstream).

Based on this evidence, the Net Present Value of the total costs that would be incurred by this sector over the period 2023-2040 as well as annual-equivalent costs were estimated. The results are presented in Table 4-61 below.

Table 4-61 Total 'adjustment costs' for the paper products sector estimated over 2023-2040 across policy scenarios, as NPV over the period or annualised (medium (low-high) bn). Note that bn refers to billions.

Additional costs	PS1	PS2	PS3
Net Present Value of total 'adjustment' costs over the period (2023-2040)	€45bn (€10-70 bn)	€60 bn (€20-155 bn)	€50* bn (€35-55 bn)
Annualised or annual-equivalent 'adjustment costs'	€3 bn/year (€0.5-5 bn/y)	€4.5 bn/year (€1.5-11.5 bn/y)	€4* bn/year (€2.5-4 bn/y)

*Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets. *Please note that adjustment costs do not only depend on unit costs but also on the scale of transformation that is viable. In this case, despite there being higher unit costs of transformation under PS3, the scale is more limited due to a lack of viability, so total, absolute costs are lower than those under PS2.*

That is, the costs of industrial transformation for the paper products sector could surpass €45 billion in Net Present Value, equivalent to over €3 billion each year over 2023-2040. Despite these transformative investments and expenditures, industrial activity in the EU-27 could likely be negatively affected and reductions with knock-on economic and social implications have been estimated in the following section.

The paper products sector in scope would likely be affected especially under PS2 and more so under PS3. Reductions in sectoral sales turnover against the baseline are estimated at -2% (-6% – 0%) under PS1, rising to -10% (-20% – 0%) under PS2 and a large -70% (-90% – -50%) under PS3. These are presented in Table 4-62 below.

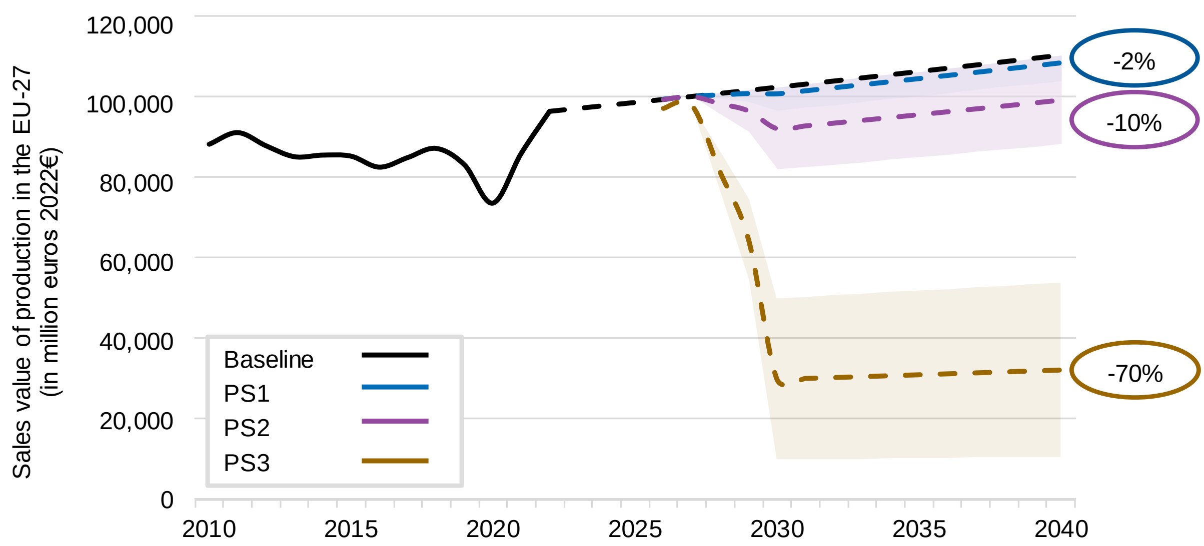
Table 4-62 Estimated reduction in the paper products sector manufacturing activity in the EU-27 against the 2040 baseline (medium (low-high)%)

Indicator	PS1	PS2	PS3
Estimated percentage **reduction of the sales value of the paper products sector in the EU-27, against the baseline**	-2% (-6% – 0%)	-10% (-20% – 0%)	-70% (-90% – -50%)

Source: Ricardo analysis based on evidence collected from stakeholders and evidence-based assumptions presented in previous subsections.

The evidence collected suggests that an average of €1 bn/year of sectoral production activity could be lost under PS1, which could be around 5 or 45 times worse under PS2 and PS3 respectively. It must be noted that these estimates depend on evidence collected from companies, which may be overestimating the criticality of silicone polymers within their manufacturing processes and/or intermediate or final products. We have used the available evidence to develop quantified uncertainty ranges. For example, at the lower end of our estimates, the impact could range from no losses under PS1, €0.6 bn/year of losses under PS2 to €30 bn/year under PS3. These impacts are presented in Figure 4-27 below.

Figure 4-27 Sales value of the production of the paper products sector in the EU-27 across the baseline and policy scenarios (€ million)



Notes: Please note that the dashed lines represent future projections and the shaded areas represent the uncertainties. There are three shaded areas corresponding to the uncertainty bounds for the three policy scenarios, with some overlaps between these areas. The transparency of the shading has been adjusted so that overlapping shaded areas remain visible, albeit this results in the appearance of more than three shaded areas.

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Both exports and imports have been assumed to decline proportionately, maintaining the sectors' baseline current account balance.

The reduction in production activity would have knock-on implications on sectoral employment. Estimated impacts on industrial activity across the sector, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by paper products sector could be affected under each policy scenario. The outputs of this analysis are presented in the Table 4-63 below.

Table 4-63 Average impacts on annual employment supported, in FTE, by the paper products sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by paper products sector in	-1,000 jobs (-5,000 – -0)	- 9,000 jobs (-19,000 – 0)	- 66,000 jobs (-84,000 – -47,000)

Indicator	PS1	PS2	PS3
scope against the baseline (FTE)			

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Conclusion

Finally, the results of this assessment and comparison of socio-economic impacts suggest that under all three policy scenarios there could be a negative impact on the paper products sector in the EU, even when broad exemptions are taken into account.

All policy scenarios are likely to result in a net decrease in production activity and job losses in the EU, with the impact worsening progressively from PS1 to PS3. Respectively**,**

- The sales value of production in the paper products sector within the EU-27 could decrease by 2% under PS1, 10% under PS2, and 70% under PS3,
- The average impact on annual employment, measured in FTE, in the paper products sector from 2023 to 2040 could range from a decrease of 1,000 jobs under PS1, 9,000 jobs under PS2, to 66,000 jobs under PS3.

4.3 SOCIAL IMPACTS

This section considers the broader impacts of the three policy scenarios on the EU-27 society, especially through the job market; the availability, quality and performance and/or price of consumer products and how this affects EU-27 consumers and households; and the effects on technological development and the digital economy.

4.3.1 Employment in the EU-27

The **policy scenarios under consideration could lead to a reduction in the jobs supported across the D4, D5, D6 and silicone polymer industries as well as the 'downstream users'**, directly as a result of the negative impacts on industrial activity and GVA estimated in earlier sections. The reductions in direct employment across the supply chain are proportionately lower than the reduction in sales turnover. This has been estimated by reviewing historical trends and confirmed by the businesses that participated in the online survey. This is partly driven by the rigidity of the labour market and the need to retain employees to meet any additional regulatory requirements. For example, evidence on the impacts of REACH[318] suggests that additional compliance costs led to increased labour requirements in the chemicals sector, all else held equal; not only due to needing additional staff but also due to additional remuneration, skills, training and/or retraining costs.

Hundreds and thousands of jobs could be lost across the upstream D4, D5, D6 and silicone polymer manufacturing industries under each policy scenario. The estimates developed for this study are presented in the Table below.

Table 4-64 Average impacts on annual employment supported, in FTE, by the D4, D5, D6 and the silicone polymer industries from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by D4, D5, D6 and the silicone polymer industries against the baseline (FTE)	- 700 FTE (-8,000 – 0)	- 14,000 FTE (-25,000 – -3,000)	- 30,000 FTE -

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

Even more employment opportunities could be lost across the 'downstream user' sectors in scope of this Study. Silicone polymers play a critical role in 'downstream user' sectors. This means that the scale of impacts on employment in these sectors might also be large. Estimated impacts on industrial activity across these sectors, historical evidence and evidence from the consultation were used to estimate how the levels of employment supported by downstream sectors could be affected under each policy scenario. The outputs of this analysis are presented in the Table below.

Table 4-65 Average impacts on annual employment supported[319], in FTE, by the 'downstream user' sector from 2023-2040, when compared to the baseline (medium (low-high))

Indicator	PS1	PS2	PS3
Direct **employment supported** by	-30,000 FTE (-360,000 – -400)	- 325,000 FTE (-970,000 – -60,000)	- 1,250,000 FTE (-1,720,000 – -900,000)

[318] Ibid footnote 297

[319] That is, the difference between employment levels with the baseline in any given year over the period of assessment.

Indicator	PS1	PS2	PS3
'downstream user' industries in scope against the baseline (FTE)			

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

A reduction in employment (FTE) across upstream and downstream markets could also lead to decreases in disposable income and thus consumption in the economy, which would have additional, induced effects, leading to further employment losses against the baseline. Input-Output matrices were used to characterise these multiplier effects in the EU economy and estimate the additional employment losses due to induced effects. The Annexes describe the methodology in more detail.

Overall, hundreds of thousands of quality jobs could be lost in the EU from the adoption of the policy scenarios, with knock-on socioeconomic consequences. These total impact estimates are presented in the Table below.

Table 4-66 Annual average impacts on employment supported, in FTE, by the D4, D5, D6, silicone polymer and 'downstream user' industries from 2023-2040 (medium (low-high))

Indicators	PS1	PS2	PS3
Total (direct, indirect and induced) impacts on the **employment supported** by the industries in scope, against the baseline (FTE)	- 80,000 FTE (-970,000 – -900)	- 890,000 FTE (-2,640,000 – -180,000)	- 2,460,000 FTE (-3,330,000 – -1,770,000)

Source: Ricardo analysis based on evidence collected from stakeholders and publicly available, Eurostat datasets.

These employment losses against the baseline could be monetised using good practice methodologies such as set out in Dubourg (2016)[320]. However, a qualitative analysis is sufficient given that the monetisation of environmental impacts has not been possible.

4.3.2 Consumers and households

The availability of silicone polymers and 'downstream user' products would be reduced, especially under PS2 and PS3, which could negatively affect consumer choice. Silicone polymers have critical applications and/or roles to play across a diverse range of industrial and consumer goods, including medical devices, cars, airplanes, etc. Lower availability of silicone polymers might lead to the partial disruption of downstream supply chains and lead to lower supply in consumer products, some of which might perform key functions in the lives of European households.

The quality and performance of consumer products could also be negatively affected under each of the policy scenarios. Silicone polymers are valued for their unique properties, such as durability, flexibility, and heat resistance, which contribute to the performance and functionality of industrial and consumer products. Substituting these substances with alternative materials may not always replicate the same level of functionality or may introduce unforeseen compatibility issues, leading to potential compromises in product performance. For example, service lives are likely to be reduced when compared to the baseline.

[320] Dubourg, Richard (2016). Valuing the social costs of job losses in applications for authorisation. Available at: https://echa.europa.eu/documents/10162/13555/unemployment_report_en.pdf/e0e5b4c2-66e9-4bb8-b125-29a460720554

Product costs and thus consumer accessibility may also be negatively affected under each of the policy scenarios. As supply chains adjust to a reduction in supply of silicone polymers, prices could rise and additional costs purchasing available silicone polymers and/or sourcing alternative materials could increase, exacerbated by the necessary investments in new technologies, machinery and product adjustments or reformulation where applicable. Higher costs of production could, to some extent, be passed on to final consumers in the form of higher, final product prices. Any supply-side reductions on product availability could drive prices up even further, exacerbating these impacts on consumer prices and product accessibility.

Overall, consumers and households are likely to be negatively affected directly and indirectly. Companies participating in the online survey predominantly agree that these policy scenarios would have a negative or very negative impact on consumers.

4.3.3 Technological development and the digital economy

The 10-year Digital Agenda for Europe in 2010 first identified the key enabling role of information and communication technology (ICT) in reaching Europe's wider goals. This digital agenda was developed further in 2015 and, in 2020, the second five-year strategy "Shaping Europe's Digital Future" was introduced. The EU's digital ambitions were then cemented in 2021 by the "10-year digital compass: the European way for the digital decade". There are a number of technologies which support the digital agenda, two of which are semiconductors and optical (glass) fibres.

Optic (glass) fibres allow for the transmission of information at high-speed over long distances. Optic fibres require the use of SiO_2 which is often produced using D4, in an effort to reduce the environmental risks that arise from the generation of SiO_2 from $SiCl_4$[321]. Responses to the stakeholder consultation in this Study noted that optic fibres do not contain D4 but rely on it for their production. **Business participants reported that 80% of global fibre optic production capacity could be potentially affected by the policy scenarios. If this is accurate, it would challenge the EU's ability to implement its Digital Agenda.**

A standard single mode optic fibre consists of a core, cladding and a protective coating. The core and cladding are commonly made from fused silica, which, despite its strength, requires a protective coating to prevent abrasions, microbend losses and static fatigue[322]. Protective coatings are applied immediately after newly drawn fibres exit the furnace and are then cured using heat or ultraviolet light. There are a number of coating materials that can be used, such as urethane acrylate oligomer resins, fluoroacrylates, polyimides and silicone-based coatings, such as PDMS. In high temperatures, degradation of some of these coatings may occur due to mechanical stress and it was found that the thermal properties of silicone-based coatings make them favourable for optic fibres operating at elevated temperatures and in harsh environments (strong acids or alkalis). Thus, **if silicone-based protective coatings were no longer available or as available across the policy scenarios, the use of poorer performing alternatives, where available, could also have a negative effect on the EU's implementation of its Digital Agenda.**

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321 Choi. J., Lee. T. K., Park. S. G., Lee. G. H., Jun. G. S. An. S. J. (2018) Formation of optical fiber preform using octamethylcyclotetrasiloxane. Korean Journal of Materials Research, 28, 6-11. DOI: 10.3740/MRSK.2018.28.1.6

322 Janani. R., Majumder. D., Scrimshire. A., Stone. A., Wakelin. E., Jones. A. H., Wheeler. N. V., Brooks. W., Bingham. P. A. (2023) From acrylates to silicones: A review of common optical fibre coatings used for normal to harsh environments. Progress in Organic Coatings, 180, 107557. https://doi.org/10.1016/j.porgcoat.2023.107557

Ultra-high-purity electronic-grade D4 is the key precursor of low-dielectric constant SiCOH films to manufacture integrated circuits for the semiconductor industry[323]. It is deposited via chemical vapour deposition, with it being chemically converted during the plasma process and impurities removed by a specialised thermal oxidiser. This means that no D4 should remain in the final chip. However, silicone polymers are used in the semiconductor assembly process as adhesives, encapsulants and thermal insulating materials (TIM). Evidence suggests that the silicone polymers remain embedded in the semiconductor component during the use phase.[324] Semiconductors are key for a number of industrial value chains and are becoming increasingly important, with estimations that demand for chips will double by 2030. This has been recognised by the European Commission, with Commission President Ursula von der Leyen setting out the vision for Europe's chip strategy in 2021. The European Chips Act aims to address semiconductor shortages by mobilising significant investment and set measures to prepare for any future supply chain disruption, which includes increasing Europe's production capacity to 20% of the global market by 2030[325, 326]. **The availability and/or performance of semiconductors could be negatively affected under the policy scenarios**, depending on the concentrations of D4 required for the effective manufacture of specific semiconductors. It is acknowledged that an acceptable purpose exemption under PS2 is included for the use of D4 in the manufacture of semiconductor wafers; whilst no exemption exists under PS3, which could lead to a complete disruption of the EU semiconductor manufacturing industry, working against the EU's green and digital transition.

4.3.4 Overall social impacts in the EU-27

In summary, the most significant impacts on the EU society could be negative, including a potential loss of hundreds of thousands quality job opportunities when compared to the baseline; negative impacts on the availability, quality and performance and cost of final products for consumers and households, affecting their daily lives in ways that could be impactful; and steps against the EU's digital transition through a range of technical complexities, but especially through potentially negative impacts on the EU manufacturing and/or importing of optic fibres and semiconductors.

The social impact conclusions are summarised qualitatively in the Table below, using the scoring framework described in Section 4.1 and, in more detail, in the Annexes.

Table 4-67 Qualitative, social impact ratings

Broad category	PS1	PS2	PS3
Employment	-0.5	-1.5	-2.5
Consumers and households	-0.5	-0.5	-0.5
Technological development and the digital economy	-1.0	-2.0	-3.0

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this assessment, it is concluded that the policy scenarios could have an increasingly negative, overall social impacts on the EU. The ratings have been reviewed

[323] Guo. W., Guo. S., Zhao. X., Yuan. Z., Zhao. Y., Chang. X., Li. H., Zhao. H., Wan., Y, Yan. D., Ren. Z., Fan. X., Gao. X. (2022) Simultaneous Distillation-Extraction for Manufacturing Ultra-High-Purity Electronic-Grade Octamethylcyclotetrasiloxane (D4). Journal of Industrial and Engineering Chemistry, 109, 275-286. https://doi.org/10.1016/j.jiec.2022.02.015

[324] European Semiconductor Industry Association (ESIA) (2023) Position Paper: Potential EU nomination of D4, D5 and D6 to the UN Stockholm Convention on POPs. Available: 20230713_ESIAPosition-D4D5D6.pdf (eusemiconductors.eu)

[325] European Commission (no date) European Chips Act. Available: European Chips Act - European Commission (europa.eu)

[326] European Commission (2022) Commission Recommendation (EU) 2022/210 on a common Union toolbox to address semiconductor shortages and an EU mechanism for monitoring the semiconductor ecosystem. Available: EUR-Lex - 32022H0210 - EN - EUR-Lex (europa.eu)

and recalibrated against the -5/+5 scoring framework, for a comparison of the balance of impacts across impact categories, costs and benefits. The Table below presents the qualitative ratings given to the overall social impacts of each of the policy scenario for these comparisons. The methodological Annexes explain the recalibration exercise.

Table 4-68 Overall social impact ratings

Broad category	PS1	PS2	PS3
Overall social impacts	-0.5	-1.0	-2.0

Source: Ricardo analysis based on the evidence presented in this Study.

4.4 ENVIRONMENTAL IMPACTS

This section presents the assessment of the most significant environmental impacts of the policy scenarios in scope of this Study. The impacts have been assessed qualitatively and, where possible, this is supported by quantitative analysis. The assessment is structured as follows:

- Section 4.4.1 – A recap of the baseline
- Section 4.4.2 – Emissions reductions
- Section 4.4.3 – Environmental quality and resources (water, soil and air)
- Section 4.4.4 – Biodiversity and ecosystem impacts
- Section 4.4.5 – Effects on waste production, generation and recycling
- Section 4.4.6 – Effects on the use of resources, transport and energy, and climate

4.4.1 Baseline conditions and structure of environmental assessment

Although emissions are estimated to be reduced significantly under the Baseline scenario already, by around 90% when compared to historical emissions (see Section 2.2.1), the Commission considers that concerns remain related to the outstanding emissions of D4, D5 and D6. These concerns are driven primarily by the persistence of D4, D5 and D6 in sediment and the risk of irreversibility; their potential for toxicity, bioaccumulation and trophic magnification through some food chains; and their potential for long-range transport leading to deposition and exposure of organisms in remote regions, resulting in transboundary concerns (see Section 2.2.2 and 2.2.3).

There are conflicting evidence and opinions on the environmental fate and behaviour of D4, D5 and D6, with ongoing research and discussions on the PBT/long-range transport potential of these substances (see Section 2.3). Overall, evidence from the scientific papers reviewed as part of this Study disagree with the toxicity risk of these substances. This is because the experimental conditions appear unrealistic, the effect concentrations found in laboratory conditions are significantly over the concentrations measured in the environment[327], among others[328]. Moreover, scientific evidence reviewed defends that bioaccumulation though the food chain is unlikely[329] and, in cases where the top levels of the food chain could accumulate these substances in their lipidic tissues, D4, D5 and D6 would in fact be metabolised and excreted. Persistence is also debated, with irreversibility being questioned under realistic

[327] Ibid footnote 163, 166

[328] Hall AP, Elcombe CR, Foster JR, Harada T, Kaufmann W, Knippel A, Küttler K, Malarkey DE, Maronpot RR, Nishikawa A, Nolte T, Schulte A, Strauss V, York MJ (2012) Liver hypertrophy: a review of adaptive (adverse and non-adverse) changes--conclusions from the 3rd International ESTP Expert Workshop. Toxicol Pathol. 40, 971-994. doi: 10.1177/0192623312448935. Epub 2012 Jun 21. PMID: 22723046.

[329] Ibid footnotes 217-221, 229

conditions in which more complex micro and macrobiotic communities take part in the degradation of these compounds[330].

Based on this conflicting evidence base, the Study team has not ruled out the potential for risk to the environment due to the continued (but low) emissions of these substances from products already placed on the market (i.e., 'background emissions') after the proposed REACH restriction enters into force and from impurities in silicone polymers from derogated uses. However, as long-range transport is still an ongoing discussion in the scientific community, due to concerns that current research methodologies and data are not sufficient to prove that the presence of these substances in remote regions is not from local sources (see section 2.2.2.1), this concept won't be assessed further in this Study. In order to reflect the ongoing scientific debate, the environmental impacts of D4, D5 and D6 shall be considered in two ways: Option A – Commission evidence presented in the draft Annex D report; and Option B – broader scientific evidence. Table summarises the PBT status in the baseline scenario, according to the two evidence bases.

Table 4-69 Baseline environmental considerations

	Baseline: 90% emissions reduced			
	Option A (EU Commission evidence)	**Impact (Y/N)**	**Option B (broader scientific evidence)**	**Impact (Y/N)**
Persistence	Exposure will be reduced, but 10% emissions will remain, plus 'background emissions'. Accumulation over time, irreversibility.	Y	Exposure will be reduced, but 10% emissions will remain, plus 'background emissions'. Degradation expected. Less accumulation over time.	Y
Long range transport [a]	Transport through air and water currents in suspended solids to remote regions. Transboundary environmental impacts.	N/A	Unlikely long-distance transport through air and water. Potential for local source emissions not properly evaluated.	N/A
Bioaccumulation	Concentration in sediment reduced – lower risk, but concern about biomagnification through the food chain. Higher risk for benthopelagic food webs. Potential for accumulation in upper trophic levels.	Y	Concentration in sediment reduced – no risk, biomagnification through the food chain not consistent, top chain organisms excrete and metabolise the compounds.	N
Toxicity	Reliable evidence can be considered to show a potential impact of D4, D5 and D6 in sediment organisms, and D5 in soil invertebrates and plants. Low potential for impact is still an environmental risk under the precautionary concept.	Y	Potential impact of D4, D5 and D6 in sediment and soil organisms unlikely as available environmental concentrations < toxicity thresholds. Lower toxicity observed in natural sediment. Fast degradation and volatilization expected in soil.	N

a: Discussion ongoing, not evaluated further.

4.4.2 Emissions reduction per Policy Scenario

With the entry into force of the proposed REACH restriction (see baseline scenario), estimates suggest that historical emission might be reduced by 90%, which would result in a reduction of 1 438 – 1 609 tpa emissions considering all compartments (air and water). The remainder of 10% is estimated to comprise 597-708 tpa (42-44% of remaining emissions) of D4, D5, D6

[330] Ibid footnotes 132,133

as impurities from silicone polymers in mixtures and articles and 841-901 tpa (56-58% of remaining emissions) as a result of the other derogated uses for e.g., medical devices, cleaning and restoration of art techniques and mixtures with concentrations of D4, D5, D6 >0.1% w/w[331]. It is noted in the supporting REACH restriction reports that emissions from the manufacture of D4, D5 and D6 are considered negligible as a result of existing operating conditions and risk management measures[332].

Our assessment on the inclusion of these substances in the Stockholm Convention covers three policy scenarios that have been developed by Cefic and their members, based on indications of considerations by the Commission, as well as previous examples of nominations to the Stockholm Convention (see Section 3.2). The policy scenarios (PS1, PS2, and PS3) would lead to an increase in the scope of prohibitions, as a result of the removal of derogations corresponding to uses with concentrations of D4, D5, D6 ≤0.1% w/w. Additionally, these scenarios go from broad exemptions for the production of silicone polymers (PS1) to the total prohibition on the manufacture and use of D4, D5 and D6 (PS3).

Based on a stakeholder consultation and a literature review, the emissions of impurities from silicone polymers that would remain under each of the Policy Scenarios have been estimated. As a result, the inclusion of these substances in the Stockholm Convention Annex B (restriction; PS 1 and 2) or A (elimination; PS3) could result in emissions reductions as presented in Table 4-70 below.

Table 4-70 Potential emission reductions for the baseline and each policy scenario

Scenario	Emission reduction from baseline (%)	Remaining emissions of impurities from silicone polymers[a] (Tpa)	Remaining emissions from other use (Tpa)	Steady-state environmental stock (t)
Baseline	-	597-708	841-901	36-41
Policy Scenario 1	57-59%	585-694	0 [b]	14-18
Policy Scenario 2	76-78%	322-382	0 [b]	8-9
Policy Scenario 3	100%	0	0 [b]	0

a: Emissions coming from any other sources will be rejected after the inclusion in any of the Stockholm convention Annex A/ B
b: Emissions from products that are currently in use and those in the waste phase (i.e., 'background emissions')

It is estimated that remaining emissions of D4, D5 and D6 from silicone polymers under policy scenario 1 could be equivalent to 41-43% of the baseline emissions (i.e., ~3% of total emissions prior to REACH restriction of D4, D5 and D6 entering into force). These estimates account for the threshold for D4, D5 and D6 of ≤0.1% w/w for the placing on the market of polymers and formulations of polymers, the potential substitution rates that industry may be able to achieve and are considered in Section4.2.1.2, and the estimated potential reduction in the sales of silicone polymers of around 2% against the baseline by 2040.

Under policy scenario 2, the remaining emissions could be equivalent to 22-24% of baseline emissions from silicone polymers (i.e., ~2% total emissions prior to restriction entering into force). This would mean relatively higher emissions reductions than under policy scenario 1,

[331] Ibid footnote 50
[332] Ibid footnotes 50, 78,79,80

which would be partly driven by the estimated 45% reduction of silicone polymer sales against the baseline by 2040. Under policy scenario 3, the complete prohibition on the manufacture and use of D4, D5 and D6 could mean a total reduction of emissions from new products. Yet, it should be taken into account that emissions would remain from products that are currently in use and those in the waste phase (i.e., 'background emissions'), with the steady-state environmental stock reducing to zero over time.

4.4.2.1 What the reduction in emissions means for PBT

A reduction in emissions as a result of the policy scenarios could result in positive environmental impacts related to PBT effects. The differences between these expected impacts based on the evidence base (Option A – Commission evidence presented in the draft Annex D report; and Option B – broader scientific evidence) have been summarised in Table .

Table 4-71 Summary of emission reductions on PBT effects

Effect	Option	Scenario 1 (~60% total Baseline emissions reduction, ~3% from current emissions)	Scenario 2 (~80% total emissions reduction, ~2% from current emissions)	Scenario 3 (100% emission reduction)
Persistence	Option A (EU Commission evidence)	Lower emissions and exposure. Sediment persistence concern remains. Uncertainty coming from 'background emissions'.	Lower emissions and exposure than PS1. Uncertainty coming from 'background emissions'.	Very low emissions and exposure. Uncertainty coming from 'background emissions'.
	Option B (broader scientific evidence)	Lower emissions and exposure. Sediment persistence concern remains. Uncertainty coming from 'background emissions'. Degradation expected. Less accumulation over time.	Lower emissions and exposure than PS1.	Very low emissions and exposure.
Bioaccumulation	Option A (EU Commission evidence)	Despite lower emissions and exposure, due to the high persistence, hydrophobicity and uncertainty of remaining 'background emissions', bioaccumulation and trophic magnification risk remains.	Lower emissions and exposure leading to less available D4, D5, D6	Very low emissions and exposure leading to low amount of available D4, D5, D6
	Option B (broader scientific evidence)	No risk.	No risk.	No risk.
Toxicity	Option A (EU Commission evidence)	Potential toxicity of D4, D5 and D6 in sediment organisms still considered due to high persistence and uncertainty. Low potential D5 toxicity in soil invertebrates and plants unlikely, due to fast	Lower potential toxicity concern than PS1 for D4, D5 and D6 in sediment organisms, especially D5 (already close to the solubility point)	Very low potential for toxicity to sediment organisms. D5 soil toxicity very unlikely

Effect	Option	Scenario 1 (~60% total Baseline emissions reduction, ~3% from current emissions)	Scenario 2 (~80% total emissions reduction, ~2% from current emissions)	Scenario 3 (100% emission reduction)
		degradation and volatilisation of already low emissions (accumulated in sludge from silicone polymers and spread onto soil, volatilised)	due to lower emissions. D5 soil toxicity unlikely	
	Option B (broader scientific evidence)	No risk	No risk	No risk

Overall, the three policy scenarios could have some positive environmental impacts across the EU-27 under Option A (Commission evidence presented in the draft Annex D report), with some exceptions (e.g., unlikely D5 soil toxicity under Scenarios 2 and 3, explored in more detail in Section 2.2.3.3). Under Option B (broader scientific evidence), no risk is identified with toxicity and bioaccumulation in any of the policy scenarios (i.e., no additional environmental benefits as compared to the proposed REACH restriction), and a potential positive impact may only be observed in relation to their high persistence in sediment.

The environmental impacts considered under Option A and B are described in the following sub-sections, capturing the most significant impact categories:

- Quality of natural resources (water, soil, air)
- Biodiversity, including flora, fauna, ecosystems and landscapes
- Waste production, generation, and recycling
- Efficient use of resources, transport and energy and climate.

4.4.3 Quality of natural resources (water, soil, air)

Option A - Commission evidence presented in the draft Annex D report

The evidence presented by the European Commission suggests that water (especially sediment) and soil quality could be affected by the exposure to D4, D5 and D6. Therefore, a reduction in the tonnes of silicone polymers placed on the EU market could have positive environmental impacts over time.

The extent to which these three substances affect the quality of the water-sediment interface has not been quantified clearly yet. However, since these chemicals are considered very persistent in sediment and have shown potential toxic effects on sediment organisms, they can remain an important risk for the quality of the aquatic environment. Impacts have been observed for D4 on the survival and reproduction of Oligochaeta (*Lumbriculus variegatus*)[333] and D5-D6 on the emergence rate of Diptera larvae (*Chironomus riparius*)[334]. As representatives of the macrobiotic (benthic) sediment community, a reduction in their numbers resulting from potential toxic effects could be translated into a decrease in nutrient cycling and organic matter break down in aquatic ecosystems, and a decrease in water clarity, since they

[333] Ibid footnote 174
[334] Ibid footnote 179

consume organic particles[335]. Further, this could mean an increase in turbidity, and lower potential to act as natural filters of pollutants[336] or a reduction in sediment structure stability, which is also related to an increase in turbidity and the potential for development of anoxic systems[337]. One could also think about the risk of resuspension and/or release from sediment into water. However, adsorption/desorption studies have demonstrated that when D4, D5 and D6 adsorb to sediment particles, they have very fast desorption kinetics[338] and the desorbed D4, D5 and D6 have relatively fast hydrolysis kinetics in sea water (due to high pH).

The properties of silicone polymers are such that removal during wastewater treatment is likely to be mainly by adsorption onto sewage sludge (see Section 2.1.2), which when spread onto soil has potential to become a route of exposure of D4, D5 and D6 for terrestrial organisms and plants[339]. Evidence suggests that D4 may have an effect on the reproduction of earthworms[340], and D5 may affect soil arthropods survival and reproduction[341], earthworm reproduction[342], and plant (barley) root and shoot development[343] (see Section 2.2.3.3), all of which may have an impact on soil quality. The root systems of vegetation and the activities of soil invertebrates, such as earthworms, contribute to improving soil structure. This enhanced structure allows better water infiltration and aeration, promoting overall soil health[344].

Despite this, there is a low probability that cVMS will be persistent in soil due to their rapid dissipation rates[345,346,347]. Some studies show the potential of D6 to stay in soil for around 200 days in highly humid soil, due to the very high affinity for organic surfaces[348]. Yet, no lab- or field-based studies have been performed with D6 in soil and current data do not allow reliable half-lives to be derived. Moreover, there is a lack of measured environmental data for D4 and D6. Data on D5 is not abundant but it has been observed that the concentrations of D5 in agricultural fields recently spread with biosolids, have been measured at <1 µg g^1 based on dry mass[349], which is below the effect concentration. As such, any impact to soil quality should be taken with care.

Air is the main receiving compartment, with degradation times between 6-17 days, which can be considered relatively long. Thus, this may be a relevant exposure pathway for air-breathing mammals, as well as leading to long-range transport potential. However, no conclusive studies are available on air-breathing organisms and human exposure has been proven an unlikely risk (See Annex 1). Moreover, the ongoing discussion on long-range transport (recognised by RAC) does not allow for clear conclusions on this topic. Therefore, the impact on air quality remains uncertain and cannot be concluded on, based on the available evidence.

Overall, the evidence presented by the Commission on the presence and impacts of D4, D5, D6 in the soil and aquatic compartments confirm that the quality of these two compartments may be affected, especially water quality. Any changes to policy that would

[335] Covich, A. P., Palmer, M. A., & Crowl, T. A. (1999) The role of benthic invertebrate species in freshwater ecosystems: zoobenthic species influence energy flows and nutrient cycling. BioScience, 49, 119-127. https://doi.org/10.2307/1313537
[336] Ibid footnotes 132,133
[337] Meding, M. E., & Jackson, L. J. (2003). Biotic, chemical, and morphometric factors contributing to winter anoxia in prairie lakes. Limnology and Oceanography, 48, 1633-1642. https://doi.org/10.4319/lo.2003.48.4.1633
[338] Ibid footnote 157
[339] Ibid footnotes 78, 79, 80
[340] Ibid footnote 89
[341] Ibid footnote 188
[342] Ibid footnote 187
[343] Ibid footnote 89
[344] Lavelle, P., Decaëns, T., Aubert, M., Barot, S., Blouin, M., Bureau, F., ... & Rossi, J. P. (2006) Soil invertebrates and ecosystem services. European journal of soil biology, 42, S3-S15. https://doi.org/10.1016/j.ejsobi.2006.10.002
[345] Ibid footnote 89
[346] Ibid footnote 90
[347] Ibid footnote 91
[348] Ibid footnote 88
[349] Ibid footnote 194

reduce D4, D5, D6 emissions and exposure may, therefore, have positive implications on water and soil quality and resources. However, the most significant reduction in emissions will be coming through the baseline (from the proposed REACH restrictions), which would be a greater driver of the impacts described in this Section than the policy scenarios under assessment in this Study. This said, due to the high persistence of these substances, the low, but remaining emissions from silicone polymers, as well as from 'background' sources cannot be disregarded and risks due to slow degradation and accumulation as part of the steady-state environmental stock will remain.

On the one hand, the scale of impact between scenarios is uncertain and it has not been possible to quantify. The information required to do this is not available, including the concentrations of D4, D5 and D6 across the whole range of ecosystem types in the EU-27 as well as direct quantifiable effects, which very complex to disentangle under an environmental context affected by multiple stress factors, some of them resulting in more significant impacts than those corresponding to D4, D5, D6 (i.e. impact of these substances is shadowed).

On the other, the remaining emissions estimated under Policy Scenario 1 represent 41-43% of the baseline emissions (i.e., ~3% of total emissions prior to restriction entering into force), in Policy Scenario 2, these represent 22-24% of baseline emissions from silicone polymers (i.e., ~2% total emissions prior to restriction entering into force), and, in Policy Scenario 3, no emissions would remain. It is considered that any environmental benefits from these emissions reductions would be proportional, and thus higher under Policy Scenario 3, taking into account the fate and behaviour of these substances and the small difference in environmental concentrations and risks resulting from highly persistent compounds.

Option B – broader scientific evidence

The differences between Option B and Option A rely on the available evidence that supports a negligible sediment and soil toxicity potential and, therefore, that negative water and soil quality impacts are unlikely.

Firstly, a reduction in concentration and exposure over time is expected, based on defined biodegradation processes of D4, D5, D6 in sediment. In that, under natural conditions, concentrations are expected to be lower as a result of abiotic processes, but also due to the interference of eukaryotes in sediment which contribute to biodegradation. [350,351].

Secondly, despite some persistence risk being recognised under Option B, the scientific community defends that: the D4 toxicity study had significant flaws, including non-synchronized worms, high pH, and insufficient equilibration time; the D5 concentration after recommended correction was well above the solubility limit (therefore not toxic); and the majority of D6 studies show no toxic effect to sediment organisms. Also, several authors suggest that artificial sediment might be causing a negative impact on organism responses. Governmental studies, such as Canada[352,353,354] or Australia[355], remark the low toxicity potential of D5 and D6 and their low ecological risk, while D4 toxicity in water and sediment

[350] Ibid footnote 133
[351] Ibid footnote 166
[352] Environment Canada, Health Canada (2008a). Screening Assessment for the Challenge. Octamethylcyclotetrasiloxane (D4). Chemical Abstracts Service Registry Number 556-67-2. Ottawa (ON): Government of Canada. November 2008.
[353] Siloxane D5 Board of Review. 2011. Report of the Board of Review for Decamethylcyclopentasiloxane (D5). Ottawa, ON, Canada. October 20, 2011. 83 pages.
[354] Environment Canada, Health Canada (2008c). Screening Assessment for the Challenge. Dodecamethylcyclohexasiloxane (D6). Chemical Abstracts Service Registry Number 540- 97-6. Ottawa (ON): Government of Canada. November 2008.
[355]Australia IMAP Assessment. 2017. Cyclic volatile methyl siloxanes: environmental tier II assessment https://www.industrialchemicals.gov.au/sites/default/files/Cyclic%20volatile%20methyl%20siloxanes_%20Environment%20tier%20II%20assessment.pdf).

should be considered, as well as its bioaccumulation potential. Nevertheless, D4 toxicity in water and sediment is categorised as 'uncertain' in the Australia IMAP Assessment (2017) due to the low ecologically relevant exposure conditions tested.

Moreover, the potential for trophic dilution of these substances in marine and freshwater environments has been reported in several studies[356,357,358] and even if that would occur, cVMS are expected to be metabolised and excreted[359]; which reinforce the conclusion that there is unlikely to be a toxic effect related to bioaccumulation.

Despite uncertain degradation rates and the continued emissions of these substances from products already placed on the market (i.e., 'background emissions') in the use phase, Option B gives weight to the fact that the majority of the measured concentrations under current emission scenarios are significantly below the toxicity thresholds.

With respect to soil quality, the fate and behaviour of these substances, with fast degradation in dry soils and volatilisation in humid soils[360] resulting in very fast dissipation rates, bears weight as evidence for low impact under Option B. Overall current data do not allow reliable half-lives to be derived that can be compared with the Annex D and Annex XIII criteria. Additionally, the low availability of data on field measured soil concentrations for D4 and D6, and available D5 data reporting concentrations in biosolids several orders of magnitude below the toxicity threshold[361], reinforce the justification that evidence is not conclusive enough as to prove toxicity impacting soil quality under Option B. Therefore, under Option B, this impact can be considered negligible or lacking enough data as to draw conclusions.

In summary, the impact of the three policy scenarios on water and soil quality are expected negligible under this Option B, particularly as a result of the limited reductions in emissions of D4, D5 and D6 that are estimated under the Policy Scenarios over and above the reductions that would already be achieved under the baseline scenario, as well as the additional scientific evidence identified that considers the realism of studies done in laboratory conditions. The assessment and conclusion (or lack thereof) on air quality outlined under Option A remains valid in this Option B.

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[356] Ibid footnote 218. Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2009c) Interim Report: Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in the aquatic marine food webs in inner and outer Oslofjord, Norway. Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[357] Powell, D. E., Schøyen, M., Øxnevad, S., Gerhards, R., Böhmer, T., Koerner, M., ... & Huff, D. W. (2018). Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) in the aquatic marine food webs of the Oslofjord, Norway. Science of the total environment, 622, 127-139.

[358] Powell DE, Woodburn KB, Drottar K, Durham J and Huff DW (2009a). Trophic dilution of cyclic volatile methylsiloxane (cVMS) materials in a temperate freshwater lake. Unpublished HES Study No. 10771-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).

[359] Andersen. 2008. Are highly lipophilic volatile compounds expected to bioaccumulate with repeated exposures? Tox Letters, 179:85-92

[360] Ibid footnote 87

[361] Ibid footnote 194

4.4.4 Biodiversity, including flora, fauna, ecosystems and landscapes

Option A - Commission evidence presented in the draft Annex D report

The study team has reviewed an array of relevant scientific literature to determine the potential toxicity to aquatic, sediment and terrestrial organisms. The starting point of this assessment was the evidence presented in the Commission's Annex D report to support the conclusion on toxicity criteria of the Stockholm Convention. The evidence reviewed has not identified a risk to mammals or human health under real-world conditions, whereas some evidence may point to chronic toxicity in sediment invertebrates - survival and development (D4, D5, D6), as well as the impact of chronic exposure on terrestrial plants - root dry weight and length or shoot length (D5), and invertebrates - survival and reproduction (D4 and D5) (see section 2.2.3.2 and 2.2.3.3). Table 4-72 presents a summary of the overall potential toxic effects identified for the three substances.

Table 4-72 Summary outcome of the review of evidence used by the Commission to evidence toxicity of D4, D5 and D6 in aquatic, sediment and terrestrial organisms

D4	Effect	Conclusion	Notes
Fish	14-day NOEC of 4.4 µg/L was found in a prolonged acute test based on mortality.[362]	Toxic effects at maximum exposure level over extended period. Impact not "relevant" for the Impact Assessment as exposure conditions not realistic.	Because of the limited solubility in water and the volatility of the material, the maximum solubility limits established during the functional water solubility trials and the tests would represent or exceed the theoretical maximum exposure concentrations that would be expected to occur in the natural environment.
Aquatic invertebrates	Toxic to aquatic invertebrates (Daphnia magna) with a 21-day NOECsurvival of 7.9 µg/L.[363]		
Algae	D4 exerted a growth rate inhibition of 11% when tested at the saturation level and can be interpreted as a moderate chronic toxicity to algae.[364]		
Sediment	NOEC on survival/reproduction for D4 is <0.73 mg/kg dw, obtained in a 28-day study with *Lumbriculus variegatus*. Value extrapolated for comparison with pelagic organisms to <2µg/l (below its water solubility of 56.2 µg/l)[365]	**Potentially toxic to sediment organisms**	Flaws in study performance such as non-synchronized worms, high pH, and insufficient equilibration time.
Terrestrial	Some effects were observed on the reproduction of the earthworm *Eisenia fetida*, with 56-day NOEC value of 75 mg/kg dw, a LOEC value of 130 mg/kg dw and an EC50 value of >130 mg/kg dw.[366]	**Potentially toxic to terrestrial earthworms, but impact 'not relevant' for impact assessment, due to the difficulty to assess environmental concentrations, expected to be low.**	Due to the high volatility and fast degradation described for D4 in soil, together with the lack of measured data, conclusions on the risk to soil organisms should be taken with care.
D5	**effect**	**conclusion**	**notes**
Fish	No toxic effects in neither short- nor long-term studies at	No impact detected	

[362] Ibid footnote 163
[363] Ibid footnote 163
[364] Ibid footnote 170
[365] Ibid footnote 174
[366] Ibid footnote 89. Available at: Registration Dossier - ECHA (europa.eu)

	concentrations up to (or close to) its water solubility limit.[367]		
Aquatic invertebrates	No toxic effects in neither short- nor long-term studies at concentrations up to (or close to) its water solubility limit.[368]	No impact detected	
Algae	No toxic effects in neither short- nor long-term studies at concentrations up to (or close to) its water solubility limit.[369]	No impact detected	
Sediment	The lowest NOECs for long-term sediment toxicity studies for D5 are 70 mg/kg dw for *Chironomus riparius*[370] and 62-130 mg/kg dw for *Hyalella Azteca*[371,372]. Extrapolating the value for *Ch. riparius* for comparison with pelagic organisms around 14µg/l (just below its water solubility of 17.03 µg/l).	**Suggests potential for toxicity at high concentrations**	
Terrestrial	Significant effects were observed for the arthropod *F. candida* (adult survival and juvenile production)[373], earthworm *Eisenia andrei* (reproduction)[374] and barley plant species *H. vulgare* (shoot length and dry mass and root dry mass), with toxicity estimates (IC50) ranging from 209 to 2051 mg kg-1 [375, 376].	**Potentially toxic to terrestrial invertebrates and plants. Difficult assessment as lack of environmental data or reported data below effect concentrations.**	Effects are species and environmental context dependent. Concentrations of D5 in agricultural fields recently spread with biosolids, have been measured at <1 µg g[1] based on dry mass[377].
D6	**effect**	**conclusion**	**notes**
Fish	No effects are seen in any of these studies up to the solubility limit of D6.[378]	No impact detected	
Aquatic invertebrates	No effects are seen in any of these studies up to the solubility limit of D6.[379]	No impact detected	
Algae	No effects are seen in any of these studies up to the solubility limit of D6.[380]	No impact detected	

[367] Ibid footnote 87. Annex 3
[368] Ibid footnote 87. Annex 3
[369] Ibid footnote 87. Annex 3
[370] Ibid footnote 179
[371] Ibid footnote 180
[372] Ibid footnote 181
[373] Ibid footnote 188
[374] Ibid footnote 187
[375] Ibid footnote 90
[376] Ibid footnote 87. Annex 3
[377] Ibid footnote 194
[378] Ibid footnote 91
[379] Ibid footnote 91
[380] Ibid footnote 91

Sediment	NOEC for long-term sediment toxicity studies is < 22 mg/kg dw for *Chironomus riparius*[381]. Value extrapolated for comparison with pelagic organisms to <0.7µg/l (below its water solubility of 5.3 µg/l).	**Potentially toxic to sediment organisms**	Concern about the use of artificial sediment and its impact on negative effects
Terrestrial	Limited toxicity data for terrestrial organisms including birds.	No impact detected	

The evidence presented in the Commission draft Annex D report suggests there may be a concern for toxicity to sediment organisms, which may have a knock-on effect on biodiversity, as the tested species are considered representative of the benthic macrobiotic community within the sediment compartment. In that sense, it is known that any loss of species could have a detrimental effect on the functioning of the ecosystem. This is because there are numerous food-web linkages in which one species interacts positively or negatively with others, or in which the addition or loss of a single species alters food-web dynamics. Also, different species comprise distinct functional groups that provide ecological integrity[382]. Therefore, even if only one species would be affected, it could be expected that a negative impact on the biodiversity of aquatic ecosystems could be observed. Moreover, these species are selected as they are historically used reference species which are easy to work with under laboratory conditions[383], but they are also known to present traits that makes them generally pollution tolerant[384], which would mean that an effect observed in the reference species could imply that other more sensitive species are at higher risk. Therefore, biodiversity impact cannot be discarded.

Moreover, in relation to the impacts described in the previous Section, a decrease in water clarity related to the reduced degradation of organic matter or a reduction in sediment structure stability, could negatively impact the development of submersed aquatic plants[385], and consequently the biodiversity of the aquatic community.

Quantification of the benefits related to a potential reduction in toxicity is a very complex task for several reasons. Firstly, sediment toxicity thresholds identified in this assessment are based on No Effect Concentrations (NOECs). An EC50 (effect concentration affecting 50% of the population) would be a more quantifiable endpoint, but in most cases only long-term NOECs were determined. Secondly, where data on the population size for that organism or taxonomic group (for which the testing species can be representative) was available at a regional EU-27 level, EC50 or EC10 values could potentially be used for quantification of impact, but in this case such data is unavailable.

With respect to soil quality and its impact on toxicity and biodiversity of the terrestrial community, evidence suggests that earthworm reproduction may be affected by D4 and D5, and D5 may also have an effect on invertebrate survival and plant shoot and root development (see Table 4-72). An IC50 (concentration at which a substance inhibits a specific biological

[381] Ibid footnote 182
[382] Covich, A. P., Palmer, M. A., & Crowl, T. A. (1999) The role of benthic invertebrate species in freshwater ecosystems: zoobenthic species influence energy flows and nutrient cycling. BioScience, 49, 119-127. https://doi.org/10.2307/1313537
[383] Ibid footnotes 174,179
[384] Xu, M., Wang, Z., Duan, X., & Pan, B. (2014) Effects of pollution on macroinvertebrates and water quality bio-assessment, Hydrobiologia, 729, 247-259. https://doi.org/10.1007/s10750-013-1504-y
[385] Kerr, S.J. (1995) Silt, turbidity and suspended sediments in the aquatic environment: an annotated bibliography and literature review. Ontario Ministry of Natural Resources, Southern Region Science & Technology Transfer Unit Technical Report TR-008. 277 pp.

response by 50%) has been derived for the D5 impact on plant development, which suggests there could be a link between the impact of root and shoot development and a reduction on barley crop yield[386,387]. However, the relationship between root biomass and plant productivity is complex and can be influenced by various factors such as soil type, nutrient availability, and environmental conditions[256].

Moreover, plant toxicity has been demonstrated as species specific. Barley has been described as a resilient and adaptative species[388], also potentially tolerant to pollution[389]. This could imply higher sensitivities of other plant species under similar exposure concentrations. Therefore, the impact on plant toxicity of a reduction in emissions cannot be discarded.

In the case of invertebrates, *Eisenia andrei*, *Eisenia fetida* and *Folsomia candida* are standard species selected based on ecological relevance, ease of maintenance in the laboratory, and short-generation time[390]. Soil invertebrates are key mediators of soil function for the diversity of ecosystem processes. Incorporation of litter into soil, the building and maintenance of structural porosity and aggregation in soils through burrowing, casting and nesting activities, the control of microbial communities and activities, plant protection against some pests and diseases, acceleration of plant successions, are among the many effects they have on other organisms through their activities[391], that is, they are important contributors to terrestrial ecosystem stability and biodiversity promoters.

Overall, this means that any reduction in emissions of D4, D5, and D6 could have positive impacts on biodiversity by reducing the risk of toxic effects highlighted above. Quantification is, however, not possible. In the case of plants, without knowing the proportion of barley field area, the percentage of productivity affected by a variable reduction in development cannot be clearly quantified. In the case of invertebrates, total population size is unknown.

Finally, the evidence available against this Option A suggests that D4, D5, D6 may bioaccumulate up the trophic chain, with a potential risk for accumulation on lipidic tissues of mammals. However, no direct toxic effects under worst case exposure scenarios could be demonstrated for rats or humans; and no studies were found proving a toxic effect related to the concentrations reached through bioaccumulation and/or biomagnification through the food chain. Therefore, a toxic impact on higher trophic levels is unlikely and it has not been considered in the assessment. No data on bioaccumulation studies in terrestrial organisms have been identified and concentrations measured in lower trophic levels have been recognised to be low[392]. Therefore, there might not be any added toxicity risk resulting from bioaccumulation in the described soil and sediment organisms.

Extrapolating 'laboratory values' to effects on EU-wide biodiversity is difficult, considering that there are many other factors that can affect organisms and plants direct and indirectly, as in the case of water quality. Based on this specific evidence, however, emission reductions for

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386 Rosati, A., Paoletti, A., Al Hariri, R., & Famiani, F. (2018) Fruit production and branching density affect shoot and whole-tree wood to leaf biomass ratio in olive. Tree Physiology, 38(9), 1278-1285. DOI: 10.1093/treephys/tpy009

387 Sierra Cornejo, N., Hertel, D., Becker, J. N., Hemp, A., & Leuschner, C. (2020) Biomass, morphology, and dynamics of the fine root system across a 3,000-m elevation gradient on Mt. Kilimanjaro. Frontiers in plant science, 11, 13. https://doi.org/10.3389/fpls.2020.00013

388 Newton, A. C., Flavell, A. J., George, T. S., Leat, P., Mullholland, B., Ramsay, L., ... & Bingham, I. J. (2011) Crops that feed the world 4. Barley: a resilient crop? Strengths and weaknesses in the context of food security. Food security, 3, 141-178. DOI: 10.1007/s12571-011-0126-3

389 Ayachi, I., Ghabriche, R., Kourouma, Y., Ben Naceur, M. B., Abdelly, C., Thomine, S., & Ghnaya, T. (2021) Cd tolerance and accumulation in barley: screening of 36 North African cultivars on Cd-contaminated soil. Environmental Science and Pollution Research, 28, 42722-42736. https://doi.org/10.1007/s11356-021-13768-y

390 Alves, P. R. L., & Cardoso, E. J. B. N. (2016). Overview of the standard methods for soil ecotoxicology testing. Invertebrates: Experimental Models in Toxicity Screening. Rijeka: InTech, 35-56. DOI: 10.5772/62228

391 Lavelle, P., Decaëns, T., Aubert, M., Barot, S., Blouin, M., Bureau, F., ... & Rossi, J. P. (2006). Soil invertebrates and ecosystem services. European journal of soil biology, 42, S3-S15. https://doi.org/10.1016/j.ejsobi.2006.10.002

392 Ibid footnotes 209-215

D4, D5 and D6 as a result of the policy scenarios could reduce the potential for toxicity in sediment organisms due to a reduction in environmental concentrations.

Finally, it is not possible to quantify or assess robustly whether the alternatives to silicone polymers and downstream user products that would be introduced under the policy scenarios would have any other positive or negative impacts on biodiversity.

Option B – broader scientific evidence

The differences between this Option B and Option A rely on the evidence supporting that the sediment and soil toxicity potential and, therefore, the biodiversity impacts are unlikely. The rationale underpinning these conclusions are set out in Section 4.4.3, Option B evidence description. The evidence presented in these sections justifies that the risks for any toxicity impact and, therefore biodiversity impacts, under the policy scenarios are negligible. Therefore, any benefits from reducing emissions of D4, D5 and D6 across the applications in scope would be negligible too.

4.4.5 Waste production, generation, and recycling

D4, D5 and D6 have a wide range of uses, with direct use restricted in the baseline scenario (as noted in Section 2.1). The uses captured by the three policy scenarios are those related to silicone polymers which contain D4, D5 and D6 as impurities.

A large number of silicone polymer applications are in articles or complex objects such as vehicles, construction products, low-carbon energy systems (e.g., solar panels), electronics and medical devices, with the silicone polymers in a cured form or as silicone fluids (e.g., heat transfer fluids). This means that waste streams are complex due to the presence of a large number of other materials and may require dismantling and sorting prior to waste management.

EU statistics on the treatment of municipal solid waste indicate that, when recycling is omitted, 60% of solid waste is landfilled and 40% is incinerated, although the actual rates will vary depending on the Member State. When considering plastic waste, it was found that, in 2018, 32.5% of post-consumer plastic waste was recycled, 42.6% was incinerated and 24.9% was landfilled. Between 2006 and 2018, a notable shift was seen in the treatment of plastic waste, with recycling rates increasing by 100%, incineration by 77% and landfilling decreasing from 50% to 24.9%.[393]

Silicones often represent a very small percentage of the overall weight of a product e.g. ~3 kg in an average internal combustion engine (ICE) car, which is comprised from a variety of articles[394,395], and so they are often not seen as critical for recycling, when combined with the volume of new polymers created, versus the volume of new silicone polymers, the focus on recycling has mostly been on plastic products. This being said, it is possible to chemically recycle silicones by breaking down silicone polymers to their monomer form and reintroduce them for new polymerisation reactions, with some companies making use of such siloxane recycling streams. At present, it is considered that the majority of silicone polymers are incinerated in the EU (liquid silicones – D4, D5 and D6 and liquid silicone polymers, and solid silicone polymers), with some landfill, but the recycling of silicones continues to grow and offers environmental benefits to the creation of new silicone polymers from virgin monomers.

[393] PlasticsEurope (2020) Plastics – the Facts 2020. Available: https://www.plasticseurope.org/en/resources/publications/4312-plastics-facts-2020

[394] NOTE. electric vehicles tend to contain 3-4 times the amount dependent on care and battery size

[395] Ibid footnote 4

The manufacture of silicone polymers is an energy-intensive process, which yields a socially and economically valuable product and so the recycling of out-of-specification or end-of-life silicone polymers, such as PDMS, to produce cyclic monomers or functional oligomers, is strategically important for society, the economy and the environment, presenting a potentially sustainable solution to a high demand product. Historically, the recycling of silicone polymers has been limited due to complexities and tends to be based on downcycling via mechanical processing, with limited chemical recycling. Chemical recycling offers benefits over downcycling as products can achieve the same high-performance requirements as virgin materials.

Chemical recycling methods based on halogenated reagents do exist but are limited for silicone polymers. Other methods have been developed, such as the depolymerisation of silicone oil using a mixture of $KOSiMe_3$ and a polydentate complexing agent[396]. Some manufacturers are using chemical recycling methods to recycle silicone polymers back to their monomers, especially liquid silicone waste. This may be an internal process or using external partners. At present, this activity tends to be located outside of the EU-27 but companies are carrying out feasibility studies to expand the scope of their chemical recycling efforts and bring these into the EU-27. The timeframe for bringing chemical recycling of silicone polymers to the EU-27 varies by company, with a range of 3-10 years. This suggests that chemical recycling of silicone polymers could increase in the baseline scenario.

Although an Annex A or B Stockholm Convention listing for D4, D5 and D6 does not have a direct impact on obligations under the Waste Framework Directive (2008/98/EC[397]) (nor other control of waste legislation such as the WEEE Directive 2012/19/EU[398] or the RoHS Directive 2011/65/EU[399]), following the implementation of a Stockholm Convention listing into the EU POPs Regulation, waste that contains D4, D5 and D6 would be subject to monitoring and reporting obligations. Where wastes contain or are contaminated with D4, D5 or D6 within the concentration limits referred to in Article 7 of the POPs Regulation, they must be disposed of or recovered in a way to ensure that the D4, D5 and D6 content is destroyed or irreversibly transformed, such that the remaining waste does not exhibit POP characteristics. It should be noted that the recycling, reclamation and re-use of D4, D5 and D6 from waste, even after the recovery operations outlined above, would be strictly prohibited. This means that the current siloxane recycling streams would have to cease.

At present, neither wastes containing siloxanes nor silicone polymers containing D4, D5 or D6 as impurities are managed as hazardous waste subject to controls under the Basel Convention as they are not listed in Annex I to the Convention or subject to an Annex I category. However, Article 6 of the Stockholm Convention limits the trade in waste that contains chemicals listed in Annex A, B or C, as well as prohibiting the recycling of waste unless the substance is present below a “low POP threshold” as prescribed in the Basel Convention. In the case of PBDEs, the COP created specific exemptions to modify Article 6 that permitted the recycling of PBDE-containing articles under specific circumstances, without reliance on the Basel Convention “low POP” level. In theory, this could also be introduced for the recycling of siloxanes or

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[396] Vu. N. D., Boulègue-Mondière. A., Durand. N., Raynaud. J., Monteil. V. (2020) Back-to-cyclic monomers: chemical recycling of silicone waste using a [polydentate ligand–potassium silanolate] complex. Green Chemistry. 25, 3869. Available: Back-to-cyclic monomers: chemical recycling of silicone waste using a [polydentate ligand–potassium silanolate] complex (rsc.org)

[397] European Commission (2008) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives. Available: EUR-Lex - 02008L0098-20240218 - EN - EUR-Lex (europa.eu)

[398] European Commission (2012) Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE). Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012L0019-20180704

[399] European Commission (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011L0065-20240201

silicone polymers containing D4, D5 and D6 as impurities, but this would be the exception to the rule and cannot be guaranteed.[400]

The strict conditions on the treatment of wastes containing POPs listed in the Stockholm Convention would mean that under all three of the policy scenarios considered in this Study, the circularity of D4, D5 and D6 containing silicone polymers would be significantly impacted and most likely would have to cease entirely. In all policy scenarios, it is estimated that incineration rates for waste disposal of affected products could increase. This would be considered a detriment to the EU circular economy objectives.

Moreover, a number of key sectors targeted by the Commission's Circular Economy Action Plan rely on the use of silicone polymers, such as electronics, construction, batteries and vehicles. In all policy scenarios, the recycling of silicone polymers would be prohibited, and no new silicones could be used, potentially impacting the ability of key sectors to repair or re-use articles and complex objects. In some of these applications alternatives may exist, yet it is acknowledged that their service life is likely to be lower due to their inferior functionalities and recovery and recycling operations may also be difficult. This means that the use of alternatives may increase the need for repair or replacement, potentially generating more waste. Unless these alternatives can be recycled, these impacts would work against the Circular Economy Action Plan.

Although recycling of silicones is currently low compared to incineration, the policy scenarios under consideration would hinder recycling further, which would not contributing to the growth of recycling rates and/or facilitate economic circularity.

4.4.6 Efficient use of resources, transport and energy, climate

A core aim of the EU Green Deal is the decarbonisation of EU society, with the aim to be carbon-neutral by 2050 and reducing greenhouse gas (GHG) emissions by 55% in 2030 compared to 1990. There are a number of building blocks under the EU Green Deal which work together to meet this goal, such as: supplying clean, affordable, and secure energy; energy and resource efficient building and renovating; sustainable and smart mobility. Carbon neutrality is an ambitious goal and requires the cooperation of all sectors, as well as the use of novel, low-carbon alternatives to current systems. As outlined in Section 0, silicone polymers are used in a large number of sectors, many of which are known contributors to GHG emissions, with silicones being considered key chemicals for driving decarbonisation and reducing GHG emissions.

It has been estimated that 75% of the EU GHG emissions come from energy production and consumption and to address this there is a need to phase out the use of coal, decarbonise the gas sector and expand the use of renewable energy sources, whilst ensuring the EU energy supply is secure and affordable.[401] Silicones are a key material to ensure this green energy transition and can also support in ensuring that energy needs are reduced over time. To assess the importance of silicones in supporting the EU Green Deal, a review of relevant literature has been carried out. This section presents the findings of the literature review, identifies key sectors of concern and qualitatively assesses how the three policy scenarios may affect the use of renewable energies, and the energy intensity of the economy.

[400] Covington & Burling LLP (2024) Memorandum: Knock-On Effects of Listing D4, D5, and D6 under the Stockholm Convention.

[401] European Commission (2019) The European Green Deal. COM(2019) 640 final. Available: EUR-Lex - 52019DC0640 - EN - EUR-Lex (europa.eu)

4.4.6.1 Low-carbon energy

Silicone polymers and D4, D5 and D6 have key applications in clean energy production, such as being used as sealants, bonding agents, and lubricants in wind turbines; and encapsulants, conductive adhesives and solar cells in photovoltaic panels. Due to their physico-chemical properties, silicones are advanced functional materials and exhibit high durability and weatherability; strong adhesion and sealing; and good heat dissipation.

It has been estimated that a wind turbine with 8MW production capacity and 4000 annual full load hours can produce 32 000 MWh of electricity per year[402]. Wind turbines that use silicone lubrication can produce 8% more energy than a wind turbine using synthetic oils[403]. Therefore, the use of silicone could result in an annual benefit of 2370 MWh/ year. Denkstatt (2022) estimated the lifecycle GWP for wind turbines using silicone lubricants versus those using synthetic oils, based on an electricity mix of 0.41 kg CO_2eq/kWh.[404] Table 4-73 presents the findings. It is noted by Denkstatt that although there are higher efforts needed in the production of silicone lubricants compared with synthetic, there is an advantage contributing to the overall benefits in the use phase where wind turbines using silicone lubricants can products 8% more energy. When considering the net benefit of the use of silicones over alternatives, negative values in the table represent a benefit in terms of emissions savings, with a positive result indicating no benefit. For silicone lubricants and synthetic lubricants there is a negative net benefit of silicone per kilogram which indicates a positive GHG benefit. The benefit-impact ratio was calculated by dividing the benefit (achieved by the silicone lubricant) by the GHG emissions from the production and end-of-life (EoL) phases of the silicone lubricant. As the benefit-impact ratio value is >0 (315), the benefit of using silicone lubricants rather than synthetic lubricants is bigger than the impact of production and EoL. This methodology was used by Denkstatt in all calculations presented in this Study.

Table 4-73 GWP effects of wind turbines using silicone or synthetic lubricants over 25 years of operation[405]

Wind turbines		GWP Kg/ CO_2eq / FU*	GWP Kg/ CO_2eq / kg Silicone product
Silicone lubricants	Total (production and transport, use, end of life)	77 475	7
Synthetic lubricants	Total (production and transport, use, end of life)	24 437	2080
Net benefit from silicones	Total (production and transport, use, end of life)	-24 360	-2073
Ratio benefit-impact		315	

*Functional unit (FU) = 8 MW capacity of wind power, 25 years operation

[402] Umweltbundesamt (2021) Aktualisierung und Bewertung der Ökobilanzen von Windenergie- und Photovoltaikanlagen unter Berücksichtigung aktueller Technologieentwicklungen

[403] Ibid footnote 54

[404] Denkstatt (2022) The role of silicones for the EU Green Deal. Available: CES-GD-Report_Vers.-2.6_denkstatt-20221024-final-version-1.pdf (silicones.eu)

[405] Ibid footnote 404

The data presented above would suggest that in order to reach the EU clean energy targets, it would be most beneficial to allow the continued use silicone polymers for low-carbon energy generation as they increase energy production as well as displaying net benefits compared to their alternatives. As the concentration of D4, D5 and D6 in the silicone polymers used in low-carbon energy applications is not definitely known and will vary depending on the application, it is difficult to assess the difference in scale of impact between the three Policy Scenarios. It can be concluded that policy scenarios 2 and 3 would have a significant impact on the availability of key materials used to facilitate the generation of low-carbon energy as no acceptable purpose exemptions exist and so the use of silicone polymers containing D4, D5 and D6 impurities ≤0.1% for these applications would have to cease.

4.4.6.2 Construction

At present, residential buildings are responsible for 40% of EU energy consumption, with GHGs emitted by buildings being approximately 0.4 Gt CO_2-eq in 2020. Silicones can directly contribute to an increase in energy efficiency of renovated and newly constructed buildings due to their key functional properties. As an example, silicone-based construction products are at least twice as durable as alternatives which can reduce lifecycle costs through the extension of their service life. Silicone-based construction products can also reduce water uptake by up to 80%, which in turn increases the service life of the article in which they are used. Another benefit of using silicone-based construction products is an improvement in energy efficiency, which can be demonstrated by a reduction in U-value of 0.2 w/(m^2K) for a building façade with structural glazing/ insulating glass, resulting in lower demand for heat and energy[406].

Denkstatt (2022) investigated the lifecycle GWP of a silicone structural glazed system compared with that of a dry glazing thermally improved system (both of which use insulating glass units). Structural glazing is an innovative way to design glass building façades and is only attainable through the use of silicone sealants. Such sealants tend to consist of 45% silicone (PDMS), 50% calcium carbonate, and 5% pigments and adhesion promoters[407]. Table 4-74 presents the lifecycle GWP of the two façade systems. The net benefit for use of a silicone structural glazed system is -29 Kg/ CO_2eq / kg Silicone product, which leads to a benefit-impact ratio of 8. Although lower than that seen for wind turbines, there is still a notable benefit to the energy efficiency of buildings and the need for heating and cooling.

Table 4-74 Lifecycle GWP of a silicone structural glazed system and a dry glazing thermally improved system[408]

HQ sealants and adhesives		GWP Kg/ CO_2eq / FU*	GWP Kg/ CO_2eq / kg Silicone product
Silicone structural glazed system	Total (production and transport, use, end of life)	21 166	4.1
Dry glazing thermally improved system	Total	170 441	33.4

[406] Wolf. A (2010) Contributions of silicone technology to sustainable architecture. Dow Corning Construction Solutions

[407] Carbary, L. et al. (2009) Comparisons of Thermal Performance and Energy Consumption of Facades Used in Commercial Buildings. Glass Performance Days. Available: (PDF) Comparisons of Thermal Performance and Energy Consumption of Facades Used in Commercial Buildings (researchgate.net)

[408] Ibid footnote 404

HQ sealants and adhesives		GWP Kg/ CO_2eq / FU*	GWP Kg/ CO_2eq / kg Silicone product
	(production and transport – EPDM gasket and aluminium frame), use – effect of U -value and effect of air filtration, end of life)		
Net benefit from silicones	Total (production and transport, use, end of life)	-149 275	-29
Ratio benefit- impact		8.0	

*Functional unit (FU) = 1 building

The continued use of silicone polymers in the construction industry would be dictated by the concentration of D4, D5 and D6 as impurities. Due to the properties required for construction sealants, the impurity concentrations can be higher than 0.1% w/w and this would prevent use for certain applications under all three policy scenarios. Alternatives with similar or worse performance might be available for some of these and other applications under the Policy Scenarios. Moreover, the energy efficiency of buildings could be impacted by any lack of availability of specialist products under the policy scenarios, which would directly impact the ability of the EU to meet its Green Deal objectives.

4.4.6.3 Sustainable and smart mobility

Available evidence suggests that the transport and mobility sector are responsible for 25% of the EU GHG emissions and would require a 90% GHG reduction to accomplish the EU Green Deal objectives[409]. The use of silicones in the mobility sector can lead to fuel reductions from e.g., the application of silicone resin coatings in the production of lightweight automotive glazing, replacing heavier glass parts, as well as other uses such as seals, isolators, and encapsulations in vehicle construction. A 2012 study estimated that fuel savings as a result of weight reduction could be around 20% as a result of using silicones[410]. Estimates from Germany and UK suggested that this could equate to a fuel saving of €202 per car, per year.[411] Silicones have also proven important for batteries and energy storage in electric vehicles (EV), including, but not limited to, protecting batteries from temperature extremes and dirt, and sealing and cushioning the battery, which can contribute to longer service lives, faster recharging and greater ranges[412].

Denkstatt (2022) identified one of the key applications of silicones in the mobility sector as automotive bonding, which can lead to a reduction in fuel consumption and subsequent GHG emissions due to its weight-saving properties. To investigate the benefit of these weight savings, silicone automotive bonding was compared with the spot-welding method, in which two steel or metal parts are welded together. In order to meet the stability requirements, spot-welded materials tend to be thicker and heavier than steel parts glued together with silicone

[409] European Commission. (2019) The European Green Deal. COM(2019) 640 final. Available: [EUR-Lex - 52019DC0640 - EN - EUR-Lex (europa.eu)]

[410] Denkstatt (2012) Si Chemistry Carbon Balance

[411] Ibid footnote 54

[412] European Commission. (2018) A Clean Planet for all A European strategic long-term vision for a prosperous, modern, competitive and climate neutral economy. COM(2018) 773 final. Available: https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2018)773&lang=en

bonding. Spot-welding also consumes more energy and is more sensitive to external influences than silicone-based adhesive bonding. It should be noted that there are other lighter alternatives, such as reinforce plastic or aluminium, but they were not assessed in the Denkstatt study.

Table 4-75 presents the lifecycle GWP effects of silicone automotive bonding in cars versus the alternative spot welding and heavier materials. The use of silicone polymer-based automotive bonding shows a fuel saving benefit leading to a benefit-impact ratio of 34.07 and resulting in lower GWP.

Table 4-75 life cycle GWP effects of automotive bonding and spot welding and heavier materials[413]

Automotive bonding		**GWP Kg/ CO_2eq / FU***	**GWP Kg/ CO_2eq / kg Silicone product**
Silicone automotive bonding	Total (production and transport, use, end of life)	5.3	6.7
Spot welding and heavier materials	Total (production and transport, use, end of life)	182	228
Net benefit from silicones	Total (production and transport, use, end of life)	-177	-221
Ratio benefit/ impact		34	

*Functional Unit (FU) = 1 car

As noted above, silicone is used for sealing, bonding, thermal and electrical insultation in EV batteries. Heat dissipation and thermal management are key concerns for EVs, where lithium-ion batteries can change their structure and dimensions during charging and discharging. It is therefore important that thermal insulating materials (TIM) in EV batteries exhibit structural flexibility and long-term softness. As thermally conductive silicones have a very low moduli and do not show thermo-oxidative hardening during service life, they present benefits compared to the use of organic polymers which can undergo thermal aging leading to irreversible structural changes resulting in hardening over time[414, 415]. Interviews carried out in Denkstatt (2022) indicated a lifetime extension for TIM of 5-50 % when using silicones, which may suggest that silicone-based TIM could extend the service life of EV batteries by 8-10 years. It should be noted that epoxy and polyurethane are also currently used in EV batteries.

Table 4-76 compares the lifecycle GWP for EV batteries which use silicone or epoxy as thermal interface materials. A noted above, one of the benefits of using silicone is the extension of battery life, this results in reduced use of raw materials and energy over the service life of the vehicle as there may be less frequent replacement of the battery. It is this

[413] Ibid footnote 404

[414] Chowdhury. A. S. M. R., Rabby. M.M., Kabir. M., Das. P.P., Bhandari. R., Raihan. R., Agonafer. D. (2021) A Comparative Study of Thermal Aging Effect on the Properties of Silicone-Based and Silicone-Free Thermal Gap Filler Materials. Materials 2021, 14, 3565. DOI: 10.3390/ma14133565

[415] Walter. P. (2022) Silicone-Based Thermal Interface Materials for Electric Vehicles. adhesion ADHESIVES+SEALANTS 19, 22–25. https://doi.org/10.1007/s35784-022-0387-6

reduction in raw material and energy use that contributes to the high net benefit of using silicone rather than epoxy (-3295.2 kg/ CO_2eq / kg Silicone product).

Table 4-76 life cycle GWP effects of silicone and epoxy as thermal interface material (TIM) in EV batteries[416]

Thermal interface material in EV batteries		GWP Kg/ CO_2eq / FU*	GWP Kg/ CO_2eq / kg Silicone product (TIM)
Silicone application: TIM, 10 yr. lifetime of battery	Total (production and transport silicone, use, production and transport battery cells, end of life)	5 738	13 191
Alternative application: epoxy, 8 yr. lifetime of battery	Total (production and transport epoxy, use, production and transport battery cells, end of life)	7 171	16 486
Net benefit from silicones	Total (production and transport, use, end of life)	-1 433	-3 295
Ratio benefit/ impact		212	

*Functional unit (FU) = 1dm^3 TIM, 10 years

Silicones are used in a number of different components use by the transport and mobility sector. They have critical impacts on vehicle weight, which in turn affect fuel efficiency and are key to the continued expansion of manufacturing and use of EVs in the EU. Under policy scenarios 1 and 2, the continued benefit of silicone polymer use is directly linked to the concentration of the impurities of D4, D5 and D6. Where manufacturers can utilise silicone polymers with impurity concentrations ≤0.1%, benefits may continue to be realised. In policy scenario 3, where no exemptions exist, there would be a return to alternative materials, which may see an increase in fuel use due to weight increases of vehicles, and a decrease in the uptake of EVs as a result of a lack of availability of high performing seals, bonds and TIM. This would have a direct impact on the EU's ability to meet the Green Deal objectives.

4.4.6.4 Digital

Key uses of siloxanes in the digital sector are discussed in Section 4.3.3. Another use of siloxanes in the digital sector is in light emitting diodes (LEDs). LEDs exhibit lower optical losses, increased brightness and duration, and greater protection and reliability which increase the service life (10-20 years compared to 3-4 years for halogen equivalents), reducing the need for replacement and subsequent waste generation[417]. LED lights currently use 90% less energy than other lighting systems[418] and are widely used in a number of areas

[416] Ibid footnote 404

[417] European Commission (2018) Memo – New Ecodesign rules for light bulbs, applicable from September 2018. Available: memo-light_bulbs_applicable_from_september_2018_0.pdf (europa.eu)

[418] Ibid footnote 54

such as traffic lights, display media, and general lighting systems[419]. It was estimated that high power LEDs held approximately 38% of the market share in 2019. The benefits from using LEDs compared to traditional lighting systems has been acknowledged by the European Commission and regulatory efforts have been made to promote the use of more energy efficient LEDs[420].

Silicones are used in the reflector, encapsulating material, TIM, and as a bonding adhesive in LEDs and may be considered critical elements of LED design. To explore the environmental benefits of LED use, Denkstatt (2022) compared the use of silicone as an encapsulant or a lens, to optical grade epoxy. This was chosen due to the larger amount of encapsulant material used compared to the amount of TIM or bonding adhesive and the lack of data related to silicone as a reflector material. The benefits considered were therefore related to the extended service life of the product.

The choice of epoxy encapsulant for LEDs comes with a number of disadvantages as epoxy can suffer from material yellowing and heat generation which affects the service life of the product. Moreover, the useful lifetime[421] of LEDs based on lumen output can be affected by the choice of material, with the lumen output for an epoxy encapsulant reducing by approximately 81% (for 350 mA constant current for 1500 h) as opposed to a reduction of 1-5.5% for a silicone encapsulant[422]. This “useful lifetime” metric allows the two encapsulants to be compared.

Table 4-77 presents the lifecycle GWP impacts of energy efficient lighting using LEDs. It is noted that the production phase of the LED lamp has a greater impact on GWP effect than the end-of-life phase. The benefit from using silicone rather than epoxy is driven by the small mass of the silicone encapsulant material (0.3% of the total LED lamp weight).

Table 4-77 GWP effects of LED using silicone or epoxy encapsulants

LED		GWP Kg/ CO_2eq / FU*	GWP Kg/ CO_2eq / kg Silicone product (TIM)
LED lamp with silicone encapsulant	Total (production and transport – lamp production excluding encapsulant + silicone encapsulant production, use, production and transport battery cells, end of life)	3	11
LED lamp with epoxy encapsulant	Total (production and transport – lamp production excluding encapsulant + epoxy encapsulant production,	6	22

[419] Kim, J., Ma, B., & Lee, K. (2013). Comparison of effect of epoxy and silicone adhesive on the lifetime of plastic LED package, Electronic Materials Letters, 9, 429-432. https://doi.org/10.1007/s13391-013-0024-2

[420] See Energy labelling requirements for lighting products (europa.eu), and Commission Regulation (EU) 2019/2020 laying down ecodesign requirements for light sources and separate control gears pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulations (EC) No 244/2009, (EC) No 245/2009 and (EU) No 1194/2012. Available: Regulation - 2019/2020 - EN - EUR-Lex (europa.eu)

[421] The timespan from first-time use to a drop in the luminous flux beneath 70%. Ibid footnote 419

[422] Lin, Y. H., You, J. P., Lin, Y. C., Tran, N. T., & Shi, F. G. (2010). Development of high-performance optical silicone for the packaging of high-power LEDs. IEEE Transactions on Components and Packaging Technologies, 33(4), 761-766. doi: 10.1109/TCAPT.2010.2046488

LED		GWP Kg/ CO_2eq / FU*	GWP Kg/ CO_2eq / kg Silicone product (TIM)
	use, production and transport battery cells, end of life)		
Net benefit from silicones	Total (production and transport, use, end of life)	-3	-11
Ratio benefit/ impact		2	

*Functional unit (FU) = light duration of 1500h

When it comes to the impacts on the digital sector, all three policy scenarios could have significant impacts on the ability of the EU to meet their green and digital ambitions. Key foundations of these agendas will be unintentionally impacted, with the lack of availability of optic fibres and semiconductors, in particular, potentially having very significant negative impacts on the EU.

4.4.7 Overall environmental impact for each policy scenario

In summary, it is most likely that neutral or potentially even net negative impacts on the environment could result from the adoption of any of the policy scenarios.

On the one hand, a reduction in emissions of D4, D5 and D6 could have environmental benefits on the quality of natural resources and biodiversity; however, there are conflicting evidence bases on the environmental fate and behaviour and toxicity of D4, D5 and D6 (see Sections 4.4.3 and 4.4.4). The evidence presented by the European Commission and the classification for persistence raises concerns for the environmental fate and behaviour of D4, D5 and D6. However, a literature review performed for this Study concluded that the toxicity risk of D4, D5 and D6 is negligible due to laboratory conditions not being reflective of real-world environmental conditions. A body of evidence identified in scientific literature and assessed as part of this Study questions the environmental fate and behaviour properties put forward by the European Commission. As a result, two parallel assessments were carried out leading to two sets of qualitative ratings, Option A (Commission evidence presented in the draft Annex D report) and Option B (broader scientific evidence), for impact categories '*quality of natural resources'* and '*biodiversity'*.

On the other hand, the evidence available suggests that there could likely be negative impacts on *'waste production, generation and recycling'* and *'resources, transport, energy and climate'*. Recycling would be negatively affected under all policy scenarios, given the presence of D4, D5, D6 as impurity in waste products, and the incineration of siloxanes and silicone polymers would continue, which could also have negative impacts on the environment. In addition, available evidence suggests that there could be a negative impact on resources, transport, energy and GHG emissions under the policy scenarios (increasing from PS1 to PS3) as a result of the baseline replacement with alternatives that are worse performing and more energy intensive, leading to higher energy consumption and more GHG emissions, all other things held equal.

The environmental impact conclusions are summarised qualitatively in the Table below, using the scoring framework described in Section 4.1 and, in more detail, in the Annexes.

Table 4-78 Qualitative, environmental impact ratings

Broad category	Evidence base Option	PS1	PS2	PS3
Quality of natural resources (water, soil, air), including Option A and Option B	Option A (EU Commission evidence)	+0.5	+1.0	+1.5
	Option B (broader scientific evidence)	0	0	0
Biodiversity, including Option A and Option B	Option A (EU Commission evidence)	+0.5	+0.5	+1.0
	Option B (broader scientific evidence)	0	0	0
Waste production, generation and recycling	N/A	-0.5	-0.5	-0.5
Resources, transport, energy and climate	N/A	-1.0	-2.0	-3.0

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this assessment, it is concluded that all policy scenarios could have either neutral or negative, overall environmental impacts on the EU (Option A and Option B respectively). The ratings have been reviewed and recalibrated against the -5/+5 scoring framework, for a comparison of the balance of impacts across impact categories, costs and benefits. The Table below presents the qualitative ratings given to the overall environmental impacts of each of the policy scenarios for these comparisons. The methodological Annexes explain the recalibration exercise.

Table 4-79 Qualitative, environmental impact ratings

	Evidence base Option	PS1	PS2	PS3
Overall environmental impacts, for Option A and Option B respectively	Option A (EU Commission evidence)	0	0	-0.5
	Option B (broader scientific evidence)	-0.5	-0.5	-1.0

Source: Ricardo analysis based on the evidence presented in this Study.

4.5 UNCERTAINTIES AND LIMITATIONS

As is inherent with all *ex-ante* assessments, there are uncertainties and limitations to the analysis. In the case of this assessment, these are linked to the uncertainty of the policy initiative, the availability of quality data, and the relatively high level of complexity for how these policy scenarios may affect the EU's D4, D5, D6 and silicone polymer industries, the 'downstream user' sectors, wider society and the environment.

Firstly, at the time of writing, the nomination to the Stockholm Convention has not been made and the final nomination remains uncertain and under development. This means that the policy details are not yet clear, and assumptions have been required. Policy assumptions have been quality assured to ensure they reflect the policy debate in so far as is possible. As discussions are ongoing, the assumptions made in this assessment may not accurately reflect the regulatory changes that enter into force. However, the assessment carried out and its outputs are highly dependent on these assumptions and, therefore, reflect the same level of uncertainty.

Secondly, the data available has limitations. There is limited historical evidence of relevance, given that the policy scenarios considered for future implementation go over and above any other policies implemented in the EU and internationally related to D4, D5 and D6. It has been, therefore, necessary to rely on a consultation of businesses to gather evidence as to the potential actions they may take as a response to a Stockholm Convention listing and the associated costs and benefits, as pertinent. The data gathered through the consultation exercises is limited by the sample of respondents and their understanding and assessment of how a Stockholm Convention listing for D4, D5 and D6 may affect their operations. The sample is not statistically representative but captures a large proportion of the upstream sales turnover (>80%). However, a limited coverage was attained for the downstream sectors in scope. The evidence has nevertheless been used to illustrate the potential scale of the effects that the policy scenarios may have across very diverse and complex downstream sectors that rely, in some way, on D4, D5 and D6 and/ or silicone polymers. Moreover, the sample also comprises a disproportionate number of large firms. This is not deemed a significant issue since over 50% of manufacturing output is generated by large firms, and a comparative analysis between SME versus large enterprise impacts was not possible due to sample limitations.

Thirdly, the known uncertainties were quantified as part of the ranges presented in the main results tables and diagrams. These present possible lower and upper bound effects and select a ‘medium’ or central estimate that, based on the available evidence, appears to be most likely. However, given the limitations, it is acknowledged that any point along the ranges presented in this Study offer a reasonable conclusion.

In more detail, sensitivity analysis was performed to examine how different assumptions regarding the affected product portfolio and potential level of substitution under each policy scenario may affect the estimated adjustment costs and product withdrawals, which appear to present the largest economic impacts. Possible, yet unlikely, lower and upper bounds are present alongside the main conclusions throughout the report. In addition, matrices were developed that understand the sensitivity of the potential production losses in the EU when compared against the baseline to different possible levels of affected portfolio and substitution rates. These conclude that:

- Under PS1, there is high likelihood that overall production in the EU will be lower than the baseline projections (i.e., losses), with possible scenarios of no production losses, especially downstream, which have low or very low likelihood of occurrence. In all scenarios, industry would incur one-off and recurring adjustment costs.
- Under PS2, there is high likelihood that overall production in the EU will be lower than the baseline projections (i.e., losses), with possible scenarios of limited production losses (especially downstream) which have very low likelihood of occurrence. In all scenarios, industry would incur one-off and recurring adjustment costs.
- Under PS3, there is high likelihood that overall production in the EU will be lower than baseline projections (i.e., losses), and there is no scenario (i.e., zero likelihood) in which production could reach baseline levels. In all scenarios, industry would incur one-off and recurring adjustment costs.

These are presented in Annex 4.

Fourthly, uncertainties were also explored as part of the estimation of potential emissions reductions across the policy scenarios. The sensitivity of cost-effectiveness estimates is also explored in Section 5.1, and sensitivities to the MCA outputs are considered in the following paragraphs and Annex 4.

The policies under consideration will affect the EU chemicals sector, wider society and the environment in multiple and complex ways. In this context, two key impact drivers on businesses were considered: direct and indirect reductions in the manufacture, import and use of D4, D5, D6 and silicone polymers; and additional regulatory burden, thus potentially affecting the economic viability of certain operations in the EU. The extent to which these impacts affect sub-sectors and businesses, and how these businesses may respond, will vary, including whether or not business will discontinue, reformulate or substitute the use and manufacture of certain products. Any of these actions will incur transitional and/or recurring costs when compared to the baseline. Therefore, an informed simplification of the impact pathway, based on the project team expertise, was introduced, with inherent limitations. For environmental impacts, the scientific discourse surrounding the environmental fate and behaviour of D4, D5 and D6 means that it is very difficult to estimate the true environmental costs and benefits and so emission reductions and steady-state environmental stock have been derived based on data reported in the Restriction dossier and supporting documents.

All of these uncertainties were considered when conducting a qualitative assessment of the impacts across Policy Scenarios. The MCA, qualitative ratings were determined for the policy scenario impacts on the shortlisted economic, social and environmental categories based on the 'medium' or central outputs of the analysis undertaken and/or evidence available. However, sensitivity analysis was also undertaken based on the lower and upper bounds of the core impacts, to explore the extent to which conclusions might be affected, if at all. The conclusions using upper bound estimates were aligned with those of the 'medium' case. Thus, a more detailed investigation was undertaken of the following cases: (i) using 'low' costs of industrial transformation (i.e., affected portfolio, substitution, etc) coupled with 'low' environmental benefits (i.e., lower bound emissions reductions); (ii) 'low' costs of industrial transformation coupled with 'medium' environmental benefits (which could be possible if industry finds ways to achieve emissions reductions with lower costs but unlikely given the available evidence); and (iii) 'low' costs of industrial transformation and 'high' environmental benefits on quality of natural resources and biodiversity (which is even more unlikely, as to achieve these environmental benefits, the evidence suggestions large investments and energy intensive activities are required).

In all of these possible but unlikely scenarios (in which lower bound industrial costs are compared against lower to upper bound environmental benefits on the quality of natural resources and biodiversity), the sensitivity analysis concluded that overall societal benefits remain lower than overall costs (i.e., benefit: cost ratio remains lower than 1). This is aligned with the conclusions reached through the cost-effectiveness analysis presented in Section 5.1 below, which concludes that even lower bound estimates of adjustment costs per kg of D4, D5, and D6 emissions reductions are higher than the 'accepted' costs of any other action undertaken in the past to restrict the use and/or reduce emissions of other persistent substances (or these substances in other applications, such as cosmetics). More details concerning the sensitivity analysis of the MCA are presented in Annex 4.

Moreover, there are also a number of known unknowns, such as how technological progress may affect the D4, D5, D6 and silicone polymer industry as well as the wider society and whether and how this would interact with the impacts of a Stockholm Convention listing. Further, international trade and competitiveness are likely to affect the EU chemicals sector, but these effects are not considered in depth, primarily due to limitations in the evidence available. These are further sources of uncertainty.

These, and other assumptions, offer a workable and reasonable approach to assessing impacts of the Policy Scenarios considered, albeit with limitations.

5. COMPARISON OF THE POLICY SCENARIOS

This section outlines the overall conclusions that are supported by the Study, building on the latest Commission's Better Regulation Guidelines and available evidence; and summarises an assessment of cost-effectiveness and the qualitative balance of impacts, costs and benefits cross each of the three Policy Scenarios.

5.1 COST-EFFECTIVENESS OF THE POLICY SCENARIOS

Persistent substances raise concerns due to their potential to remain and accumulate over long periods of time in environmental compartments, which could lead to negative effects on humans and the environment over time. However, 1) it is difficult to predict the scale of any of these potential impacts using current testing and modelling approaches, and 2) current methods do not allow for the estimation of a "safe" concentration or the identification of when such a concentration would be breached. This means that, at this stage, the quantification of risks associated with D4, D5 and D6 emissions is not possible.

In some cases, persistent substances can have other properties, such as toxicity, which can be quantitatively assessed and monetised, in terms of potential damages in humans and the environment. In this case, however, the lack of evidence means that the valuation of any potential benefits from reduced emissions via standard impact pathway approaches is not possible.

The SEAC has established guidance on how to use cost-effectiveness methodologies at least to compare the compliance costs that the European society are 'willing to pay' to reduce emissions of persistent substances, based on historical evidence of adopted chemical restrictions[423]. The Table below presents the costs per kilogram of persistent chemical release reductions (or reductions in the steady-state environmental stock of these chemicals) for recent REACH restrictions.

Table 5-1 Cost-effectiveness of recent REACH restrictions on persistent chemicals

Substance(s)	€/kg of releases or 'releases that remain in the environment' (*)
Lead in shot in wetlands	9 €/kg
Lead in PVC (under decision-making)	308 €/kg
D4, D5 in wash-off cosmetics	415 €/kg
DecaBDE	464 €/kg
Phenylmercury compounds	649 €/kg
PFOA-related substances	734 €/kg
PFOA	1,649 €/kg
D4, D5 and D6 (in the Annex XV dossier proposing restrictions)	104 €/kg (*)

Source: Committee for Risk Assessment (RAC), Committee for Socio-Economic Analysis (SEAC) (2019). Opinion on an Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4); Decamethylcyclopentasiloxane (D5) and Dodecamethylcyclohexasiloxane (D6). (*) Previous assessments did not

[423] ECHA (2023) Evaluation of restriction reports and applications for authorisation for persistent substances in SEAC. Available: af4a7207-f7ad-4ef3-ac68-685f70ab2db3 (europa.eu)

consider the steady state level of releases that remain in the environment, so estimates are not completely comparable with this.

These estimates can be used as "benchmarks" for comparison[424] against the abatement costs estimated for the policy scenarios under consideration, so to develop insights about the merits or lack thereof of the policy scenarios under consideration.

For this comparison, two statistics have been developed based on the annualised adjustment (or compliance) costs estimated for Section 4.2.1.2: Option 1, dividing these costs by the annual emission reductions,; and Option 2, dividing these costs by the reduction in the steady-state environmental stock of these substances, noting that the estimates of emissions or steady-state environmental stock are presented in Section 4.4.2.

The Table below presents the overall cost-effectiveness estimates, and the Annexes provide a more detail description of the methodology.

Table 5-2 Cost-effectiveness of the Stockholm Convention listings[425]

Substance(s)	€/kg of emission reductions or reductions in the releases that remain in the environment
D4, D5 and D6 - Option 1 'Emissions' (emissions reductions)	25,000 €/kg (8,000 – 45,000 €/kg)
D4, D5 and D6 - Option 2 'Steady state' (reductions of emissions that remain in the environment in steady state)	960,000 €/kg (370,000 – 1,710,000 €/kg)

Source: Ricardo analysis based on the evidence presented in this Study.

As set out by SEAC in their 2019 opinion on the Annex XV dossier proposing restrictions on D4, D5 and D6, it is most appropriate to consider the adjustment costs that could be incurred for each kg of reduction in the releases of chemicals that remain in the environment (i.e., option 2). In this case, it has been estimated that the emissions of D4, D5 and D6 that would remain in the steady-state environmental stock when compared to the baseline would be relatively low (see Table 4-70), whereas the adjustment costs could be very large, resulting in a 'central' estimate of €960,000 for each kg of steady state environmental stock reductions.

This could be explained by the role that silicone polymers play across multiple downstream user industries. For example, even though the weight of silicone polymers used in products may be low, e.g., 3kg in an average car, and subsequent, potential emissions of D4, D5 and/or D6 would be considerably lower than for cosmetic applications, the final products rely on silicone polymers, sometimes in critical ways. In cases where product adjustments can be made and/or alternatives are available, significant investments may be required to achieve similar levels of final product performance, thus leading to high adjustment (or compliance) costs when compared to the limited emission reductions.

In addition, the cost-effectiveness estimates presented in Table 5-2 do not take into account the opportunity costs that result from the Stockholm Convention listings, which on this occasion are defined as potential losses of production activity in the EU when compared

[424]Ibid footnote 65

[425] Cost effectiveness estimates were developed for each of the three policy scenarios; however, the scale of these estimates was observed to be similar across the scenarios, and hence, there were no additional insights from presenting the individual scenario estimates. As a result, average cost effectiveness estimates have been presented in the Table.

against the baseline. If production losses are included, the abatement costs per kg of steady-state environmental stock reductions could be many times higher.

In conclusion, the estimated abatement costs under these policy scenarios are many times higher than the highest values from the recent REACH restrictions (e.g., PFOA). Based on this, it is considered that the policy scenarios under consideration are unlikely to be cost-effective ways of further reducing D4, D5 and D6 emissions. These results have fed into the analysis of the balance of economic, social, and environmental impacts, and the balance of costs and benefits below.

5.2 BALANCE OF ECONOMIC, SOCIAL AND ENVIRONMENTAL IMPACTS

The outputs of this impact assessment from Section 0 and 5.1 resulted in a set of comparable ratings for the policy scenarios across the broad economic, social and environmental impact categories and overall costs and benefits. These outputs are the result of analysis all of the evidence collected, and analysis performed and captured in earlier sections of this Study.

Table 5-3 below reiterates the colour-coding used to summarise the qualitative assessment of impacts referring to the direction (positive or negative) and magnitude (small or large) of any expected impacts. A more detailed description of the qualitative assessment methodology and other analytical methods employed in this report can be found in the Annexes.

Table 5-3 Scoring and colour coding used to present the assessment conclusions

Strongly negative	Negative	Weakly negative	No or limited impact	Weakly positive	Positive	Strongly positive	Unclear
-5	-3	-1	0	+1	+3	+5	N/A

Table 5-4 below summarises the aggregated economic, social, and environmental impacts by policy scenario from a societal perspective, covering all pertinent stakeholders: industry (large and smaller businesses), citizens and workers, third countries. These ratings have been aggregated from an analysis across 19 economic, social, and environmental impact categories (some of which were combined as they were interconnected), which were shortlisted for in-depth assessment as a result of a screening exercise summarised in Annex 2. Please note that, as set out in Section 4.4, two approaches and evidence bases were employed to assess the environmental impacts, which led to two sets of ratings as captured below.

Table 5-4 Overview of the economic, social, and environmental impacts for each Policy Scenario

Policy Scenario	Economic impacts	Social impacts	Environmental impacts	
			Option A (EU Commission evidence)	Option B (broader scientific evidence)
PS1 – Annex B listing broad exemptions	-0.5	-0.5	0	-0.5
PS2 – Annex B acceptable purpose exemption	-1	-1	0	-0.5

Policy Scenario	Economic impacts	Social impacts	Environmental impacts	
			Option A (EU Commission evidence)	Option B (broader scientific evidence)
PS3 – Annex A prohibition	**-2**	**-2**	**-0.5**	**-1**

Source: Ricardo analysis based on the evidence presented in this Study.

In conclusion, all policy scenarios appear to have a negative balance of economic, social and environmental impacts, no matter which option of the environmental impact assessment is selected. The scale of social and environmental impacts remains largely unknown and has required drawing on expert input building on the limited available evidence and opinion to develop conclusions. However, the estimated emissions abatement costs support this, as they appear to surpass substantially the highest abatement costs of any of the recent adopted REACH restrictions. **It should also be acknowledged that although policy scenario 1 appears to be a globalisation of the current and proposed REACH restrictions, it is more restrictive in reality, due to the additional conditions that are set on manufacturing, use and waste practices under the Stockholm Convention**.

5.3 BALANCE OF COSTS AND BENEFITS

The balance of costs and benefits to EU society provides additional insights into the merits of each policy scenario and how likely they are to contribute to addressing the problems outlined in this report (see Section 2.2), as well as meeting the EU's general objectives in a cost-effective way.

The impacts across the broad categories have, therefore, been grouped into social costs and benefits for a relatively more straightforward comparison of the options. Table 5-5 brings together the aggregated economic, social, and environmental impacts by policy scenario from a societal perspective, covering all pertinent stakeholders: industry (large and smaller businesses), citizens and workers, third countries. Again, two versions of the benefits are presented based on the two strands of the environmental assessment.

These ratings have been aggregated and re-calibrated from an analysis of 19 economic, social, and environmental impact categories (some of which were combined as they were interconnected) that were selected for in-depth assessment. Similar colour-coding is used, again, to refer to the direction (positive or negative) and size (small or large) of any expected impacts.

Table 5-5 Costs and benefits of the Policy Scenarios

Policy Scenario	Costs	Benefits		Benefit: Cost Ratio	
		Option A (EU Commission evidence)	Option B (Broader scientific evidence)	Option A (EU Commission evidence)	Option B (Broader scientific evidence)
PS1 – Annex B listing broad exemptions	-2.0	+0.5	<+0.5	0.3	0.2

Policy Scenario	Costs	Benefits		Benefit: Cost Ratio	
		Option A (EU Commission evidence)	Option B (Broader scientific evidence)	Option A (EU Commission evidence)	Option B (Broader scientific evidence)
PS2 – Annex B acceptable purpose exemption	-3.5	+1.0	+0.5	0.3	0.1
PS3 – Annex A prohibition	-5.0	+1.0	<+0.5	0.2	0.1

Source: Ricardo analysis based on the evidence presented in this Study.

In conclusion, the benefits of each of the policy scenarios under assessment are assessed to be lower, in scale, than the costs. The assessment has highlighted a range of costs that could be incurred across economic and social dimensions, and some costs concerning even environmental dimensions, such as resources, energy and climate. In addition, some potential benefits have been identified, associated with innovation and research (economic), the quality of natural resources and biodiversity (environmental), especially under Option A (Commission evidence presented in the draft Annex D report) of the environmental assessment. These benefits are considered to be of insufficient scale, which is represented by a benefit: cost ratio (BCR) lower than 1 across all policy scenarios, with a slightly lower BCR for PS2 and PS3[426].

5.4 CONCLUSIONS

Finally, the outputs of this assessment and comparison of impacts across three policy scenarios for the Stockholm Convention listing of D4, D5 and D6 suggest that:

- Achieving reductions in the emissions and/or the steady-state environmental stock of D4, D5 and D6 could require high abatement costs, many times over the highest values estimated from the recent REACH restrictions, which reflect current 'willingness to pay' for the reduction in emissions or the presence of persistent substances in the environment.
- All policy scenarios are likely to have an overall negative balance of economic, social, and environmental impacts and increasingly from PS1 to PS3. In addition, the negative impacts on economic and social dimensions could be significant, including billions of production activity and thousands of jobs lost in the EU when compared against the baseline.
- The overall benefits of the policy scenarios are assessed to be lower, in scale, than the costs, with Benefit: Cost Ratios estimated to be lower than one, and relatively lower for PS2 and PS3.

These conclusions would not support the adoption of any of the policy scenarios considered in this Study and would instead suggest that alternative measures should be explored and defined, which could achieve the zero-pollution objectives of the

[426] The sensitivity of the qualitative impact ratings and resulting benefit: cost ratios to the assumptions regarding costs of industrial transformation, emissions reductions, waste production and resource efficiency (described in Section 4.5) was tested and the benefit: cost ratios were observed to be less than 1 in all cases. These results are presented in Annex 4.

European Union whilst maintaining coherence with the broader European Green and Digital transition agenda.

Annexes

A1 ANNEX 1: REFERENCE RELIABILITY AND RELEVANCE SCORING

This section covers the methodology and the resulting reliability and relevance scoring applied to the references used in this assessment.

Methodology

A score has been applied to each source according to its reliability and relevance. Table _A 1 shows the methodology to apply a reliability score to each source of information to determine if the evidence should be used in this assessment.

Table _A 1 Methodology for the reliability scoring of evidence sources.

Criteria	Type of evidence	Scoring		
Test substance D4/5/6*	All types	**Score 1**	**Score 0**	
Published in peer reviewed journal or data referenced published in peer reviewed journal*	Journal articles, review papers, evaluations, opinions	If yes, or all data referenced comes from a peer reviewed journal or validated test method. **Score 1**	If no but majority of data referenced comes from a peer reviewed journal or validated test method. **Score 0.5**	Not published in peer reviewed journal, data referenced unpublished and not validated test method. **Score 0**
Methodology described (if reviewing test report of a validated test method the answer is yes as the test guideline is a published and full methodology)*	All types	**Score 1**	**Score 0**	
Methodology considered reliable/ reasonable (expert judgement)	All types	**Score 1**	**Score 0**	
Are the statistical methods for data analysis given and applied in a transparent manner	All types	**Score 1**	**Score 0**	
Validated test method used*	Test data (including tests referenced)	**Score 1**	**Score 0**	
Type of test	Test data (including tests referenced)	In vivo, **Score 1**	In vitro, **Score 0.75**	In silico, **Score 0.5**
GLP lab used	Test data (including tests referenced)	If yes, **Score 1**	If unknown, **Score 0.5**	If no, **Score 0**

Criteria	Type of evidence	Scoring		
Number of tests/ observations used to support conclusions (tests that support conclusion)	Journal articles, review papers, evaluations, opinions	If ≥2, **Score 1**	If 1, **Score 0.5**	**Unknown, Score 0**

These scores were then converted into three key categories as shown in Table _A 2.

Table _A 2 Conversion of the reliability scoring.

Final reliability score	Total score for Test reports	Total score all other evidence
1 - must meet all relevant * criteria	>5.5 to 7	>7 to 9
2 - must meet all relevant * criteria	>4 to 5.5	>5.5 to 7
3 - must meet all relevant * criteria	3 to 4	4 to 5.5
4 - **does not meet all * criteria**	n/a	n/a

Subsequently, the reliability score has been combined with a relevance score to produce a final 'evidence score' and determine whether a source should be included. The outputs are summarised in the Table _A 3 below.

Table _A 3 Calculation of final decision on evidence sources.

Relevance		Reliability			
		1	2	3	4
1	Directly evidences (supports or goes against) problem identified by the Commission	2 Use as evidence	3 Use as evidence with clear reasoning	4 Potentially can be used as evidence but needs justification	5 Should not be used unless clear justification
2	Indirectly evidences (provides insight to allow assessment but does not provide solid conclusion on its own) problem identified by the Commission	3 Use as evidence with clear reasoning	4 Potentially can be used as evidence but needs justification	5 Should not be used unless clear justification	6 Do not use as evidence
3	Does not relate to a problem identified by the Commission	4 Potentially can be used as evidence but needs justification	5 Should not be used unless clear justification	6 Do not use as evidence	7 Do not use as evidence

Scoring

Table _A 4 presents the references included in the problem definition with a score of 5 or below based on the scoring in Table _A 3.

Table _A 4 References and usability scores.

Reference	Usability score

Reference	Usability score
ECHA (2020) Background Document to the Opinion on the Annex XV dossier proposing restrictions on D4; D5 and D6. Available: https://echa.europa.eu/documents/10162/f148d6f2-4284-a3c1-fd08-8cdaddf73978	3 Use as evidence with clear reasoning
European Chemicals Agency (no date) Registration Dossier Octamethylcyclosiloxane. Available: Registration Dossier - ECHA (europa.eu) (last accessed 03.11.2023)	2 Use as evidence
Xu S. (2009a) Aerobic transformation of octamethylcyclotetrasiloxane (14C-D4) in aquatic sediment systems HES Study No. 10885-108	2 Use as evidence
Xu S. (2009b) Anaerobic transformation of octamethylcyclotetrasiloxane (14C-D4) in aquatic sediment systems. HES Study No. 11101-108	2 Use as evidence
D4 OECD Guideline 111. Hydrolisis. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
CERI (2007) Bioconcentration study of octamethylcyclotetrasiloxane (test item number K-1788) in carp. Study No 505113. Chemicals Evaluation & Research Institute (CERI). In Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Dow Corning (2007) 14C-Octamethylcyclotetrasiloxane (14C-D4): Dietary bioaccumulation in the rainbow trout (Oncorhynchus mykiss) under flow-through test conditions. Unpublished HES Study No. 10166-101, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	2 Use as evidence
CERI (2010) Bioconcentration study of octamethylcyclotetrasiloxane (test item number K-1788) in carp. Study No 505177. Chemicals Evaluation & Research Institute (CERI) (report in Japanese). In Registration Dossier - ECHA (europa.eu)	2 Use as evidence
D4 56 day NOEC, LOEC, EC50 Eisenia fetida OECD Guideline 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei)). Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
European Chemicals Agency (no date) Registration Dossier Decamethylcyclopentasiloxane. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
D5 OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems). Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
D5 OECD Guideline 111 (Hydrolysis as a Function of pH). Available: https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14807/5/2/3/?documentUUID=60ca12b5-bc22-468c-95db-a263e7d88ff5	2 Use as evidence
CERI (2010) Bioconcentration study of decamethylcyclopentasiloxane (test item number K-1842) in carp. Study No 505175. Chemicals Evaluation & Research Institute (CERI) (report in Japanese). In Registration Dossier - ECHA (europa.eu)	2 Use as evidence
D5 21-day Daphnia EC50, NOEC OECD Guideline 211 (Daphnia magna Reproduction Test). Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Lee RM (2009). Decamethylcyclopentasiloxane (D5) – Early life-stage test with rainbow trout (Oncorhynchus mykiss) following OECD Guideline #219 and OPPT draft Guideline 850.1400. Study No. 13937.6105, Springborn Smithers Laboratories, Massachusetts. Study submitted to CES (Centre Européen des Silicones, European Chemicals Industry Council (CEFIC)).	2 Use as evidence
Parrott J, Alaee M, Wang D and Sverko E (2010). Fathead minnow (Pimephales promelas) egg-to-juvenile exposure to decamethylcyclopentasiloxane (D5). Environment Canada, 10th December 2010.	3 Use as evidence with clear reasoning
Krueger HO, Thomas ST and Kendall TZ (2008) D5: A Prolonged Sediment Toxicity Test with Chironomus riparius using Spiked Sediment. Final Report, Project Number 570A-108, Wildlife International Ltd, Maryland. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	2 Use as evidence
Springborn Smithers (2009). 28-Day Toxicity Test Exposing Freshwater Amphipods (Hyalella 26odell) to D5 Applied to Sediment Under Static-Renewal Conditions Following	2 Use as evidence

Reference	Usability score
OPPTS Draft Guideline 850.1735. Unpublished Study No. 13937.6101. Springborn Smithers Laboratories, 790 Main Street, Wareham, Massachusetts. Available: Registration Dossier - ECHA (europa.eu)	
Stafford JM (2012) Japanese quail (Coturnix coturnix japonica) reproduction toxicity range-finding test with decamethylcyclopentasiloxane. Unpublished Study Number 12023.4101, Smithers Viscient Laboratory, Snow Camp, North Carolina. Study sponsor: Silicones Environmental Health and Safety Committee. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
D5 toxicity to soil macroorganisms except arthropods: long-term. OECD 222; Smithers Viscient (2015). Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Unnamed (2011). D5 Eisenia Andrei toxicity. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
European Chemicals Agency (no date) Registration Dossier Dodecamethylcyclohexasiloxane. Available: Registration Dossier - ECHA (europa.eu) (last accessed 03.11.2023)	3 Use as evidence with clear reasoning
OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems). Available: Registration Dossier - ECHA (europa.eu)	3 Use as evidence with clear reasoning
Kozerski G (2009). Estimation of the hydrolysis half-life of Dodecamethyl-cyclohexasiloxane (D6) (CAS No. 540-97-6) at pH 7.0 and 25°C. Dow Corning Corporation, Health and Environmental Sciences, Auburn, MI 48611, report number 11090-102.	4 Potentially can be used as evidence but needs justification
CERI (2010c) Test Report 2, 2, 4, 4, 6, 6, 8, 8, 10, 10, 12, 12-Dodecamethyl-cyclohexasiloxane. Chemicals Evaluation and Research Institute, Japan. In Registration Dossier - ECHA (europa.eu)	2 Use as evidence
D6 Fish 90 day NOEC Springborn Smithers (2009). Available: Registration Dossier - ECHA (europa.eu)	3 Use as evidence with clear reasoning
Drottar KR (2005) 14C-Dodecamethylcyclohexasiloxane (14C-D6): Bioconcentration in the Fathead Minnow (Pimphales promelas) under Flow-Through Test Conditions. Unpublished HES Study No. 9882-102. Auburg, MI: Health and Environmental Sciences, Dow Corning Corporation.	3 Use as evidence with clear reasoning
Springborn Smithers Laboratories (2006). Dodecamethylcyclohexasiloxane (D6): Full Lifecycle Toxicity Test with Water Fleas, Daphnia magna, under Static Renewal Conditions. Silicones Environmental, Health and Safety Council. Unpublished Study Number 12023.6149. Wareham, MA: Springborn Smithers Laboratories. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Dow Corning (2009). Dodecamethylcyclohexasiloxane (D6) (CAS Number 540-97-6): Toxicity to the Freshwater Alga (Pseudokirchneriella subcapitata) under closed bottle test conditions. Dow Corning Corporation. Health and Environmental Sciences (HES), Auburn, MI., USA. Unpublished HES Study No. 10743-102. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Wildlife International Limited (2009) D6: Prolonged sediment toxicity test with Chironomus riparius using spiked artificial sediment. Unpublished study. Project No. 570A-109B. Wildlife International, Ltd. 8598 Commerce Drive Easton, Maryland 21601, USA. In Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Springborn Smithers Laboratories (2010a). D6 – Sediment-Water Lumbriculus Toxicity Test using Spiked Sediment, Following OECD Guideline 225. Springborn Smithers Laboratories, 790 Main Street, Wareham, Massachusetts. Springborn Smithers Unpublished Study No. 13937.6109. Available: Registration Dossier - ECHA (europa.eu)	2 Use as evidence
Springborn Smithers Laboratories (2010b). D6 – Toxicity Test with Sediment-Dwelling Midges (Chironomus riparius) Under Static Conditions, Following OECD Guideline 218. Springborn Smithers Laboratories, 790 Main Street, Wareham, Massachusetts.,	2 Use as evidence

Reference	Usability score
Springborn Smithers Unpublished Study No. 13937.6108. Available: Registration Dossier - ECHA (europa.eu)	
European Commission (2023). EU proposal to list D4, D5 and D6 to the Stockholm Convention on POPs. [online] Available at: https://echa.europa.eu/documents/10162/63ce2062-0f0b-130f-3cb1-5c84071e7082.	3 Use as evidence with clear reasoning
ECHA (2018a) Support document for identification of octamethylcyclotetrasiloxane (D4) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: Annex XV report (europa.eu)	3 Use as evidence with clear reasoning
ECHA (2018b). Support document for identification of decamethylcyclopentasiloxane (D5) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: Annex XV report (europa.eu)	3 Use as evidence with clear reasoning
European Chemicals Agency (2018c) Support document for identification of dodecamethylcyclohexasiloxane (D6) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: Annex XV report (europa.eu)	3 Use as evidence with clear reasoning
European Chemicals Agency (2015) Persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7, CAS No: 556-67-2) and Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9, CAS No. 541-02-6). Annex 2-3	3 Use as evidence with clear reasoning
Environment Agency (2009a) Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane. Environment Agency Science Report, SCHO0309BPQZ-E-P, April 2009. ISBN 978-1-84911-031-0.	3 Use as evidence with clear reasoning
Environment Agency (2009b) Environmental risk evaluation report: Decamethylcyclopentasiloxane. Environment Agency Science Report SCHO0309BPQX-E-P, April 2009. ISBN 978-1-84911-029-7.	3 Use as evidence with clear reasoning
Environment Agency (2009c) Environmental risk evaluation report: Dodecamethylcyclohexasiloxane. Environment Agency Science Report SCHO0309BPQY-E-P, April 2009. ISBN 978-1-84911-030-3.	3 Use as evidence with clear reasoning
Chandra G (1997) Organosilicon materials. The Handbook of Environmental Chemistry, Volume 3 Anthropogenic Compounds, Part H. Berlin: Springer-Verlag	4 Potentially can be used as evidence but needs justification
Whelan MJ, van Egmond R, Gore D and Sanders D (2010) Dynamic multi-phase partitioning of decamethylcyclopentasiloxane (D5) in river water, Water Research 44, 3679–3686. https://doi.org/10.1016/j.watres.2010.04.029	3 Use as evidence with clear reasoning
Fackler PH, Dionne E, Hartley DA and Hamelink JL (1995) Bioconcentration by fish of a highly volatile silicone compound in a totally enclosed aquatic exposure system. Environ. Toxicol. Chem., 14, 1649-1656. https://doi.org/10.1002/etc.5620141004	2 Use as evidence
Krueger HO, Thomas ST and Kendall TZ (2008) Octamethylcyclotetrasiloxane (D4): A bioaccumulation test with Lumbriculus variegatus using spiked sediment. Final Report, Project Number: 570A-111, Wildlife International Ltd, Maryland. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	2 Use as evidence
Krueger HO, Thomas ST and Kendall TZ (2008) D5: A bioaccumulation test with Lumbriculus variegatus using spiked sediment. Final Report, Project Number: 583A-110, Wildlife International Ltd, Maryland. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	2 Use as evidence
Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2009c) Interim Report: Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in the aquatic marine food webs in inner and outer Oslofjord, Norway. Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	2 Use as evidence
Powell DE, Durham J, Huff DW, Böhmer T, Gerhards R and Koerner M (2010b). Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) materials in	2 Use as evidence

Reference	Usability score
the aquatic marine food webs of the inner and outer Oslofjord, Norway. HES Study No. 11060-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Unpublished Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	
CERI (2011). D4 and D5 Dietary Accumulation Study in Carp. Report 642-10-S-5608, Chemicals Evaluation & Research Institute (CERI) (report in Japanese). In Registration Dossier - ECHA (europa.eu)	3 Use as evidence with clear reasoning
Dow Corning (2006b). 14C-Decamethylcyclopentasiloxane (14C-D5): Dietary Bioaccumulation in the Rainbow Trout (Oncorhynchus mykiss) under Flow-Through Test Conditions. Unpublished HES Study No. 10057-108. Auburg, MI: Health and Environmental Sciences, Dow Corning Corporation.	2 Use as evidence
Borgå K, Fjeld E, Kierkegaard A and McLachlan M (2012). Food web accumulation of cyclic siloxanes in Lake Mjøsa, Norway. Environ. Sci. Technol., 46, 6347–6354.	4 Potentially can be used as evidence but needs justification
Borgå K, Fjeld E, Kierkegaard A and McLachlan M S (2013). Consistency in trophic magnification factors of cyclic volatile methyl siloxanes in pelagic freshwater food webs leading to brown trout. Environ. Sci. Technol., 47, 14394-14402.	4 Potentially can be used as evidence but needs justification
Sousa, J. V.; McNamara, P. C.; Putt, A. E.; Machado, M. W.; Surprenant, D. C.; Hamelink, J. L.; Kent, J. K.; Silberhorn, E. M.; Hobson, J. F. Effects of octamethylcyclotetrasiloxane (OMCTS) on freshwater and marine organisms. Environ. Toxicol. Chem. 1995, 14, 1639−1647.	3 Use as evidence with clear reasoning
Trac LN, Schmidt SN and Mayer P (2018). Headspace passive dosing of volatile hydrophobic chemicals – Aquatic toxicity testing exactly at the saturation level. Chemosphere, 211, 694–700.	3 Use as evidence with clear reasoning
Panagopoulos, D., & MacLeod, M. (2018). A critical assessment of the environmental fate of linear and cyclic volatile methylsiloxanes using multimedia fugacity models. Environmental Science: Processes & Impacts, 20(1), 183-194.	4 Potentially can be used as evidence but needs justification
Velicogna J, Ritchie E, Princz J, Lessard ME and Scroggins R (2012). Ecotoxicity of siloxane D5 in soil. Chemosphere, 87, 77-83.	2 Use as evidence
Norwood WP, Alaee M, Brown M, Galicia M and Sverko E (2010). Decamethylcyclopentasiloxane (D5) spiked sediment: Bioaccumulation and toxicity in the benthic invertebrate Hyalella azteca. Environment Canada, 22nd September 2010.	2 Use as evidence
McGoldrick, D. J., Chan, C., Drouillard, K. G., Keir, M. J., Clark, M. G., & Backus, S. M. (2014). Concentrations and trophic magnification of cyclic siloxanes in aquatic biota from the Western Basin of Lake Erie, Canada. Environmental pollution, 186, 141-148. https://doi.org/10.1016/j.envpol.2013.12.003	2 Use as evidence
Jia, H., Zhang, Z., Wang, C., Hong, W. J., Sun, Y., & Li, Y. F. (2015) Trophic transfer of methyl siloxanes in the marine food web from coastal area of northern China. Environmental Science & Technology, 49, 2833-2840. DOI: 10.1021/es505445e	2 Use as evidence
Lehmann R G, Varaprath S, and Frye C L. (1994). Degradation of silicone polymers in soil. Environmental Toxicology and Chemistry, 13, 1061–1064. Degradation of silicone polymers in soil - Lehmann - 1994 - Environmental Toxicology and Chemistry - Wiley Online Library	4 Potentially can be used as evidence but needs justification
ECHA (2018) Agreement of the MSC on the identification of octamethylcyclotetrasiloxane (D4) as a substance of very high concern because of its PBT and vPvB properties, Adopted on 13 June 2018. Available: 680ea46d-b626-1606-814e-62f843fe2750 (europa.eu)	2 Use as evidence
ECHA (2018) Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier proposing harmonised classification of OCTAMETHYLCYCLOTETRASILOXANE. Available: echa.europa.eu/documents/10162/2af6a9de-216c-dc41-859d-95aa8c9c14a7	2 Use as evidence
Krueger HO, Thomas ST and Kendall TZ (2009) D4: A prolonged sediment toxicity test with Lumbriculus variegatus using spiked artificial sediment. Project Number 570A-110B.	2 Use as evidence

Reference	Usability score
Wildlife International Ltd, Maryland. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC).	
Sierra Cornejo, N., Hertel, D., Becker, J. N., Hemp, A., & Leuschner, C. (2020) Biomass, morphology, and dynamics of the fine root system across a 3,000-m elevation gradient on Mt. Kilimanjaro, Frontiers in plant science, 11, 13. https://doi.org/10.3389/fpls.2020.00013 (Lower Reliab. Score as it doesn't refer specifically to cVMS, but used as it is closely related to the potential effect on soil organisms)	5 Should not be used unless clear justification
Norwegian Environment Agency and COWI (2017). Screening programme 2017 Testing laboratory: Not reported. Study No. M-1063. Report date: 2018 Available: M1063.pdf (miljodirektoratet.no)	2 Use as evidence
TemaNord (2005) Siloxanes in the Nordic Environment. TemaNord 2005:593, Nordic Council of Ministers, Copenhagen. Available from: https://www.norden.org/en/publication/siloxanes-nordic-environment	2 Use as evidence
Schlabach M, Andersen MS, Green N, Schøyen M and Kaj L (2007) Siloxanes in the environment of the Inner Oslofjord. Report 986/2007, Norwegian Pollution Control Authority, Oslo. https://www.nilu.no/wp-content/uploads/dnn/27-2007-msc.pdf	2 Use as evidence
Durham J, Leknes H, Huff D, Gerhards R, Boehmer T, Schlabach M, Green N, Campbell R and Powell D (2009) An inter lab comparison of cyclic siloxanes in codfish collected from the Oslo Fjord. Poster presented at the SETAC Europe 19th Annual meeting, 31 May-4th June 2009, Göteborg, Sweden. Available: An inter lab comparison of cyclic siloxanes in codfish collected from the Oslo Fjord. - NILU	3 Use as evidence with clear reasoning
Powell DE, Durham J, Kim J and Seston RM (2014) Interim report – trophic transfer of cyclic volatile methylsiloxanes (cVMS) and selected polychlorinated biphenyl (PCB) across the aquatic food web of Lake Champlain, USA. Unpublished HES Study No. 12349-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Sponsor CES (Centre Européen des Silicones).	2 Use as evidence
Picard C (2009) D4 – Sediment-water Lumbriculus toxicity test using spiked natural sediments, following OECD Guideline 225. 27 August 2009. Springborn Smithers Laboratories, Wareham, Massachusetts, Study No 13937.6013. Unpublished study submitted to CES 96 (Centre Européen des Silicones, European Chemicals Industry Council (CEFIC)).	2 Use as evidence
Gobas, F.A.P.C. and Lee, Y.-S. (2019). Growth-Correcting the Bioconcentration Factor and Biomagnification Factor in Bioaccumulation Assessments. Environ Toxicol Chem, 38: 2065-2072. DOI: 10.1002/etc.4509 (Lower Reliab. Score as it doesn't refer specifically to cVMS, but used as it is closely related as biochemical processes affecting degradation of highly hydrophobic organic compounds)	5 Should not be used unless clear justification
Selck H. and Forbes V. (2018). Current risk assessment frameworks misjudge risks of hydrophobic chemicals. Environmental Science & Technolgy 52, 1690-1692. (Lower Reliab. Score as it doesn't refer specifically to cVMS, but used as it is closely related as biochemical processes affecting degradation of highly hydrophobic organic compounds)	5 Should not be used unless clear justification
Selck, H., Windfeld, R., & Van Dinh, K. (2019). Biotransformation of benthic invertebrates impacts persistence and bioaccumulation of sediment-associated cyclic siloxanes (D4, D5, D6). In Society of Environmental Toxicology and Chemistry North America 40th Annual Meeting (pp. 91-91). Society of Environmental Toxicology and Chemistry.	3 Use as evidence with clear reasoning
Kim, J., Mackay, D., & Whelan, M. J. (2018). Predicted persistence and response times of linear and cyclic volatile methylsiloxanes in global and local environments. *Chemosphere*, *195*, 325-335.	2 Use as evidence
Gobas, F. A., Powell, D. E., Woodburn, K. B., Springer, T., & Huggett, D. B. (2015a). Bioaccumulation of decamethylpentacyclosiloxane (D5): A review. Environmental Toxicology and Chemistry, 34(12), 2703-2714.	2 Use as evidence
Gobas, F. A., Xu, S., Kozerski, G., Powell, D. E., Woodburn, K. B., Mackay, D., & Fairbrother, A. (2015b). Fugacity and activity analysis of the bioaccumulation and environmental risks of decamethylcyclopentasiloxane (D5). Environmental Toxicology and Chemistry, 34(12), 2723-2731.	2 Use as evidence

Reference	Usability score
Andersen, M. E., Reddy, M. B., & Plotzke, K. P. (2008). Are highly lipophilic volatile compounds expected to bioaccumulate with repeated exposures?. *Toxicology letters*, *179*(2), 85-92.	2 Use as evidence
Woodburn, K. B., Seston, R. M., Kim, J., & Powell, D. E. (2018). Benthic invertebrate exposure and chronic toxicity risk analysis for cyclic volatile methylsiloxanes: comparison of hazard quotient and probabilistic risk assessment approaches. *Chemosphere*, *192*, 337-347.	2 Use as evidence
Borgå K, Fjeld E, Kierkegaard A and McLachlan MS (2013b). Consistency in trophic magnification factors of cyclic volatile methyl siloxanes in pelagic freshwater food webs leading to brown trout. Environmental Science & Technology, 47, 14394 − -14402. Available from:	4 Potentially can be used as evidence but needs justification
Borgå K, Fjeld E, Kierkegaard A and McLachlan M (2012). Food web accumulation of cyclic siloxanes in Lake Mjøsa, Norway. Environ. Sci. Technol., 46, 6347–6354.	4 Potentially can be used as evidence but needs justification
Bridges, J., & Solomon, K. R. (2016). Quantitative weight-of-evidence analysis of the persistence, bioaccumulation, toxicity, and potential for long-range transport of the cyclic volatile methyl siloxanes. *Journal of Toxicology and Environmental Health, Part B*, *19*(8), 345-379.	2 Use as evidence
Mackay, D., Cowan-Ellsberry, C. E., Powell, D. E., Woodburn, K. B., Xu, S., Kozerski, G. E., & Kim, J. (2015). Decamethylcyclopentasiloxane (D5) environmental sources, fate, transport, and routes of exposure. Environmental toxicology and chemistry, 34(12), 2689-2702.	2 Use as evidence
Fairbrother, A., & Woodburn, K. B. (2016). Assessing the aquatic risks of the cyclic volatile methyl siloxane D4. Environmental Science & Technology Letters, 3(10), 359-363.	2 Use as evidence
Nusz, J. B., Fairbrother, A., Daley, J., & Burton, G. A. (2018). Use of multiple lines of evidence to provide a realistic toxic substances control act ecological risk evaluation based on monitoring data: D4 case study. Science of the Total Environment, 636, 1382-1395.	2 Use as evidence
Fairbrother, A., Burton, G. A., Klaine, S. J., Powell, D. E., Staples, C. A., Mihaich, E. M., ... & Gobas, F. A. (2015). Characterization of ecological risks from environmental releases of decamethylcyclopentasiloxane (D5). *Environmental Toxicology and Chemistry*, *34*(12), 2715-2722.	2 Use as evidence
Powell, D. E., Schøyen, M., Øxnevad, S., Gerhards, R., Böhmer, T., Koerner, M., ... & Huff, D. W. (2018). Bioaccumulation and trophic transfer of cyclic volatile methylsiloxanes (cVMS) in the aquatic marine food webs of the Oslofjord, Norway. Science of the total environment, 622, 127-139.	3 Use as evidence with clear reasoning
Powell, D.E., Woodburn, K.B., Drottar, K., Durham, J., and Huff, D.W. (2009a). Trophic dilution of cyclic volatile methylsiloxane (cVMS) materials in a temperate freshwater lake. Unpublished HES Study No. 10771-108, Health and Environmental Sciences, Dow Corning Corporation, Auburn. Study submitted to CES (Centre Européen des Silicones, European Chemical Industry Council (CEFIC)).	2 Use as evidence

A2 ANNEX 2: SUMMARY OF ANALYTICAL METHODS USED IN PREPARING THE ECONOMIC AND SOCIAL IMPACT ASSESSMENT SUPPORT STUDY

A2.1 OVERVIEW

This Annex provides a summary of the analytical methods employed in this impact assessment support study including for the mapping (168A2.2), and screening of impacts (168A2.3), the characterisation of the baseline (A2.4A2.4), the stakeholder consultation strategy (A2.5), the impacts assessment methodology(A2.6), and the policy scenario comparison (A2.7)

A2.2 MAPPING OF IMPACTS

The potential impacts of each policy measure or groups of similar measures have been mapped employing impact pathway and theory of change approaches. These potential impacts have been being categorised in line with the Better Regulation Guidelines Tools #18 (identification of impacts) and #56 (typology of costs and benefits)[427]. This mapping exercise produced a longlist of 34 potential impacts from the adoption of the policy scenarios.

[427] European Commission (2021) Better Regulation Toolbox. URL: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox/better-regulation-toolbox-0_en#relatedlinks

Table _A 5 Mapping of impacts

#	**Potential impacts of the policy scenarios (a draft)**	Specific impact category	Primary broad nature of impact	Affected parties	Relation with underlying initiative	Frequency	Likelihood
1	PS1) Annex B broad exemption polymers: withdrawal of non-polymer and polymers with conc. D4/5/6 >0.1% w/w products, substitute/reformulate, R&D, capex, opex and other implications of product restrictions PS2) Annex B exemption specific uses of polymers: Similar types of potential impact PO1 PS3) Annex A prohibition: Similar types of potential impact PO1 but covers all products containing or using D4/5/6	i. Conduct of business (e.g., withdrawal of substances, developing substitutes, reformulating products, adapting production processes, cost avoidance through reduction in sick leave, etc.)	Economic	Enterprises	Both	One-off and recurring	High
2	PS1, 2) Updating dossiers, proposals, Safety Data Sheets, transport admin requirements (Rotterdam) etc, Compliance checks and controls (especially when entering the EU market) PS3) registrations of new products/ update of existing non D4/5/6 registrations	ii. Administrative burdens on businesses (e.g., updating the Registration Dossiers, training staff, administrative adjustments to new provisions, transport administrative requirements etc.)	Economic	Enterprises	Direct	One-off	High
3	PS1-PS3) These options can have a disproportionate impact on the cost base of SMEs (SME test)	iii. Position of SMEs (additional costs or burden on smaller businesses; SME test)	Economic	Enterprises/ SMEs	Both	One-off and recurring	Medium
4	PS1-PS3) Direct restrictions may result in an increasing pressure to increase specific investments in finding and developing alternatives; however, potentially worse business prospects could have the opposite effect on overall investment by companies in the EU-27	iv. Innovation and research (e.g., effects on research and development, new production methods, alternative methods to animal testing, identification and analysis of nanomaterials, etc.)	Economic	Enterprises	Indirect	One-off	High
5	PS1 - PS3) could have significant implications on the costs of doing business, which could affect competitiveness of all relevant sectors	v. Sectoral competitiveness, trade and investment flows (e.g., costs of doing business, capacity to innovate, market share impacts, etc.)	Economic	Enterprises	Indirect	One-off and recurring	Medium
6	PS1-PS3) could affect the free movement of goods and services and, in particular, restrict it	vi. Functioning of the internal market and competition (e.g., free movement of goods and services, reduction in consumer choice, etc.)	Economic	All parties	Indirect	One-off and recurring	Medium

#	Potential impacts of the policy scenarios (a draft)	Specific impact category	Primary broad nature of impact	Affected parties	Relation with underlying initiative	Frequency	Likelihood
7	PS1 - PS3) would likely lead to increased administrative activity by public authorities, increased enforcement requirements, data management, etc.	vii. Public authorities and budgets (e.g., changes to the administrative activity carried out by public authorities from increased requirements as well as the alignment and potential synergies with other legislation, financial and human resources, etc.)	Economic	Public authorities	Direct	One-off	High
8	PS1-PS3) could incentivise the production of more sustainable products, albeit evidence may be limited as to the extent to which this might happen. potential disruption to key sectors and use of less environmentally friendly alternatives	viii. Sustainable consumption and production (e.g., effects on the relative prices of environmentally friendly versus unfriendly products and the transition to safe and sustainable chemicals)	Economic	All stakeholders	Indirect	One-off and recurring	Medium
9	PS1-PS3) could have positive effects on the availability of resources such as fish and land, etc.	ix. Efficient use of resources (e.g., effects on the availability and use of resources such as fish, wood, etc.)	Economic	All stakeholders	Indirect	One-off and recurring	Low
10	PO1-3) EU requirements may have spillover effects onto third countries: 1) supply chain effects -adjustments may be required/costs; 2) goods consumed may also evolve if the EU chemicals sector also adjusts their exports	x. Third countries, developing countries, and international relations (e.g., effects on adjustment costs in developing countries or goods and services produced or consumed, etc.	Economic	Global citizens	Both	One-off and recurring	High
11	PS1 - PS3) Potential changes in product availability, prices and quality	xi. Capital movements; financial markets; stability of the euro	Economic	Consumers	Indirect	One-off and recurring	Medium
12	PS1 - PS3) Potential changes in product availability, prices and quality	xii. Consumers and households (e.g., effects on consumers' ability to access goods and services, their prices, quality, etc.)	Social	Consumers	Indirect	One-off and recurring	Medium

#	**Potential impacts of the policy scenarios (a draft)**	Specific impact category	Primary broad nature of impact	Affected parties	Relation with underlying initiative	Frequency	Likelihood
13	PS1-PS3) Restrictions in use/manufacture of potentially harmful products would reduce exposure and, thus, potentially benefit human health in the EU PS1-PS3) Impacts on public health would have knock-on implications on EU health systems NB 1) reduction in disease/mortality; 2) increase in years of live lived, which could also lead to increases in probability of disease and associated burden later in life. These effects would be considered.	xiii. Public health & safety and health systems (e.g., health and safety of individuals/populations as captured by their life expectancy, mortality (YLL) and/or morbidity (YLD), etc.)	Social	EU residents, enterprises	Direct	Recurring	Low
14	PS1- PS3) limited impact	xiv. Governance, participation and good administration (e.g., public is more/less informed, access to information)	Social	All stakeholders	Indirect	Recurring	low
15	PS1-PS3) limited impact on culture	xv. Culture (e.g., effects on preserving cultural heritage, etc.)	Social	All stakeholders	indirect	Recurring	low
16	PS1-PS3) Unclear effects on employment. On the one hand, more regulatory requirements lead to more employment needs, but increases in regulatory costs put pressure on businesses to increase their efficiency, which could lead to employment reductions	xvi. Employment (e.g., new jobs created or lost, etc.)	Social	EU residents	Both	Recurring	Medium
17	PS1- PS3) limited impact	xvii. Property rights; intellectual property rights	Social	EU residents	indirect	Recurring	low
18	PS1- PS3) limited impact	xviii. Fundamental rights	Social	EU residents	indirect	Recurring	low
19	PS1- PS3) limited impact	xix. Working conditions, job standards, and quality	Social	EU residents	indirect	Recurring	low
20	PS1- PS3) limited impact	xx. Food safety, food security and nutrition	Social	EU residents	indirect	Recurring	low
21	PS1- PS3) potential for relocation of silicone polymer industries outside of EU	xxi. Resilience, technological sovereignty, open strategic autonomy, security of supply	Social	EU residents	direct	Recurring	medium
22	PS1- PS3) limited impact	xxii. Fraud, crime, terrorism, and security, including hybrid threats	Social	EU residents	indirect	Recurring	low

#	**Potential impacts of the policy scenarios (a draft)**	Specific impact category	Primary broad nature of impact	Affected parties	Relation with underlying initiative	Frequency	Likelihood
23	PS1- PS3) limited impact	xxiii. Education and training, education, and training systems	Social	EU residents	indirect	Recurring	low
24	PS1- PS3) limited impact	xxiv Income distribution, social protection, and social inclusion (of particular groups)	Social	EU residents	indirect	Recurring	low
25	PS1- PS3) potential disruption to semiconductor and glass fibre production impacting wider electronics	xxv Technological development / digital economy	Social	EU residents	direct	Recurring	medium
26	PS1- PS3) limited impact	xxvi Climate	Environmental	All stakeholders	Indirect	Recurring	Medium
27	PS1-PS3) Reduction in the manufacture/use of D4/5/6 may lead to reduced releases to air, water and soil and thus improve their quality	xxvii Quality of natural resources (water, soil, air)	Environmental	All stakeholders	Direct	Recurring	Medium
28	PS1-PS3) Changes to environmental exposure to D4/5/6 through the use/disposable of waste into the environment could affect the survival of fauna and flora, and thus, biodiversity	xxviii Biodiversity, including flora, fauna, ecosystems and landscapes	Environmental	All stakeholders	Direct	Recurring	Medium
29	PS1-PS3) Changes to environmental exposure to D4/5/6 through the use/disposable of waste into the environment could affect the health of animals and, therefore, their welfare	xxix. Animal welfare (e.g., impact on the health of animals from testing, impact on outdoor animals from environmental exposure, etc.)	Environmental	All stakeholders	Indirect	Recurring	Low
30	PS1-PS3) Changes manufacture/use of chemicals could affect the waste generated during manufacture and the disposal of products	xxx. Waste production, generation, and recycling	Environmental	All stakeholders	Direct	Recurring	Medium
31	PS1- PS3) limited impact	xxxii Efficient use of resources (renewable and non-renewable)	Environmental	All stakeholders	Indirect	Recurring	Medium
32	PS1- PS3) limited impact	xxxiii Land use	Environmental	All stakeholders	Indirect	Recurring	Low
33	PS1- PS3) limited impact	xxxiv The likelihood or scale of environmental risk	Environmental	All stakeholders	Indirect	Recurring	Medium
34	PS1- PS3) potential disruption to the low-carbon energy sector	xxxv Transport and the use of energy	Environmental	All stakeholders	Indirect	Recurring	Medium

A2.3 SCREENING OF IMPACTS

The affected stakeholders for each of these specific impact categories, the underlying relationships with the initiative and the frequency and certainty of impact were also identified. Based on this, the available evidence and expert opinion, a screening exercise was performed to identify the most significant impacts for in-depth assessment across all policy scenarios, to enable a proportionate approach for the assessment of impacts.

The screening exercise has been primarily qualitative, based on the evidence available at early stages of the project and reviewed periodically, and following the Better Regulation Guidelines[428]. Each specific impact category has been scored across the following dimensions using different qualitative scales: the expected magnitude of potential impact (-5 - +5 score, where the sign reflects the direction of impact, whilst the number reflects the scale of impact); the likelihood of impact (0 - +3 score, where a higher number reflects a higher likelihood); and the importance of impact against EC's objectives (0 - +3 score, where a higher number reflects a higher importance). The Table below provides more detail.

Table _A 6 Impact screening approach

Criteria	Guidance
1 -Affected stakeholders	Select primary stakeholders affected by the impact of the/group of measure/s. • All stakeholders • Public authorities • All businesses • Businesses: Industry • Businesses: SME • Businesses: Supply chain • EU citizens • (Global citizens)
2.1 -Absolute impact: magnitude	• Select qualitatively per type of impact: • None (0) • Low (1) • Low/Medium (2) • Medium (3) • Medium/high (4) • High (5) These are considered as follows:

[428] Ibid

Criteria	Guidance
	• High: Widespread and deep effects on the EU's social and economic wellbeing, whether affecting the majority of EU residents, businesses and other actors or some of these actors in a very significant way (e.g., a transformative legislation that would increase standards for manufacturing, using and/or selling all chemicals in the EU-27 would fit in this category). • Medium: Substantial/ transformational impact on a small group of stakeholders or marginal/ small impact on a wide range of stakeholders across the EU. • Low: Marginal or small impact on a small group of stakeholders or limited impact on a wide range of stakeholders. • None: No impact expected with a high level of certainty.
2.2 -Absolute impact: likelihood	Select qualitatively per type of impact: • None (0) • Low likelihood (1) • Medium likelihood (2) • High likelihood (3) These are considered as follows: • High: Evidence points to the impact materialising in the scale identified with a high level of certainty (e.g., >75% chance) • Medium: Evidence is unclear that the impact would materialise in the scale identified although it is likely (e.g., ~ 50% chance) • Low: Evidence is limited, and the impact may not materialise at all or is unlikely to materialise in the scale identified (e.g., <25% chance). • Note: Certain (or almost certain) that the impact identified will not materialise.
2.3 -Absolute impact: direction	Select qualitatively per type of impact: • Positive • Negative • None • Unclear Note: Positive should contribute towards EU objectives, efficiency, productivity, etc. Whereas negatives do not contribute to EU objectives, increase costs or negatively affect business

Criteria	Guidance
	opportunities or people's life chances (e.g., health, employment, etc.)
3.1 -Relative impact: Disproportionately affected stakeholder group	Select the stakeholder that may be affected disproportionately if any: [From list of stakeholders] Note: These should highlight the group of stakeholders that will be significantly affected even if the overall impact is low.
3.2 -Relative impact: likelihood	Select qualitatively per type of impact: • Low likelihood (1) • Medium likelihood (2) • High likelihood (3)
3.3 -Relative impact: direction	Select qualitatively per type of impact: • Positive • Negative • None • Unclear
4 -Relationship	Select qualitatively per type of impact: • Direct • Indirect • Both
5 -Relevance	Select qualitatively per type of impact: • None • Low • Medium • High These are considered as follows: • High: all of the impact identified is intended and aligned with the objectives. • Medium: a major part of the impact identified is intended and somewhat aligned with the objectives. • Low: a small part of the impact identified against a given category is intended and somewhat aligned with the objectives. • None: the impact identified against a given category is not intended.

In general, an impact category with medium level of negative or positive impact (-2/+2 score or a higher scale negative or positive), with a medium or higher level of likelihood and would be selected for more in-depth assessment (e.g., the conduct of business is very likely to be affected significantly, especially in the cosmetics industry).

First, key economic, environmental, and social impacts that could arise from the implementation of the policy scenarios selected by Cefic were identified, based on Tool #18 of the Commission's Better Regulation Guidelines. Secondly, our chemical policy, economics and (eco)toxicology experts employed their understanding of the available evidence to develop a shortlist to be used for in-depth assessment. The shortlist comprises of the following 19 impact categories. A more detailed assessment underpinning this list is presented in the following Table.

- Conduct of business
- Administrative burdens on businesses
- Position of SMEs (SME test)
- Innovation and research
- Sectoral competitiveness, trade and investment flows
- Functioning of the internal market and competition
- Sustainable consumption and production
- Third countries
- Consumers and households
- Employment
- Technological development / digital economy
- Climate
- Quality of natural resources (water)
- Quality of natural resources (soil)
- Quality of natural resources (air)
- Biodiversity, including flora, fauna, ecosystems and landscapes
- Waste production, generation, and recycling
- Efficient use of resources (renewable and non-renewable)
- Transport and the use of energy

These 19 categories were taken forward for a more in-depth assessment of the impacts, costs and benefits of each policy scenario.

Table _A 7 Screening of impacts based on available evidence and expert opinion

#	Primary broad nature of impact	Specific impact category	Affected parties	Relevance for specific parties	**Magnitude of potential impact** (-5,5)	Likelihood	**Importance against EU objectives** (0,3)	**Most significant?** (Yes/No)
1	Economic	i. Conduct of business (e.g., withdrawal of substances, developing substitutes, reformulating products, adapting production processes, cost avoidance through reduction in sick leave, etc.)	Enterprises	SMEs	-4	3	2	Yes
2	Economic	ii. Administrative burdens on businesses (e.g., updating the Registration Dossiers, training staff, administrative adjustments to new provisions, transport administrative requirements etc.)	Enterprises	SMEs	-3	3	2	Yes
3	Economic	iii. Position of SMEs (additional costs or burden on smaller businesses; SME test)	Enterprises/ SMEs	SMEs	-3	3	2	Yes
4	Economic	iv. Innovation and research (e.g., effects on research and development, new production methods, alternative methods to animal testing, identification and analysis of nanomaterials, etc.)	Enterprises	SMEs	2	3	2	Yes
5	Economic	v. Sectoral competitiveness, trade and investment flows (e.g., costs of doing business, capacity to innovate, market share impacts, etc.)	Enterprises	SMEs	-3	3	2	Yes

#	Primary broad nature of impact	Specific impact category	Affected parties	Relevance for specific parties	**Magnitude of potential impact** (-5,5)	Likelihood	**Importance against EU objectives** (0,3)	**Most significant?** (Yes/No)
6	Economic	vi. Functioning of the internal market and competition (e.g., free movement of goods and services, reduction in consumer choice, etc.)	All parties	SMEs	-2	2	1	Yes
7	Economic	vii. Public authorities and budgets (e.g., changes to the administrative activity carried out by public authorities from increased requirements as well as the alignment and potential synergies with other legislation, financial and human resources, etc.)	Public authorities	Public authorities	0	3	0	No
8	Economic	viii. Sustainable consumption and production (e.g., effects on the relative prices of environmentally friendly versus unfriendly products and the transition to safe and sustainable chemicals)	All stakeholders	N/a	-3	2	2	Yes
9	Economic	ix. Efficient use of resources (e.g., effects on the availability and use of resources such as fish, wood, etc.)	All stakeholders	N/a	0	1	1	No
10	Economic	x. Third countries, developing countries, and international relations (e.g., effects on adjustment costs in developing countries or goods and services produced or consumed, etc.	Global citizens	N/a	-2	2	2	Yes
11	Economic	xi. Capital movements; financial markets; stability of the euro	Consumers	N/a	-1	3	1	No
12	Social	xii. Consumers and households (e.g., effects on consumers' ability to access goods and services, their prices, quality, etc.)	Consumers	N/a	-4	2	2	Yes

#	Primary broad nature of impact	Specific impact category	Affected parties	Relevance for specific parties	**Magnitude of potential impact** (-5,5)	Likelihood	**Importance against EU objectives** (0,3)	**Most significant?** (Yes/No)
13	Social	xiii. Public health & safety and health systems (e.g., health and safety of individuals/populations as captured by their life expectancy, mortality (YLL) and/or morbidity (YLD), etc.)	EU residents, enterprises	N/a	0	0	0	No
14	Social	xiv. Governance, participation and good administration (e.g., public is more/less informed, access to information)	All stakeholders	N/a	0	0	0	No
15	Social	xv. Culture (e.g., effects on preserving cultural heritage, etc.)	All stakeholders	N/a	0	0	0	No
16	Social	xvi. Employment (e.g., new jobs created or lost, etc.)	EU residents	N/a	-4	2	1	Yes
17	Social	xvii. Property rights; intellectual property rights	EU residents	N/A	0	0	0	No
18	Social	xviii. Fundamental rights	EU residents	N/a	0	0	0	No
19	Social	xix. Working conditions, job standards, and quality	EU residents	N/a	0	0	0	No
20	Social	xx. Food safety, food security and nutrition	EU residents	N/a	-1	1	1	No
21	Social	xxi. Resilience, technological sovereignty, open strategic autonomy, security of supply	EU residents	N/a	-1	1	3	No

#	Primary broad nature of impact	Specific impact category	Affected parties	Relevance for specific parties	**Magnitude of potential impact** (-5,5)	Likelihood	**Importance against EU objectives** (0,3)	**Most significant?** (Yes/No)
22	Social	xxii. Fraud, crime, terrorism, and security, including hybrid threats	EU residents	N/a	0	0	0	No
23	Social	xxiii. Education and training, education, and training systems	EU residents	N/a	0	0	0	No
24	Social	xxiv Income distribution, social protection, and social inclusion (of particular groups)	EU residents	N/a	0	0	0	No
25	Social	xxv Technological development / digital economy	EU residents	N/a	-1	2	3	Yes
26	Environmental	xxvi Climate	All stakeholders	N/a	-2	2	3	Yes
27	Environmental	xxvii Quality of natural resources (water, soil, air)	All stakeholders	N/a	2	2	3	Yes
28	Environmental	xxviii Biodiversity, including flora, fauna, ecosystems and landscapes	All stakeholders	N/a	2	2	3	Yes
29	Environmental	xxix. Animal welfare (e.g., impact on the health of animals from testing, impact on outdoor animals from environmental exposure, etc.)	All stakeholders	N/a	1	1	1	No
30	Environmental	xxx. Waste production, generation, and recycling	All stakeholders	N/a	-3	2	2	Yes

#	Primary broad nature of impact	Specific impact category	Affected parties	Relevance for specific parties	**Magnitude of potential impact** (-5,5)	Likelihood	**Importance against EU objectives** (0,3)	**Most significant?** (Yes/No)
31	Environmental	xxxii Efficient use of resources (renewable and non-renewable)	All stakeholders	N/a	-3	1	2	Yes
32	Environmental	xxxiii Land use	All stakeholders	N/a	0	0	0	No
33	Environmental	xxxiv The likelihood or scale of environmental risk	All stakeholders	N/a	0	0	0	No
34	Environmental	xxxv Transport and the use of energy	All stakeholders	N/a	-3	2	2	Yes

Justification for screening out public health and safety and health systems from social impacts

Reproductive Effects

Octamethylcyclotetrasiloxane (D4) has a harmonised classification under the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) of Repr. 2 H361f (suspected of damaging fertility). This effect and classification is based on studies in male and/or female Sprague-Dawley rats in which animals were exposed by whole-body vapour inhalation to D4 at concentrations of 70 – 700 ppm (6 hours/day, 7 days/week). Exposure in these studies began 28 or 70 days prior to mating. Exposure in females continued throughout gestation and lactation in some studies. Female rats exposed to concentrations at or above 500 ppm showed statistically significant decreases in the number of corpora lutea, number of uterine implantation sites, total number of pups born, and mean live litter size. No effects on fertility were observed during the ovarian or implantation phases, suggesting that the effects occur during the three days before and after mating. The effect is considered to be reversible. The No Observed Adverse Effect Level (NOAEL) for this effect is 300 ppm derived from a two-generation study that showed a reduction in live litter size at around 10% or less compared to controls. Experts were of the opinion that this effect and mechanism could be relevant to human health. The effects of D4 on fertility via oral or dermal routes have not been studied[429].

However, the proposed mechanism for the observed reproductive toxicity of D4 in female rats is the induction of a delay or blockage of the LH surge which is necessary for the optimal timing of ovulation. This mechanism is supported by various studies[430,431] and is related to the observation of uterine adenomas in the rat. An insufficient or blocked pre-ovulatory LH surge fails to induce complete ovulation in the rat and results in the observed effects on fertility. However, the current understanding of oestrous cyclicity as well as neural and hormonal regulation of ovulation in humans suggests that the effects of D4 on fertility, as observed in the rat, are unlikely to be relevant to humans[432,433]. While analogous pathways control ovulation in both rats and humans, there are significant differences in the mechanism for timing and release of LH which results in changes in the control of ovulation and mating behaviour between the two species. As D4 exposure is considered to cause a delay to the LH surge in rats as opposed to prolonged suppression or ablation of the surge, the mode of action is likely to not be relevant to humans[434,435].

As such, despite this harmonised classification, this health effect has not been considered in the health benefits assessment as it is believed that there is likely to be no measurable impact on fertility or subsequent benefit to healthcare systems. This is because the mechanism of action shown by female rats exhibiting fertility effects is widely considered by other experts to not be relevant to human health.

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[429] Ibid footnote 50

[430] Quinn et al., (2007) Effects of octamethylcyclotetrasiloxane (D4) on the luteinizing hormone (LH) surge and levels of various reproductive hormones in female Sprague–Dawley rats, Reproductive Toxicology, 4, 532-540. https://doi.org/10.1016/j.reprotox.2007.02.005

[431] Wolfgang Dekant, Anthony R. Scialli, Kathy Plotzke, James E. Klaunig, Biological relevance of effects following chronic administration of octamethylcyclotetrasiloxane (D4) in Fischer 344 rats, Toxicology Letters, 2017, 279, 42-53. https://doi.org/10.1016/j.toxlet.2017.01.010

[432] Ibid footnote 245

[433] Robinan Gentry, Allison Franzen, C. Van Landingham, Tracy Greene, Kathy Plotzke (2017) A global human health risk assessment for octamethylcyclotetrasiloxane (D4), Toxicology Letters, 279, 23-41. https://doi.org/10.1016/j.toxlet.2017.05.019

[434] Tony M Plant (2012) A comparison of the neuroendocrine mechanisms underlying the initiation of the preovulatory LH surge in the human, Old World monkey and rodent, Frontiers in Neuroendocrinology, 33, 160-168. https://doi.org/10.1016/j.yfrne.2012.02.002

[435] Ibid footnote 240

No adverse effects on fertility or reproduction have been observed in repeated-dose studies considering decamethylcyclopentasiloxane (D5) or dodecamethylcyclohexasiloxane (D6)[436,437,438].

Liver hypertrophy

Liver hypertrophy has been consistently observed in rat studies considering D4 and D5 exposure via inhalation and is considered to be one of the most sensitive indicators of exposure. However, the mechanism of action which causes this effect is not considered to be relevant to humans and so has no impact on human health. It has therefore not been considered in the health benefits assessment.

The liver hypertrophy is thought to be the result of significant P450 induction (CYP 2B1/2B2) (phenobarbital-like) in rodents and is fully reversible upon cessation of exposure. No immune system alterations have been observed alongside the liver enlargement, nor was there any overt hepatotoxicity. It is therefore considered to be an adaptive response[432,439,440,441,442.]

Carcinogenicity, genotoxicity and mutagenicity

Uterine endometrial adenocarcinomas have been observed in studies in F344 rats assessing chronic exposure to D5. The mode of action is thought to be caused by alterations in the oestrous cycle in the aging F344 rat, with this alteration being caused by a decrease in progesterone with an increase in the oestrogen: progesterone ratio which is most likely induced by a decrease in prolactin concentration. Available data support that exposure to D5 influences prolactin concentration. The available data support the conclusion that D5 is acting via a dopamine receptor agonist-like mechanism to alter the pituitary control of the oestrous cycle. Studies in F344 aged rats have also shown that the effects of D5 on oestrous cyclicity produced a response consistent with a dopamine-like effect and further suggest that D5 is accelerating the aging of the reproductive endocrine system in the F344 rat utilized in this study[443,444]. This mode of action for uterine endometrial adenocarcinoma tumorigenesis is therefore considered to be not relevant for humans and thus has not been considered in the health benefits assessment.

D4 and D6 are not considered to be carcinogenic in animals. D4, D5 or D6 are not considered to exert genotoxic or mutagenic effects.

Respiratory effects

Human volunteers exposed to vapours of D4 for 1-hour via the mouth showed no changes in lung function and no inflammatory effect was observed[435]. Inhalation exposure to D4 in rats for 24 months produced changes in the nasal epithelium. However, despite 24 months of exposure, only mild to minimal inflammatory responses were found at 150 ppm, and the basic integrity of the respiratory

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[436] Ibid footnote 50

[437] Ibid footnote 250

[438] Wolfgang Dekant, James E. Klaunig (2016) Toxicology of decamethylcyclopentasiloxane (D5), Regulatory Toxicology and Pharmacology, 74, S67-S76. https://doi.org/10.1016/j.yrtph.2015.06.011

[439] P. C. Klykken, T. W. Galbraith, G. B. Kolesar, P. A. Jean, M. R. Woolhiser, M. R. Elwell, L. A. Burns-Naas, R. W. Mast, J. A. Mccay, K. L. White Jr & A. E. Munson (1999) Toxicology and Humoral Immunity Assessment of Octamethylcyclotetrasiloxane (D4) Following a 28-day whole body Vapor Inhalation Exposure in Fischer 344 Rats, Drug and Chemical Toxicology, 22, 655-677. DOI: 10.3109/01480549908993174

[440] James M. McKim, Jr., Paul C. wilga, Gary B. Kolesar, Supratim Choudhuri, Ajay Madan, Leland W. Dochterman, John G. Breen, Andrew Parkinson, Richard W. Mast, Robert G. Meeks (1998) Evaluation of Octamethylcyclotetrasiloxane (D4) as an Inducer of Rat Hepatic Microsomal Cytochrome P450, UDP-Glucuronosyltransferase, and Epoxide Hydrolase: A 28-Day Inhalation Study, Toxicological Sciences,41, 29-41. https://doi.org/10.1093/toxsci/41.1.29

[441] Ibid footnote 439

[442] Ibid footnote 247

[443] James E. Klaunig, Wolfgang Dekant, Kathy Plotzke, Anthony R. Scialli (2016) Biological relevance of decamethylcyclopentasiloxane (D5) induced rat uterine endometrial adenocarcinoma tumorigenesis: Mode of action and relevance to humans, Regulatory Toxicology and Pharmacology, 74, S44-S56. https://doi.org/10.1016/j.yrtph.2015.06.021

[444] Workplace Environmental Exposure Level (2017) Decamethylcyclopentasiloxane, Toxicology and Industrial Health, 33, 16-27. https://doi.org/10.1177/0748233716670064

tract was unchanged at this dose[445]. Repeated oral, inhalation or dermal exposure to D4 is not considered to cause serious damage to health[446].

Inhalation studies in rats assessing nose-only exposure of D5 showed slight local effects on the respiratory tract and liver weight increases. The changes observed in the liver were reversible. An increase was observed in absolute and relative lung weights, which remained elevated in females after the recovery phase. In a 28-day study, D5 exposure also resulted in an increase in incidence and severity of goblet cell proliferation in the nasal cavity in male and female rats at concentrations of 160 ppm. A No Observed Adverse Effect Concentration (NOAEC) of 10 ppm was derived for this study based on local effects in the respiratory tract[438,447]. Repeated oral, inhalation (at concentrations up to the maximum reproducible vapour pressure of approximately 160 ppm) or dermal exposure is however not considered to cause serious damage to health[442].

Exposure to D6 in a sub-chronic toxicity study carried out in Sprague-Dawley rats showed increased incidence and severity of subacute inflammation and hyperplasia of nasal tissues at the mid and high dose levels (10 and 30 ppm), resulting in a NOAEC of 1 ppm being derived based on local effects in nasal tissues. Effects in the liver and lung were also observed in this study, however they were fully resolved 28 days post-exposure. Due to the conditions used in the study (whole-body exposure, 6 hours/day, 7 days/week) these effects can be considered unlikely to be relevant to humans due to the unlikeliness of replicating these conditions. The effect is considered to be a local effect caused by prolonged contact with vapours and repeated exposure to D6 orally or via inhalation is not expected to cause serious damage to health[437].

The local and respiratory effects observed in these studies are not considered relevant to human health as the dose levels and/or conditions used in the studies in rats are not considered to be reproducible through normal human exposure, nor are local effects in the nasal cavity considered to cause a serious risk to health. Therefore, this effect has not been considered in the health benefits assessment.

Justification for screening out Public authority impacts

The Union level implementation and coordination of the Stockholm Convention is managed by ECHA. Administrative costs borne by the EU Commission and its Agencies related to the implementation of a Stockholm Convention listing for a specific substance into the EU POPs Regulation are limited to the preparation and development of the dossiers to support nomination. This involves the comprehensive evaluation of the risk to human health and the environment from the substance of concern. ECHA also has a coordination role to ensure that Member State reports are compiled in a harmonised format and reported in the Union Overview report. Such reports cover the implementation of the POPs Regulation as a whole and are not substance specific. In the Commission Proposal for a recast of the POPs Regulation it was estimated that the costs to ECHA of POPs Regulation related activities would be €0.269 million and €0.163 million in 2019 and 2020 respectively (see table x). The higher costs in 2019 were expected as a result of the recast of the POPs Regulation and the need to set up an IT system to allow for harmonised reporting of the Member States, with costs expected to stabilise in the following years.[448]

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[445] Workplace Environmental Exposure Level (2017) Octamethylcyclotetrasiloxane, Toxicology and Industrial Health, 33, 2-15. https://doi.org/10.1177/0748233716670061

[446] Ibid footnote 242

[447] Leigh Ann Burns-Naas, Richard W. Mast, Robert G. Meeks, Peter C. Mann, Philippe Thevenaz (1998) Inhalation Toxicology of Decamethylcyclopentasiloxane (D5) Following a 3-Month Nose-Only Exposure in Fischer 344 Rats, Toxicological Sciences, 43, 230-2340. https://doi.org/10.1093/toxsci/43.2.230

[448] European Commission (2018) Proposal for a Regulation of the European Parliament and of the Council on persistent organic pollutants (recast) (COM(2018) 144 final). Available: resource.html (europa.eu)

Table _A 8 Estimated costs related to the Stockholm Convention 2019-2020

	2019	2020
IT system	€0.2 million	€0.1 million
Risk profile and risk management evaluation	€0.01 million	€0.01 million
Union synthesis and MS reports	€0.039 million	€0.033 million
Union Implementation Plan	€0.02 million	€0.02 million
Total	€0.269 million	€0.163 million

The costs provided for "risk profile and risk management evaluation" are not substance specific and are the total costs expected for all related activities in a single year. As such, it has not been possible to determine the actual administrative costs to the Commission or its Agencies related to a Stockholm Convention listing of D4, D5, D6.

Member State administrative costs are related to the implementation and enforcement of the POPs Regulation. This requires Member States to create National Implementation Plans and submit national reports that provide information on the manufacturing, placing on the market and use of POP substances and any stockpiles; enforcement activities, infringements and penalties; releases to the environment of unintentionally produced POPs; any derogations granted by the Member State for the treatment of POPs waste; and the implementation of the POPs regulation in accordance with the national implementation plans. National reports must be updated at least every three years and where new data or information is available, they must be updated annually. [449]These implementation and enforcement costs are not substance specific, and it is not possible to identify the costs related solely to a Stockholm Convention listing of D4, D5, D6.

Following communication with the Commission, it has been established that the Public Authority impacts related to the administrative burden would not be significant as a result of this Stockholm Convention nomination for D4, D5, D6.

A2.4 DEFINE AND CHARACTERISE THE BASELINE SCENARIO

A **quantitative baseline of the D4, D5, and D6 and silicone polymers industry and a selection of key downstream user sectors from 2011-2040 was established** (See Section 3.1.2), capturing key proxies for the industry's size, costs or expenditures, and contribution to the EU socio-economy. These proxies included industry turnover, production, gross value added, operating and capital expenditures, employment, imports, and exports. Historical evidence and data were collected from publicly available sources. The Table below provides a summary of the sources consulted.

[449] European Chemicals Agency (no date) Planning and communication of information. Available: Planning and reporting - ECHA (europa.eu)

Table _A 9 Indicators and data sources underpinning the baseline analysis[450]

Sources	Indicator
Eurostat "PRODuction COMmunautaire" (PRODCOM), also drawing on Comext	Production Value
	Imports
	Exports
Eurostat Structural Business Statistics (SBS) and drawing on turnover-production value relationship based on PRODCOM.	Turnover from sales
	Gross Value Added (GVA)
	Operating expenditure (Opex) (estimated based on Gross Operating Surplus)
	Capital expenditure (Capex)
	Employment

Accessing the data required a few steps.

Firstly, it was necessary to **define the markets of interest (or in scope)**; that is, map the sectors that pertained to the D4, D5, D6 and silicone polymers markets and downstream user industries across these databases. A detailed review as performed of the "Statistical Classification of Economic Activities in the European Community"[451] or NACE classification, which SBS aligns with, to identify the relevant sectors and subsectors. This was complemented by a more detailed review of the PRODCOM database classification, which uses a more granular categorisation of sectors by product. The two classifications are mapped, which allows for database triangulation in many cases. This review identified one PRODCOM product category for the upstream segment of the industry (Silicones, in primary forms) and 396 PRODCOM product categories for the downstream sectors in scope, which were mapped NACE codes (from 2-digit codes all to the way to the 8-digit code structure of PRODCOM classifications). The data collected from stakeholders, including data on the impacts of the three policy scenarios, was structured and organised in this sector mapping. This mapping is auditable and shareable upon request.

Secondly, once the 'markets' were defined, the **data was accessed**, downloaded and analysed across these codes. Gaps were addressed using triangulation and external sources; and the baseline, historical estimations of the size of these 'markets' across indicators were established (2010-2019). Baseline estimations set out a position for how the industry could evolve within the current regulatory framework into the future 2022-2040 (i.e., 'Do Nothing' scenario). These were developed by using historical evidence and extrapolating them into the future (especially, looking at the relationship between the industry's performance and EU-27 GDP). In establishing the historical baseline, the year of 2019 was used as a reference point for the analysis to mitigate any issues, as this is considered a relatively normal operating year that may best represent the long-term market and industry dynamics. This was, therefore, used as a reference point for the stakeholder survey.

These methods were employed for all variables of interest, including production, sales turnover, Gross Value Added, Operating Expenditure, Capital Expenditure, imports and exports.

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[450] For the sealants downstream use sector, it was not possible to establish a clear mapping of relevant codes pertaining to sealants from PRODCOM. After consulting with experts, it was decided that data from the following publicly available study would instead be used to develop a baseline: FEICA (2019) Adhesives and Sealants: Enablers of a sustainable society. Available: https://www.feica.eu/information-center/feica-publications/preview/611/adhesives-and-sealants-enablers-sustainable-society?id=ef38f028-9dfd-439d-bbc3-1cbc93f9723c&filename=Adhesives+and+Sealants%2C+Enablers+of+a+sustainable+society.pdf

[451] Eurostat (2008). NACE Rev. 2: Statistical classification of economic activities in the European Community. Available at: https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF.pdf/dd5443f5-b886-40e4-920d-9df03590ff91?t=1414781457000

A2.5 CONSULT STAKEHOLDERS AND GATHER EVIDENCE OF THE BASELINE AND POTENTIAL IMPACTS.

A consultation strategy was developed, including a mapping and prioritisation of Cefic members and stakeholders within Cefic's network in the selected downstream sectors of interest. Stakeholders were split into two broad groups: 1) Manufacturers and importers of D4, D5, D6 and silicone polymers; 2) Downstream user sectors. Two different surveys were thus designed for each of these groups:

- *Manufacturers and importers of D4, D5, D6 and silicone polymers survey*: consultation aimed to gather evidence of the socio-economic footprint of D4, D5, D6 and silicone polymer markets in the EU-27 and the potential implications of the policy scenarios; to be completed by the direct company members of Cefic and other companies that are part of the Associate Federation members of Cefic.
- *Downstream user survey*: consultation aimed to gather evidence of the socio-economic footprint of these markets, their reliance on D4, D5, D6 and/or silicone polymers, and the potential implication of policy scenarios under consideration across selected downstream user markets; to be completed by companies within Cefic's membership and network.

The surveys were thus structured in four sections, as follows:

- **Your organisation:** Gathering basic information about the company participant, for follow-ups and checks as required for the duration of the project.
- **Baseline**: A number of questions were asked to develop a quantitative baseline for the sample of respondents around key variables: employment, turnover from sales, capex, opex, R&D, imports and exports.
- **Business Impacts of the Policy Scenarios**: A set of questions to gather evidence on how the policy scenarios under consideration may affect the availability and performance of products, the extent to which adjustment/substitution opportunities might be viable, and likely impacts on key economic variables.
- **Other Impacts**: a set of questions targeting impacts on competitiveness and other more qualitative implications.

Finally, the list below summarises the types of socio-economic and other data and evidence gathered through the consultation:

- **Volume and turnover value:**
  - From the manufacturing and placing on the market of D4, D5, D6 and silicone polymers.
  - downstream products from selected markets which are manufactured and/or part of the affected value chain (i.e., containing D4, D5, D6/silicone polymers).
- **Number of employees** supported by the respondents (direct) attributable to the activities in scope
- This will also include an understanding of international trade by production value, including **exports and imports**.
- **Gross Value-Added** of the markets.
- **Capital, R&D and operating expenditure**, as well as the extent to which any of these expenditures are a direct result of baseline regulation (i.e., regulatory costs).
- **Applications or uses of D4, D5, D6/ silicone polymers** for manufacturers and importers.
- **The role of the D4, D5, D6, silicone polymers**, and their priorities across use categories for downstream users.
- **Availability (or not) of alternatives** to: D4, D5, D6, silicone polymers and/or formulations that are affected; and thus, proportion of the affected substances across use sectors that

could be substituted, reformulated or re-designed, and time needed to adopt manufacturing processes to adapt to the new regulatory environment.
- **One-off and recurring costs** of alternatives/ substitutes
- Levels of **global competitiveness.**

A2.6 ASSESSMENT OF THE ECONOMIC, SOCIAL, AND ENVIRONMENTAL IMPACTS OF THE POLICY SCENARIOS

This section details the approach and methodology employed for assessing the economic, social and environmental impacts, costs and benefits of the policy scenarios under consideration (see Section 3.2) for the nomination of D4, D5 and D6 to the Stockholm Convention. The quantitative and qualitative methods described in the following sub-sections are aligned with the Better Regulation Guidelines and Toolbox.

Quantitative approach

This section outlines the methods used to estimate the economic and social impacts. Section 4.4 has already addressed the methods for estimating environmental impacts.

Quantitative analysis, inspired on the Standard Cost and Economic Modelling approaches, was carried out to estimate impacts and costs on businesses, also relevant for the ‘One In, One Out’ considerations. Insufficient evidence was identified to isolate administrative burden. Adjustment (or compliance) costs were primarily the focus of the analysis.

The **targeted stakeholder survey** was the central source of evidence as to how businesses may be affected by the policy scenarios, complemented by secondary research and expert opinion. This also informed the baseline. The survey outputs allows us to establish an ‘internal’ baseline and considered:

- The product portfolio and turnover that could thus be affected across the value chain.
- The potential responses businesses could take upon the introduction of the policy scenarios e.g., introduce alternatives, substitute, withdraw, etc.
- One-off and recurring costs of these business responses and actions

A three-step methodology was implemented to thoroughly analyse the survey data and extract actionable insights.

- The first step involved deriving raw estimates by aggregating the impacts reported in the survey responses. To ensure a balanced representation of perspectives, these impacts were weighted based on the size of the respondent companies, recognising that larger enterprises may exert a proportionally greater influence on the overall outcome. This approach not only accounted for differences in company scale but also provided a foundation for further analysis.

- Following the calculation of raw estimates, a distributional analysis was performed. This step involved an examination of the distribution of responses to identify any notable patterns, trends, or outliers. The aim of scrutinising the data at a granular level was to uncover nuanced insights and discern underlying messages that may not have been immediately apparent. This process enabled us to refine our understanding of the data's intricacies and assess the robustness of the findings from step one.

- The internal analysis was supplemented with external evidence obtained from industry reports and follow-up conversations with key respondents. These external sources served to contextualise our findings within broader industry trends and validate our assumptions. Furthermore, engaging in dialogue with survey participants allowed us to delve deeper into specific responses, gaining valuable qualitative insights that enriched our analysis.

Based on this methodology, key percentage impacts were estimated that were later combined with broader baseline data on the evolution of economic variables to estimate the economic and social impacts of the proposed restrictions. This was done as follows:

- Potential production value losses were estimated by considering the proportion of the portfolio that would be affected, minus the proportion that would be exempted and substituted based on the 'assumptions' developed through analysing the evidence provided by businesses through the targeted consultation. That is, losses estimated are net of any substitution/ market for alternatives. These are applied to the baseline developed for this Study. Mathematically, this can be represented as follows:

  Production value loss=Production value*(1-affected portfolio)*(1-exemption)*(1-substitution)

  Where affected portfolio refers to all of the D4, D5, D6 and/or silicone polymers in the case of upstream markets OR the proportion of the production value that is reliant on the use of D4, D5, D6 and silicone polymers either directly or indirectly in the case of downstream markets. The exemption % and substitution % refers to the proportion of the affected portfolios that are exempted and/or could be potentially substituted respectively.
- Potential imports losses were estimated by considering the proportion of the domestic portfolio that would be withdraw, minus the proportion of the imports that would be substituted based on the evidence provided by business through the targeted consultation. That is, losses estimated are net of any substitution/ market for alternatives. These are applied to the baseline developed for this Study.
- Employment is assumed to be affected proportionately to how business operations might be affected, albeit any effects are estimated to be lower based on a relationship established between production and employment from the sample and published studies.
- Capital, operating and R&D expenditures are expected to fall in line with the net business size changes (turnover losses) and increase in line with the additional expenditure required to reformulate significant proportions of the business (as well as other administrative and compliance activities). The net effects depend on the size of these two impacts, albeit unit costs of production would be likely to increase in all cases.

These core impacts were presented as annual averages (or annualised over the period of 2022-2040) for a comparison against the baseline. An annualisation exercise was done as follows: The Net Present Value (NPV) of the impacts was estimated over the period 2022-2040, using a real discount rate of 3% in line with the Better Regulation Guidelines. This NPV was annualised so that the equivalent annual value for a given metric would, when discounted over the period, produce a similar/same NPV. Sometimes, these annualised figures are referred to as an average for shorthand, although they are technically slightly different than averages.

Additionally, an Input-Output methodology was employed to estimate the indirect and induced effects of the proposed Restriction options on GVA (~GDP) and employment. The total impact of a policy change on sectoral GVA encompasses three components: direct, indirect and induced effects. The direct effects refer to the immediate effect of the policy change on sectoral production and its value added. The indirect effects pertain to changes in the sector's value chain, which influence the intermediate demand for inputs in other sectors. Finally, the induced effects encompass the broader economic effects resulting from changes in compensation to employees, which consequently affect final demand and overall spending in the economy.

In order to assess the direct effects, a combination of consultations and publicly available data was employed. To estimate the indirect and induced effects, or the ripple effects on the economy resulting from the direct impacts on the manufacturers and importers of D4, D5, D6 and silicone polymers and downstream use sectors, the Leontief or Input-Output model was utilised. This model, along with its associated matrices of economic activity and interconnections, allows for the estimation of multipliers. These multipliers represent the economic activity generated throughout the supply chain and various sectors as a result of one euro spent in a specific sector.

There are two types of multipliers used in the analysis. Type I multipliers capture the direct and indirect effects, indicating the economic impacts throughout the supply chain. On the other hand, Type II multipliers also include the induced effects, assuming that final consumers do not alter their consumption patterns in response to changes in income. Therefore, Type II multipliers encompass the direct, indirect and induced effects, illustrating the impact throughout the supply chain as well as the effects on the wider economy resulting from changes in employee compensation. Mathematically, the indirect and induced effects are estimated as follows:

$$Indirect\ effect = (Type\ I\ multiplier - 1) * Direct\ effect$$

$$Induced\ effect = (Type\ I\ multiplier - Type\ II\ multiplier) * Direct\ effect$$

For the D4, D5, D6 and silicone polymers manufacturers and importers. Type I and Type II multipliers were assumed to be approximately 2.65 and 3.26, respectively. For downstream use sectors, assumptions for Type I and Type II multipliers were developed using weighted averages for the three largest sectors comprising over 80% of the total sold production (i.e., Transport, Aerospace and defence and Electronics)[452], approximately equal to 1.58 and 1.85 respectively. These assumptions were based on evidence from Eurostat, national statistical databases from various European countries, and expert judgment.

A similar approach was also followed to estimate the indirect and induced effects on employment impacts. For this analysis, the Type I and Type II multipliers for the D4, D5, D6 and silicone polymers manufacturers and importers were assumed to be around 1.96 and 2.82, respectively. For the downstream use sectors, the Type I and Type II multipliers were assumed to be around 1.79 and 2.67, respectively. These were based on the triangulation of the available evidence on the effects on employment and interlinkages within the value chain of the sectors in scope.

Qualitative approach

A qualitative thematic approach was adopted to analyse a set of questions included in the survey, covering various economic and social impacts such as competitiveness, reallocation of operations, or illicit imports, among other topics. Thematic analysis entailed systematically identifying and interpreting recurring themes within the responses to discern overarching patterns. Additionally, content analysis was employed to scrutinize this set of questions, involving the systematic categorisation and interpretation of response content to identify recurring topics or ideas. This facilitated an exploration of the prevalence and distribution of specific themes or concepts across responses, illuminating the range and diversity of perspectives within the data. These qualitative methods yielded valuable insights into respondents' perspectives, facilitating a deeper understanding of the anticipated social and economic impacts following the introduction of restrictions.

However, this approach did not yield a precise numerical assessment of the qualitative responses gathered. Consequently, it was supplemented with a qualitative scoring approach to ascertain impacts suitable for comparison across policy scenarios (see the following section for more on this).

A2.7 COMPARISON OF THE POLICY SCENARIOS

The evidence and conclusions developed through earlier tasks, were brought together to assess how these policy scenarios compare with each other and with which type and level of impacts. This will be done using cost-effectiveness analysis and a Multi-Criteria Analysis (MCA) approach, based on Tool #62 of the latest Better Regulation Toolbox and ECHA's guidelines and studies. These are described below.

Cost-effectiveness analysis

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[452] The multipliers assumptions for the downstream use sectors are based on a weighted average using the Eurostat output multipliers for following 2-digit codes: *Computer, electronic and optical products (26), Electrical equipment (27), Machinery and equipment n.e.c. (28), Motor vehicles, trailers and semi-trailers (29), Other transport equipment (30)*.

Cost-effectiveness analysis was conducted (see Section 5.1) to provide an evaluation of the policy scenarios that could be comparable with other policies previously adopted given the lack of evidence that allows for quantitative conclusions. That is, we would be able to compare the cost-effectiveness of the policy scenarios with that of other policies seeking to reduce emissions of persistent substances.

This approach focusses on the relationship between the costs incurred and how effectively the policy scenarios might reduce the emissions of persistent substances. It follows the guidelines outlined by the SEAC, employing a rigorous and established methodology.

Firstly, a set of metrics were established, and data analysed to develop cost-effectiveness indicators and estimates for comparison between the policy scenarios and estimations from other policies already adopted. These draw on some type of adjustment or compliance cost estimates, estimates of opportunity costs, and emissions reductions resulting from the policy scenarios.

As part of the analysis two different definitions of costs and two different definitions of emissions impacts were considered.

- Compliance or opportunity costs: Adjustment or compliance costs comprise the additional capital and operating expenses incurred by organisations compared to the EU-27 baseline, whereas opportunity costs include these costs as well as all of the production and/or GVA losses against the baseline from the adoption of the policy scenarios (see also Section 0 for more information on costs estimated).
- Reduction in emissions/releases or reductions in steady-state environmental stock of D4, D5, D6: Reductions in emissions/ releases refers to the flow of D4, D5 and D6 into the environment without considering any biodegradation or similar environmental dynamics, whereas reductions in steady-state environmental stock of D4, D5 and D6 take into account that whilst persistent, these substances do degrade in the environment over time and thus, where emissions into the environment remain, a steady-state stock shall be present before degradation processes have taken place (see also Section 4.4 for more information on the emissions reductions estimated).

Considering all of these options allows for a comprehensive exploration of how the costs compare with the “effectiveness” of the policy scenarios in reducing any of the types of emissions of D4, D5, and D6. Four indicators were thus developed:

- Compliance costs per releases avoided
- Opportunity costs per releases avoided
- Compliance costs per steady stock avoided
- Opportunity costs per steady stock avoided

It is our technical opinion that using opportunity costs would be a more appropriate and comprehensive approach to estimating the overall costs associated with achieving some measure of emissions reductions. However, it is also acknowledged that these estimates are even more uncertain than compliance costs. Opportunity costs are significantly larger than compliance costs, and thus employing the later would be a more conservative approach. Further, our understanding is that the approach employed in the past focusses more narrowly on compliance or adjustments costs. Therefore, we employed compliance costs estimates in this Study, as presented in Section 5.1.

Most of the historical evidence of cost-effectiveness from previous restriction proposals or similar policy scenarios from ECHA pertains to compliance costs per releases avoided, even though it is acknowledged that it would be more appropriate moving forward to focus on the environmental steady-state stock impacts instead of emissions/releases reductions of the substances of concern. However, both estimates are presented for information in our Study.

Mathematically, the Net Present Value (NPV) of the compliance costs over the period 2022-2040 were calculated using a real discount rate of 3% in line with the Better Regulation Guidelines. This NPV was annualised for comparison across policy scenarios. These annualised figures are referred to as an average for shorthand, although they are technically slightly different than averages. Annual average emissions reductions were estimated, across the two metrics. These were not discounted (i.e., discount rate of 0%), which is aligned with approaches employed by ECHA and the principles set out in the Better Regulation Guidelines, valuing emissions reductions equally over time (rather than valuing present emissions reductions more than their future counterparts). Ratios of compliance costs per releases or steady-state stock avoided were estimated to produce cost-effectiveness ratios for comparison.

The results are presented in Section 5.1 and suggest that the potential costs required to achieve emissions reductions are much higher than those estimated for other similar policy scenarios seeking to reduce emissions of persistent chemicals.

MCA-based qualitative scoring approach

An overarching qualitative framework was employed to bring together all of the evidence and analysis against each policy scenario on a scale of -5/+5, capturing both the estimated magnitude of impact as well as its likely direction when compared to the baseline. The Table below outlines how this scale would be described and presented.

Table _A 10 Coding used to present estimated impacts

Strongly negative	Negative	Weakly negative	No or limited impact	Weakly positive	Positive	Strongly positive	Unclear
-5	-3	-1	0	+1	+3	+5	N/A

The framework facilitates an iterative process that is overseen by the economist lead to ensure that all the evidence is drawn on whilst retaining internal coherence. The following five steps have been taken to assess impacts.

- Step 1: Proxy indicators were selected for the shortlisted impact categories to construct a qualitative and, where possible, quantitative evidence base of the scale of potential impacts identified.
- Step 2: The impacts of the policy measures (or options) were considered and assessed across each category by a team of chemicals policy, SEA and impact assessment experts from the consultant project team, following some general guidance, accessing the available evidence on economic, social and environmental costs presented in the study, and using their expert judgement.
- Step 3: A re-calibration exercise was carried out every time inputs from the experts were reviewed by the PM/ economist lead. This ensured that the impact ratings were challenged constructively to ensure accuracy and internal coherence.
- Step 4: An impact aggregation exercise was performed to aggregate the qualitative rating of impacts across the 19 impact categories to the level of broad impacts (economic, social and environmental) and social costs and benefits. The aggregated impacts were remapped to a -5/+5 scale by assigning a value of '-5' to the minimum aggregated impact and applying a scaling factor (equal to the ratio of '-5' to the minimum aggregated impact) to the other aggregated impacts, so that the scale of impacts presented is always from -5/+5 scale.
- Step 5: Validation and quality assurance activities was also taken by a separate team of experts within the consultant team. The European Commission will also review and provide their opinion and challenge.

In more detail, given the relatively limited quantitative evidence, a number of proxies and approaches were employed to establish qualitative scores and achieve internal coherence (Steps 1-3 above). The following list summarises, at a very high-level, a few references employed in the iterative process to reach a final position on the qualitative ratings for each option and category of impact.

- First, impacts on the conduct of business (adjustment) and administrative costs on businesses were considered across the three core policy scenarios. Evidence collected via the targeted stakeholder survey was essential to establish qualitative scores that were internally coherent (i.e., the relative position of impacts was reasonable across policy scenarios). The relative ratio of the estimated levels of the potential product withdrawal (in terms of industry sales turnover) as well as the additional costs of industrial transformation (compliance costs and opportunity costs) across the three policy scenarios were considered to ensure internal coherence in the qualitative ratings. A rating of '-5' was assigned to the largest negative impact of these impact categories (against PS3) and the relative ratios against impact estimates for other PS were used to assign suitable qualitative ratings to the other scenarios.
- Secondly, these assessments were used as an anchor or benchmark to develop impacts scores that were coherent across the other economic categories such as the position of SMEs, innovation and research, sectoral competitiveness, trade and investment flows, and sustainable consumption and production. Impacts against these categories were generally smaller in scale than the 'conduct of business' and 'administrative cost' joint category.
- Thirdly, the consultant team employed evidence-based judgement to establish qualitative scores or ratings for the other social and environmental impact categories. Under Option A, impacts on the quality of natural resources and biodiversity were positive. Given the very high costs/kg of emissions reductions estimated under the cost-effectiveness exercise, their scale was however concluded to be 25-50% of the scale of the scores determined for conduct of business/administrative burden category. Similar approaches were employed for establishing reasonable scores for other categories reflecting their direction and potential scale relative to this 'anchor' assessment.

This qualitative method provides a platform for the consultant team to triangulate the available evidence with their expert judgement, which is required especially in this context of limited evidence and complex impact pathways. The outputs of this method offer a guide or a best recommendation as to the balance of impacts, costs and benefits given the information, time and resources available, for consideration by the Commission. The conclusions are not irrefutable but present a best view. This is aligned with the principles set out in the Better Regulation Guidelines, including proportionality, and others.

Having iterated and established a rating for each impact category across each policy scenario, these **scores were aggregated and mapped onto -5/+5 scale** (Step 4 above) at the broad impact level (economic, social and environmental) and the level of costs and benefits for a higher level and more effective comparison of the policy scenarios.

This aggregation and re-calibration can only be effective if the impacts, costs and benefits are on a comparable scale. Therefore, the following steps were undertaken:

- First, the ratings for each of the broad impact categories; the costs (negative ratings); and the benefits (positive ratings) were aggregated.
- Following this, a judgment was made to map the highest score in absolute terms "-17" in costs onto the -5/+5 scale as "-5". This was done to provide as much visibility in the differences of scale of impact across policy scenarios. However, the mapping could be adjusted without any implications on the conclusions reached as the relative positions of the ratings will remain.

- This means that the scores aggregated from sub-categories to the broad categories and overall social costs and benefits for each policy scenario were re-calibrated by using this relationship, that is, multiplied by -5/-17 (or +0.3) to translate the scores onto the line -5/+5.

As a result, the qualitative scores across broad impact categories, social costs and social benefits were mapped onto the -5/+5 scale, whilst retaining the relationships identified in the bottom-up analysis of the impacts across each of the twelve specific impact categories and an additional subcategory.

Finally, a review of the outputs of the analysis was carried out by experts within the consultant team to seek **validation** (Step 5). At least two sessions were scheduled to go through the results and challenge these constructively. Further, subject matter experts reviewed the outputs and provided quality assurance. The outputs were also contrasted with the opinions of stakeholders gathered during the Study.

A3 ANNEX 3: CONSULTATION SYNOPSIS REPORT

A3.1 OVERVIEW

This report provides a more detailed presentation of the stakeholder consultation activities that were carried out as part of this support study. It outlines the consultation strategy and analysis methodology and provides a summary of the key outcomes of the consultation activities.

The aim of the consultation was to gather evidence and opinion on the policy scenarios under consideration and their likely impacts. The stakeholder consultation was performed by Ricardo consultants, in collaboration with the Cefic. It was launched on 01 November 2023 and remained open for 6 weeks until 6 December 2023. The “Downstream users” survey was reopened on 25 March 2024 until 6 May 2024. It was carried out in line with the Commission’s Better Regulation Guidelines (Chapter VII: Guidelines on Stakeholder Consultation and Chapter III, Guidelines on impact assessment).

A3.2 STAKEHOLDER PARTICIPATION

Stakeholders were split into two broad groups: 1) Manufacturers and Importers of D4, D5, D6 and silicone polymers; and 2) Downstream users (component and/ or final product manufacturers and importers). The Table below summarises the number of participants in the consultation by stakeholder group. Two different surveys were designed (see Section A2.5). Manufacturers and importers together with Silicone Polymer users were asked to fill in the Cefic Members survey, whereas downstream users were asked to fill in a different questionnaire.

Table _A 11 Stakeholder participation

Survey	Stakeholder group	Number of participants
Cefic members	Manufacturers and importers of D4, D5, D6 and silicone polymers	27
Downstream users	Downstream users	97

In terms of size of the companies which participated in the survey, the majority of them were large companies with a very limited representation of small and medium companies in the sample. The Table below provides a breakdown of the respondent companies for each survey by their size.

Table _A 12 Size of companies which participated in the consultation.

Survey	Small and Medium enterprises	Large enterprises
Manufacturers and importers	11	16
Downstream users	20	77

A3.3 METHODOLOGY

Following the closure of the public consultation and the targeted stakeholder survey, the submitted responses were analysed using Ricardo's in-house analysis tools (Microsoft Excel). This analysis considered responses of stakeholders overall and by stakeholder type, showcasing the different opinions as relevant.

- Step 1: The raw data comprised of responses from the surveys was downloaded, cleaned and encoded so that it could be analysed effectively, and meaningful outputs could be produced (e.g., 'Strongly disagree' mapped onto a -5, etc.).
- Step 2: A comprehensive distributional analysis was performed for each question in the survey. This involved an examination of the distribution of responses to identify any notable patterns, trends, or outliers. Medians, modes, 25th and 75th percentile estimates, minima and maxima were also considered.
- Step 3: Estimates of impacts were derived by averaging the impacts reported in the survey responses. Both simple and weighted averages were estimated to ensure that the views of larger respondents were given proportional consideration.
- Step 4: External evidence was gathered from annual reports and industry reports to contextualise validate the assumptions made within the analysis and also confirm coherence with broader industry trends. Follow-ups were performed to confirm responses where discrepancies were observed. Key stakeholders were engaged in dialogue to delve deeper into specific responses.

The responses to open text questions or position papers were also reviewed and/or analysed, also split by stakeholder type and issue/interest. These questions were systematically checked for overlaps to detect any coordinated responses. Each open text reply was checked against all other open text responses for their textual similarity by considering the cosine similarity of all answers against all other answers.

The outputs of this analysis are presented in the following sections within this Annex.

A3.4 SUMMARY OF FINDINGS

Key findings of opinions and evidence against the problems, policy scenarios under consideration and impacts are outlined below, structured by survey section.

Baseline

A number of questions were asked to develop a quantitative baseline for the sample of respondents comprising employment, volume and value of production or imports, capital expenditure (capex), operating expenditure (opex) and research and development (R&D) expenditure.

The Tables below provides a summary of the total baseline values of the sample by stakeholder type, including total employment, turnover, number of products, capex, opex and R&D expenditure.

Overall, the sample of manufacturers and importers represents around 60% of the D4, D5, D6 and silicone polymers market's turnover in 2019 and around 50% of employment. The Table below provides an aggregated picture of these respondents.

Table _A 13 Total baseline values across multiple indicators for the sample of manufacturers and importers of D4, D5, D6 and silicone polymers

Variable	Manufacturers & Importers
Employment (N=26)	17,000 FTE
Sold Production (N=17)	€ 2,500 million
Imports (N=25)	€ 1,700 million
Exports (N=17)	€ 450 million
Opex (N=24)	€ 1,400 million
Capex (N=22)	€ 400 million
R&D (N=18)	€ 200 million

For the downstream user industry, the survey captured a much lower share of the total industry value, with shares ranging from 2% for production value of all downstream sectors in scope to 15% for employment. The 'representativeness' of downstream sectors has severe limitations, and sensitivity analysis and expert-based input was required to develop consultation-based assumptions that could be effective. The Table below provides an aggregated picture of these downstream respondents.

Table _A 14 Total baseline values across multiple indicators for the sample of downstream user respondents

Variable	Downstream users
Employment (N=91)	125,000 FTE
Sold Production (N=86)	€ 100,000 million
Imports (N=88)	€ 15,000 million
Exports (N=78)	€ 25,000 million
Opex (N=70)	€ 25,000 million
Capex (N=72)	€ 2,000 million
R&D (N=65)	€ 4,000 million

To characterise the baseline scenario, the businesses were asked about their expected **evolution of key economic variables over the next 15 years if D4, D5, D6 were not listed in the Stockholm Convention**. Both manufacturers and importers and downstream users estimated that in this case, employment, turnover, capex, opex and R&D expenditure would increase over the next 15 years. Overall, the magnitude of these expected increases was larger for manufacturers and importers as compared to downstream users.

Business impacts

Respondents to the stakeholder consultation surveys were asked several questions regarding the business impacts of the three policy scenarios under consideration. This included questions about the proportion of their portfolio which is reliant on D4, D5, D6 and silicone polymers and the proportion of the this 'reliant' portfolio which is expected to receive exemptions under each Policy

Scenarios 1 and 2 (Policy Scenario 3 did not provide for any exemptions for the affected portfolio). In addition, respondents were also asked about the proportion of this unexempted 'affected portfolio' that they would be able to substitute or replace with alternatives.

For manufacturers and importers of D4, D5, D6 and silicone polymers, all (100%) of their portfolio of products was reliant on D4, D5, D6. Downstream users (N=81) reported that around 75% of their market was reported to be reliant on D4, D5, D6.

Both manufacturers and importers of D4, D5, D6 and silicone polymers as well as and downstream respondents within the D4, D5, D6 value chain reported higher levels of **exemptions** under Policy Scenario 1 as compared to Policy Scenario 2. The Table below provides a summary of the average exemptions rates reported by the survey respondents.

Table _A 15 Average exemption rates for the sample of respondents

Variable (unit)	Manufacturers and Importers (N=26)			Downstream users (N=81)		
Policy Scenario	*PS1*	*PS2*	*PS3*	*PS1*	*PS2*	*PS3*
Exemptions (percentage of affected portfolio)	80%	15%	0%	70%	40%	0%

A large proportion of manufacturers and importers of D4, D5, D6 and silicone polymers reported there are **no alternatives (without Dx) available with similar levels of performance**. Some respondents have identified potential alternatives for the use of D4, D5, D6 and silicone polymers in the manufacturing processes, but some of these were not observed to be viable alternatives as they would potentially contain PFAS or D4, D5, D6. For downstream users, it was reported that some sectors may benefit from a higher level of potential substitution than others. More than 90% of component manufacturers and importers reported not being aware of any alternative substances/ monomers, polymers and/or mixtures that could be used in the manufacture/import of 'components'. Further downstream, final product manufacturers also reported their lack of awareness of alternatives (90%).

The survey asked respondents to elaborate if they had any **experience with the development of new siloxane products or products related to the use of D4, D5, D6**. Around 85% of the manufacturers and importers of D4, D5, D6 and silicone polymers said that they had such experience. Similarly, around 80% the downstream user respondents said they had such experience.

The respondents with experience in the development of alternatives were further asked about the types of hurdles that they faced when bringing new products to market related to the D4, D5, D6 supply chain, and also the types of **hurdles they expected to face when bringing to market alternative products that accommodate the Stockholm Convention policy scenarios**. In response to these questions, the more than 90% of respondents said that they had faced some form of hurdles when bringing alternative products related to the D4, D5, D6 supply chain to market, and they expected to face similar hurdles when bringing new products to market which accommodate the Stockholm Convention policy scenarios, with regulatory costs, complex legal requirements and worsened product performance being the most common. Specifically, 80% of manufacturers and importers of D4, D5, D6 and silicone polymers who responded expected to face complex and difficult-to-meet legal requirements (including standards) and high regulatory costs, around 70% expected long lead times and relatively higher operating costs, and around 50% expected worsened product performance (e.g., durability). For downstream user respondents, around 70% expected to face worsened product performance and complex and difficult-to-meet legal requirements, at least 50% expected long lead times and high upfront capital costs (e.g., of removal technologies, etc.), 40% expected to face high regulatory costs and around 35% expected relatively higher operating costs.

Despite there being no alternatives available without D4, D5, D6; businesses manufacturing D4, D5, D6 and silicone polymers in the EU-27 reported they might be **able to transform part of their production under PS1 and PS2** (e.g., adjusting their manufacturing towards alternatives, removal technologies, etc), whilst such production activities would be technically and financially unviable under PS3. That is, they might be able to **manufacture substitute products** that would fit regulatory requirements under PS1 and PS2. For the sample of 27 respondents, substitution was reported to be around 50% of the affected portfolio in PS1 and around 35% of the affected portfolio in PS2. These insights, research and further expert input were also employed to develop assumptions as to potential substitution rates for downstream user sectors (see Section 4.2.1.2). These remain uncertain, whilst considered reasonable assumptions for this Study.

When asked about whether they were aware of the **cost, performance, risks to human health and/or risks to the environment** of these alternatives, over 90% downstream user respondents claimed that there were no alternatives that they were aware of and hence could not evaluate their performance on these parameters. However, there were sufficient responses from the manufacturers and importers and silicone polymer users, who said that on average, these alternative products would have a higher manufacturing cost/ price and lower performance while maintaining similar levels of transportation costs, human health risks and environmental risks.

Survey respondents were also asked to quantify the **additional one-off or capital costs and annualised recurring or operating costs of the alternatives** across the three policy scenarios under consideration. Overall, across both upstream and downstream surveys, respondents said that the additional costs were expected to be highest under Policy Scenario 3, followed by Policy Scenario 2 and Policy Scenario 1. These are presented in the Table below.

Table _A 16 Total additional costs of 'substitution' for the sample of respondents

Variable (unit)	Manufacturers and Importers (N=20)			Downstream users (N=45)		
Policy Scenario	*PS1*	*PS2*	*PS3*	*PS1*	*PS2*	*PS3*
One-off or capital costs	€ 770 million	€ 1,140 million	€ 1,870 million	€ 450 million	€ 680 million	€ 1,450 million
Annualised recurring or operating costs	€ 280 million	€ 310 million	€ 570 million	€ 280 million	€ 420 million	€ 920 million

Please note that these absolute figures and their size depend on the sample and type of respondents. For analysis and extrapolation, these were employed to estimate potential costs as a ratio to production value, the ratios were analysed in line with the usual methods (distribution analysis, etc), and the final estimates were used as a way to estimate the potential compliance/adjustment costs for the markets in scope.

Finally, stakeholders were asked to comment on how the **adoption of the Stockholm Convention policy scenarios might affect their organisation's turnover (or business activity) and employment levels over the next 15 years** (cumulatively), when compared to 2021 levels, if they responded as they had outlined within the survey. Overall, both manufacturers and importers and silicone polymer users as well as downstream user respondents expected the most adverse impacts on business and employment under Policy Scenario 3, followed by Policy Scenario 2 and Policy Scenario 1. These are presented in the Table below.

Table _A 17 Average turnover and employment impacts (cumulative over the period when compared to the baseline) of the adoption of the Stockholm Convention policy scenarios for the sample of respondents

Variable	Manufacturers and Importers (N=26)			Downstream users (N=75)		
Policy Scenario	*PS1*	*PS2*	*PS3*	*PS1*	*PS2*	*PS3*
Impact on turnover	Limited change (-5% to +5%)	Decrease significantly (-50% to -95%)	Decrease significantly (-50% to -95%)	Limited change (-5% to +5%)	Decrease slightly (-5% to -25%)	Decrease significantly (-50% to -95%)
Impact on employment	Limited change (-5% to +5%)	Decrease significantly (-50% to -95%)	Decrease significantly (-50% to -95%)	Limited change (-5% to +5%)	Decrease slightly (-5% to -25%)	Decrease significantly (-50% to -95%)

Other impacts

The final section of the survey widened the scope to consider other dimensions of impact of the policy scenarios, especially concerning global competitiveness.

Firstly, the questionnaire investigated **impacts of the proposed restriction on global competitiveness of the EU-27 industry**. Companies surveyed were asked about how the policy scenarios may further impact their competitiveness on a global scale over the next 15 years across a number of components. Overall, negative albeit low impacts are estimated across Policy Scenarios and segments of the industry. The only large negative impacts are expected under Policy Scenario 3 around production costs. The Table below presents the responses from the survey in further detail.

Table _A 18 Average impacts of a Stockholm Convention listing on global competitiveness according to the sample of respondents

	Manufacturers and Importers (N=23)			Downstream users (N=75)		
Policy Scenario	*PS1*	*PS2*	*PS3*	*PS1*	*PS2*	*PS3*
Costs of D4-6 and downstream products manufactured in the EU-27	Low negative	Medium negative	Large negative	Medium negative	Medium negative	Large negative
Relative costs of D4-6 and downstream products compared to countries that are not party to the Stockholm Convention	Low negative	Medium negative	Medium negative	Low negative	Medium negative	Medium negative
New business opportunities in third countries	Low negative	Low negative	Medium negative	Low negative	Low negative	Medium negative

	Manufacturers and Importers (N=23)			Downstream users (N=75)		
First mover advantage	No impact	No impact	No impact	No impact	No impact	No impact
Manufacturing activity that is located the EU-27	Low negative	Medium negative	Not applicable	Low negative	Medium negative	Not applicable
Investment in R&D and innovation within the EU-27	Low negative	Medium negative	Not applicable	Low negative	Low negative	Not applicable
Exports of goods to countries that are not party to the Stockholm convention	Low negative	Medium negative	Not applicable	Low negative	Low negative	Not applicable

Secondly, companies were queried about their inclination toward **relocating operations associated with D4, D5, and D6 to a country not party to the Stockholm Convention** following the proposed restrictions. Based on their responses (see Table below), it appears that downstream industries are unlikely to contemplate relocating their operations to other geographic locations, as between 50% and 70% of have not considered such moves. However, there might be a risk of relocation among manufacturers and importers of D4, D5, D6 and silicone polymers, particularly under Policy Scenarios 2 and 3.

Table _A 19 Impact of a Stockholm Convention listing on the relocation of operations linked to silicone polymers and silicone polymer formulations using D4, D5, D6

	Manufacturers and Importers (N=24)			Downstream users (N=80)		
Policy Scenario	*PS1*	*PS2*	*PS3*	*PS1*	*PS2*	*PS3*
Yes	3	12	11	13	26	34
No	12	8	11	53	37	33
Maybe	8	4	2	13	15	13

Finally, organisations were tasked with evaluating the potential for businesses to turn to **illicit imports** of D4, D5, D6 and/or products containing these substances as an impurity or otherwise, upon the implementation of the policy scenarios. Manufacturers and importers of these substances generally do not perceive there might be significant increase in illicit imports upon the introduction of the proposed policies across various scenarios. However, downstream user respondents suggest there might be more of a risk of illicit trade, especially under PS1.

Table _A 20 Impacts on illicit imports

	Manufacturers and Importers (N=24)			Downstream users (N=78)		
Policy Scenario	*PS1*	*PS2*	*PS3*	*PS1*	*PS2*	*PS3*
Yes	1	6	6	6	15	19

	Manufacturers and Importers (N=24)			Downstream users (N=78)		
No	17	13	13	64	50	44
Maybe	6	5	5	8	13	15

A4 ANNEX 4: UNCERTAINTIES AND SENSITIVITY ANALYSIS

Matrices were developed to depict the sensitivity of estimated production losses of the manufacturers and importers of D4, D5, D6 and/or silicone polymers and downstream user sectors under three policy scenarios, when compared to the baseline, due to different levels of affected portfolio (y-axis) and substitution rates (x-axis). Please note that we have used five colours to denote different levels of probability of the potential production loss estimates, darkest denoting high probability, followed by medium, low and very low in decreasing darkness, with white signifying no probability of occurrence, based on the available evidence.

The Table below presents these matrices for manufacturers and importers of D4, D5, D6 and/or silicone polymers under PS1 and PS2, noting that there is no uncertainty under PS3 as 100% of the product portfolio is affected and no substitution and/or reformulation is possible.

Table _A 21 Sensitivity of net sold production losses for the manufacturers and importers of D4, D5, D6 and/or silicone polymers due to potential product withdrawal (estimates within the heatmap) against different levels of potentially affected portfolio (vertical axis) and substitution (horizontal axis).

PS	Sensitivity matrix of net sold production losses for the manufacturers and importers of D4, D5, D6 and/or silicone polymers																		
		Substitution (% of affected portfolio in sales turnover)																	
	Potentially Affected portfolio (% of sales turnover)	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%
PS1	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	5%	5%	5%	5%	4%	4%	4%	4%	3%	3%	3%	3%	2%	2%	2%	2%	1%	1%	1%
	10%	10%	10%	9%	9%	8%	8%	7%	7%	6%	6%	5%	5%	4%	4%	3%	3%	2%	2%
	15%	15%	14%	14%	13%	12%	11%	11%	10%	9%	8%	8%	7%	6%	5%	5%	4%	3%	2%
	20%	20%	19%	18%	17%	16%	15%	14%	13%	12%	11%	10%	9%	8%	7%	6%	5%	4%	3%
	25%	25%	24%	23%	21%	20%	19%	18%	16%	15%	14%	13%	11%	10%	9%	8%	6%	5%	4%
	30%	30%	29%	27%	26%	24%	23%	21%	20%	18%	17%	15%	14%	12%	11%	9%	8%	6%	4%
	35%	35%	33%	32%	30%	28%	26%	25%	23%	21%	19%	18%	16%	14%	12%	11%	9%	7%	5%
	40%	40%	38%	36%	34%	32%	30%	28%	26%	24%	22%	20%	18%	16%	14%	12%	10%	8%	6%
	45%	45%	43%	41%	38%	36%	34%	32%	29%	27%	25%	23%	20%	18%	16%	14%	11%	9%	7%
	50%	50%	48%	45%	43%	40%	38%	35%	33%	30%	28%	25%	23%	20%	18%	15%	13%	10%	7%
	55%	55%	52%	50%	47%	44%	41%	39%	36%	33%	30%	28%	25%	22%	19%	17%	14%	11%	8%
	60%	60%	57%	54%	51%	48%	45%	42%	39%	36%	33%	30%	27%	24%	21%	18%	15%	12%	9%
	65%	65%	62%	59%	55%	52%	49%	46%	42%	39%	36%	33%	29%	26%	23%	20%	16%	13%	10%
	70%	70%	67%	63%	60%	56%	53%	49%	46%	42%	39%	35%	32%	28%	25%	21%	18%	14%	11%
	75%	75%	71%	68%	64%	60%	56%	53%	49%	45%	41%	38%	34%	30%	26%	23%	19%	15%	11%
	80%	80%	76%	72%	68%	64%	60%	56%	52%	48%	44%	40%	36%	32%	28%	24%	20%	16%	12%
	85%	85%	81%	77%	72%	68%	64%	60%	55%	51%	47%	43%	38%	34%	30%	26%	21%	17%	13%
	90%	90%	86%	81%	77%	72%	68%	63%	59%	54%	50%	45%	41%	36%	32%	27%	23%	18%	14%
	95%	95%	90%	86%	81%	76%	71%	67%	62%	57%	52%	48%	43%	38%	33%	29%	24%	19%	14%
	100%	100%	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%	45%	40%	35%	30%	25%	20%	15%

PS	Sensitivity matrix of net sold production losses for the manufacturers and importers of D4, D5, D6 and/or silicone polymers

PS2

Potentially Affected portfolio (% of sales turnover)	Substitution (% of affected portfolio in sales turnover)																	
	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%
0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
5%	5%	5%	5%	4%	4%	4%	4%	3%	3%	3%	3%	2%	2%	2%	2%	1%	1%	1%
10%	10%	10%	9%	9%	8%	8%	7%	7%	6%	6%	5%	5%	4%	4%	3%	3%	2%	2%
15%	15%	14%	14%	13%	12%	11%	11%	10%	9%	8%	8%	7%	6%	5%	5%	4%	3%	2%
20%	20%	19%	18%	17%	16%	15%	14%	13%	12%	11%	10%	9%	8%	7%	6%	5%	4%	3%
25%	25%	24%	23%	21%	20%	19%	18%	16%	15%	14%	13%	11%	10%	9%	8%	6%	5%	4%
30%	30%	29%	27%	26%	24%	23%	21%	20%	18%	17%	15%	14%	12%	11%	9%	8%	6%	4%
35%	35%	33%	32%	30%	28%	26%	25%	23%	21%	19%	18%	16%	14%	12%	11%	9%	7%	5%
40%	40%	38%	36%	34%	32%	30%	28%	26%	24%	22%	20%	18%	16%	14%	12%	10%	8%	6%
45%	45%	43%	41%	38%	36%	34%	32%	29%	27%	25%	23%	20%	18%	16%	14%	11%	9%	7%
50%	50%	48%	45%	43%	40%	38%	35%	33%	30%	28%	25%	23%	20%	18%	15%	13%	10%	7%
55%	55%	52%	50%	47%	44%	41%	39%	36%	33%	30%	28%	25%	22%	19%	17%	14%	11%	8%
60%	60%	57%	54%	51%	48%	45%	42%	39%	36%	33%	30%	27%	24%	21%	18%	15%	12%	9%
65%	65%	62%	59%	55%	52%	49%	46%	42%	39%	36%	33%	29%	26%	23%	20%	16%	13%	10%
70%	70%	67%	63%	60%	56%	53%	49%	46%	42%	39%	35%	32%	28%	25%	21%	18%	14%	11%
75%	75%	71%	68%	64%	60%	56%	53%	49%	45%	41%	38%	34%	30%	26%	23%	19%	15%	11%
80%	80%	76%	72%	68%	64%	60%	56%	52%	48%	44%	40%	36%	32%	28%	24%	20%	16%	12%
85%	85%	81%	77%	72%	68%	64%	60%	55%	51%	47%	43%	38%	34%	30%	26%	21%	17%	13%
90%	90%	86%	81%	77%	72%	68%	63%	59%	54%	50%	45%	41%	36%	32%	27%	23%	18%	14%
95%	95%	90%	86%	81%	76%	71%	67%	62%	57%	52%	48%	43%	38%	33%	29%	24%	19%	14%
100%	100%	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%	45%	40%	35%	30%	25%	20%	15%

Source: Ricardo analysis based on the responses to the online survey implemented for this Study.

Similarly, the Table below presents these matrices for downstream users of D4, D5, D6 and/or silicone polymers under the three policy scenarios.

Table _A 22 Sensitivity of net sold production losses for the downstream users of D4, D5, D6 and/or silicone polymers due to potential product withdrawal (estimates within the heatmap) against different levels of potentially affected portfolio (vertical axis) and substitution (horizontal axis).

PS	Sensitivity matrix of net sold production losses for the downstream users of D4, D5, D6 and/or silicone polymers

PS1

Potentially Affected portfolio (% of sales turnover)	Substitution (% of affected portfolio in sales turnover)																				
	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%
0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
5%	5%	5%	5%	4%	4%	4%	4%	3%	3%	3%	3%	2%	2%	2%	2%	1%	1%	1%	0%	0%	0%
10%	10%	10%	9%	9%	8%	8%	7%	7%	6%	6%	5%	5%	4%	4%	3%	3%	2%	2%	1%	0%	0%
15%	15%	14%	14%	13%	12%	11%	11%	10%	9%	8%	8%	7%	6%	5%	5%	4%	3%	2%	2%	1%	0%
20%	20%	19%	18%	17%	16%	15%	14%	13%	12%	11%	10%	9%	8%	7%	6%	5%	4%	3%	2%	1%	0%
25%	25%	24%	23%	21%	20%	19%	18%	16%	15%	14%	13%	11%	10%	9%	8%	6%	5%	4%	2%	1%	0%
30%	30%	29%	27%	26%	24%	23%	21%	20%	18%	17%	15%	14%	12%	11%	9%	8%	6%	4%	3%	1%	0%
35%	35%	33%	32%	30%	28%	26%	25%	23%	21%	19%	18%	16%	14%	12%	11%	9%	7%	5%	3%	2%	0%
40%	40%	38%	36%	34%	32%	30%	28%	26%	24%	22%	20%	18%	16%	14%	12%	10%	8%	6%	4%	2%	0%
45%	45%	43%	41%	38%	36%	34%	32%	29%	27%	25%	23%	20%	18%	16%	14%	11%	9%	7%	4%	2%	0%
50%	50%	48%	45%	43%	40%	38%	35%	33%	30%	28%	25%	23%	20%	18%	15%	13%	10%	7%	5%	2%	0%
55%	55%	52%	50%	47%	44%	41%	39%	36%	33%	30%	28%	25%	22%	19%	17%	14%	11%	8%	5%	3%	0%
60%	60%	57%	54%	51%	48%	45%	42%	39%	36%	33%	30%	27%	24%	21%	18%	15%	12%	9%	6%	3%	0%
65%	65%	62%	59%	55%	52%	49%	46%	42%	39%	36%	33%	29%	26%	23%	20%	16%	13%	10%	6%	3%	0%
70%	70%	67%	63%	60%	56%	53%	49%	46%	42%	39%	35%	32%	28%	25%	21%	18%	14%	11%	7%	3%	0%
75%	75%	71%	68%	64%	60%	56%	53%	49%	45%	41%	38%	34%	30%	26%	23%	19%	15%	11%	7%	4%	0%
80%	80%	76%	72%	68%	64%	60%	56%	52%	48%	44%	40%	36%	32%	28%	24%	20%	16%	12%	8%	4%	0%
85%	85%	81%	77%	72%	68%	64%	60%	55%	51%	47%	43%	38%	34%	30%	26%	21%	17%	13%	8%	4%	0%
90%	90%	86%	81%	77%	72%	68%	63%	59%	54%	50%	45%	41%	36%	32%	27%	23%	18%	14%	9%	4%	0%
95%	95%	90%	86%	81%	76%	71%	67%	62%	57%	52%	48%	43%	38%	33%	29%	24%	19%	14%	9%	5%	0%
100%	100%	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%	45%	40%	35%	30%	25%	20%	15%	10%	5%	0%

PS — Sensitivity matrix of net sold production losses for the downstream users of D4, D5, D6 and/or silicone polymers

PS2

Potentially Affected portfolio (% of sales turnover)	Substitution (% of affected portfolio in sales turnover)																				
	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%
0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
5%	5%	5%	5%	4%	4%	4%	4%	3%	3%	3%	3%	2%	2%	2%	2%	1%	1%	1%	0%	0%	0%
10%	10%	10%	9%	9%	8%	8%	7%	7%	6%	6%	5%	5%	4%	4%	3%	3%	2%	2%	1%	0%	0%
15%	15%	14%	14%	13%	12%	11%	11%	10%	9%	8%	8%	7%	6%	5%	5%	4%	3%	2%	2%	1%	0%
20%	20%	19%	18%	17%	16%	15%	14%	13%	12%	11%	10%	9%	8%	7%	6%	5%	4%	3%	2%	1%	0%
25%	25%	24%	23%	21%	20%	19%	18%	16%	15%	14%	13%	11%	10%	9%	8%	6%	5%	4%	2%	1%	0%
30%	30%	29%	27%	26%	24%	23%	21%	20%	18%	17%	15%	14%	12%	11%	9%	8%	6%	4%	3%	1%	0%
35%	35%	33%	32%	30%	28%	26%	25%	23%	21%	19%	18%	16%	14%	12%	11%	9%	7%	5%	3%	2%	0%
40%	40%	38%	36%	34%	32%	30%	28%	26%	24%	22%	20%	18%	16%	14%	12%	10%	8%	6%	4%	2%	0%
45%	45%	43%	41%	38%	36%	34%	32%	29%	27%	25%	23%	20%	18%	16%	14%	11%	9%	7%	4%	2%	0%
50%	50%	48%	45%	43%	40%	38%	35%	33%	30%	28%	25%	23%	20%	18%	15%	13%	10%	7%	5%	2%	0%
55%	55%	52%	50%	47%	44%	41%	39%	36%	33%	30%	28%	25%	22%	19%	17%	14%	11%	8%	5%	3%	0%
60%	60%	57%	54%	51%	48%	45%	42%	39%	36%	33%	30%	27%	24%	21%	18%	15%	12%	9%	6%	3%	0%
65%	65%	62%	59%	55%	52%	49%	46%	42%	39%	36%	33%	29%	26%	23%	20%	16%	13%	10%	6%	3%	0%
70%	70%	67%	63%	60%	56%	53%	49%	46%	42%	39%	35%	32%	28%	25%	21%	18%	14%	11%	7%	3%	0%
75%	75%	71%	68%	64%	60%	56%	53%	49%	45%	41%	38%	34%	30%	26%	23%	19%	15%	11%	7%	4%	0%
80%	80%	76%	72%	68%	64%	60%	56%	52%	48%	44%	40%	36%	32%	28%	24%	20%	16%	12%	8%	4%	0%
85%	85%	81%	77%	72%	68%	64%	60%	55%	51%	47%	43%	38%	34%	30%	26%	21%	17%	13%	8%	4%	0%
90%	90%	86%	81%	77%	72%	68%	63%	59%	54%	50%	45%	41%	36%	32%	27%	23%	18%	14%	9%	4%	0%
95%	95%	90%	86%	81%	76%	71%	67%	62%	57%	52%	48%	43%	38%	33%	29%	24%	19%	14%	9%	5%	0%
100%	100%	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%	45%	40%	35%	30%	25%	20%	15%	10%	5%	0%

PS3

Potentially Affected portfolio (% of sales turnover)	Substitution (% of affected portfolio in sales turnover)																				
	0%	5%	10%	15%	20%	25%	30%	35%	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%
0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
5%	5%	5%	5%	4%	4%	4%	4%	3%	3%	3%	3%	2%	2%	2%	2%	1%	1%	1%	0%	0%	0%
10%	10%	10%	9%	9%	8%	8%	7%	7%	6%	6%	5%	5%	4%	4%	3%	3%	2%	2%	1%	0%	0%
15%	15%	14%	14%	13%	12%	11%	11%	10%	9%	8%	8%	7%	6%	5%	5%	4%	3%	2%	2%	1%	0%
20%	20%	19%	18%	17%	16%	15%	14%	13%	12%	11%	10%	9%	8%	7%	6%	5%	4%	3%	2%	1%	0%
25%	25%	24%	23%	21%	20%	19%	18%	16%	15%	14%	13%	11%	10%	9%	8%	6%	5%	4%	2%	1%	0%
30%	30%	29%	27%	26%	24%	23%	21%	20%	18%	17%	15%	14%	12%	11%	9%	8%	6%	4%	3%	1%	0%
35%	35%	33%	32%	30%	28%	26%	25%	23%	21%	19%	18%	16%	14%	12%	11%	9%	7%	5%	3%	2%	0%
40%	40%	38%	36%	34%	32%	30%	28%	26%	24%	22%	20%	18%	16%	14%	12%	10%	8%	6%	4%	2%	0%
45%	45%	43%	41%	38%	36%	34%	32%	29%	27%	25%	23%	20%	18%	16%	14%	11%	9%	7%	4%	2%	0%
50%	50%	48%	45%	43%	40%	38%	35%	33%	30%	28%	25%	23%	20%	18%	15%	13%	10%	7%	5%	2%	0%
55%	55%	52%	50%	47%	44%	41%	39%	36%	33%	30%	28%	25%	22%	19%	17%	14%	11%	8%	5%	3%	0%
60%	60%	57%	54%	51%	48%	45%	42%	39%	36%	33%	30%	27%	24%	21%	18%	15%	12%	9%	6%	3%	0%
65%	65%	62%	59%	55%	52%	49%	46%	42%	39%	36%	33%	29%	26%	23%	20%	16%	13%	10%	6%	3%	0%
70%	70%	67%	63%	60%	56%	53%	49%	46%	42%	39%	35%	32%	28%	25%	21%	18%	14%	11%	7%	3%	0%
75%	75%	71%	68%	64%	60%	56%	53%	49%	45%	41%	38%	34%	30%	26%	23%	19%	15%	11%	7%	4%	0%
80%	80%	76%	72%	68%	64%	60%	56%	52%	48%	44%	40%	36%	32%	28%	24%	20%	16%	12%	8%	4%	0%
85%	85%	81%	77%	72%	68%	64%	60%	55%	51%	47%	43%	38%	34%	30%	26%	21%	17%	13%	8%	4%	0%
90%	90%	86%	81%	77%	72%	68%	63%	59%	54%	50%	45%	41%	36%	32%	27%	23%	18%	14%	9%	4%	0%
95%	95%	90%	86%	81%	76%	71%	67%	62%	57%	52%	48%	43%	38%	33%	29%	24%	19%	14%	9%	5%	0%
100%	100%	95%	90%	85%	80%	75%	70%	65%	60%	55%	50%	45%	40%	35%	30%	25%	20%	15%	10%	5%	0%

Source: Ricardo analysis based on the responses to the online survey implemented for this Study.

In summary, **potential production losses are at estimated to occur for all likely combinations of affected portfolio and substitution rates, with the scale of potential product losses being the smallest under PS1 and largest under PS3**. **Production losses are least likely under PS1 and most likely under PS3 based on the available evidence**.

- Under PS1, there is high likelihood that overall production in the EU will be relatively lower than the baseline projections (i.e., losses) when compared to the baseline, with possible scenarios of no production losses especially downstream which have low or very low likelihood of occurrence. In all scenarios, industry would incur one-off and recurring adjustment costs.
- Under PS2, there is high likelihood that overall production in the EU will be lower than the baseline projections (i.e., losses), with possible scenarios of limited production losses (especially downstream) which have very low likelihood of occurrence. In all scenarios, industry would incur one-off and recurring adjustment costs.
- Under PS3, there is high likelihood that overall production in the EU will be lower than baseline projections (i.e., losses), and there is no scenario (i.e., zero likelihood) in which production could reach baseline levels. In all scenarios, industry would incur one-off and recurring adjustment costs.

Next, qualitative ratings of the shortlisted economic, social and environmental impacts (described in Annex 2) were developed to test the reliance of the overall conclusions of the MCA to the assumptions made in the main body of the Study. These were based on the lower and upper bounds of the quantified effects (i.e., the ranges in the main body of the Study) that capture the uncertainties in the underlying estimates of the costs of industrial transformation, net production withdrawals, emissions reductions, etc.

Three cases were developed for testing the sensitivity of the conclusions. These are outlined in the following paragraphs. Please note that cases with 'higher bound' costs of industrial transformation would result in a worse benefit: cost ratio than under analysis based on 'medium' or central estimates. Hence, these were not considered for the purposes of sensitivity analysis.

The first case captures 'lower bound' costs of industrial transformation and 'lower bound' environmental benefits for the quality of natural resources and biodiversity. The qualitative impact ratings for the underlying impact categories are set out in the table below.

Table _A 23 Qualitative economic, social and environmental impact ratings in case (i) i.e., 'low' costs of industrial transformation and 'low' environmental benefits

Broad category	Evidence base Option	PS1	PS2	PS3
Conduct of businesses and administrative burden, functioning of the internal market, sustainable production, and position of SMEs	N/A	-0.5	-1.0	-2.5
Innovation and research	N/A	+0.5	+0.5	+0.5
Sectoral competitiveness, trade and investment flows and third countries	N/A	-0.5	-0.5	-1.0
Employment	N/A	0	-0.5	-1.5
Consumers and households	N/A	0	0	-0.5
Technological development and the digital economy	N/A	-0.5	-0.5	-1.5
Quality of natural resources (water, soil, air), including Option A and Option B	Option A (EU Commission evidence)	0	+0.5	+1.0
	Option B (broader scientific evidence)	0	0	0
Biodiversity, including Option A and Option B	Option A (EU Commission evidence)	0	0	+0.5
	Option B (broader scientific evidence)	0	0	0
Waste production, generation and recycling	N/A	-0.5	-0.5	-0.5
Resources, transport, energy and climate	N/A	-0.5	-0.5	-1.5

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this, the overall economic, social and environmental impacts are negative and the overall societal benefits are observed to be lower than the overall societal costs (i.e., benefit: cost ratio remains lower than 1), implying a negative balance of costs and benefits. This means that the estimated benefits to society from the policies under consideration are outweighed by the adjustment costs, even when considering a combination of the lowest possible adjustment costs and emissions reductions. These results are presented in the Table below.

Table _A 24 Costs and benefits of the policy scenarios in case (i) i.e., 'low' costs of industrial transformation and 'low' environmental benefits

Policy Scenario	Costs	Benefits		Benefit: Cost Ratio	
		Option A (EU Commission evidence)	Option B (Broader scientific evidence)	Option A (EU Commission evidence)	Option B (Broader scientific evidence)
PS1 – Annex B listing broad exemptions	-0.5	<+0.5	<+0.5	0.3	0.3
PS2 – Annex B acceptable purpose exemption	-1.0	<+0.5	<+0.5	0.3	0.2
PS3 – Annex A prohibition	-2.5	+0.5	<+0.5	0.2	0.1

Source: Ricardo analysis based on the evidence presented in this Study.

However, to test whether the balance of costs and benefits would shift if industry found ways to achieve emissions reductions with lower costs, a second case was developed which combined the 'lower bound' costs of industrial transformation with the 'medium' estimate of environmental benefits for the quality of natural resources and biodiversity. This could be possible but is considered to be unlikely given the available evidence.

The qualitative impact ratings for the underlying impact categories are set out in the table below.

Table _A 25 Qualitative economic, social and environmental impact ratings in case (ii) i.e., 'low' costs of industrial transformation and 'medium' environmental benefits

Broad category	Evidence base Option	PS1	PS2	PS3
Conduct of businesses and administrative burden, functioning of the internal market, sustainable production, and position of SMEs	N/A	-0.5	-1.0	-2.5
Innovation and research	N/A	+0.5	+0.5	+0.5
Sectoral competitiveness, trade and investment flows and third countries	N/A	-0.5	-0.5	-1.0
Employment	N/A	0	-0.5	-1.5
Consumers and households	N/A	0	0	-0.5
Technological development and the digital economy	N/A	-0.5	-0.5	-1.5

Broad category	Evidence base Option	PS1	PS2	PS3
Quality of natural resources (water, soil, air), including Option A and Option B	Option A (EU Commission evidence)	+0.5	+1.0	+1.5
	Option B (broader scientific evidence)	0	0	0
Biodiversity, including Option A and Option B	Option A (EU Commission evidence)	+0.5	+0.5	+1.0
	Option B (broader scientific evidence)	0	0	0
Waste production, generation and recycling	N/A	-0.5	-0.5	-0.5
Resources, transport, energy and climate	N/A	-0.5	-0.5	-1.5

Source: Ricardo analysis based on the evidence presented in this Study.

Based on this, the overall economic and social impacts are negative but the overall environmental impact is positive. However, the balance of costs and benefits remains negative as the overall societal benefits are still observed to be lower than the overall societal costs (i.e., benefit: cost ratio increases in Option A assessment but remains lower than 1). This means that even if industry found ways to achieve the emissions reductions with lower costs, the estimated benefits to society from the policies under consideration would be outweighed by the adjustment costs. These estimates are presented in the Table below.

Table _A 26 Costs and benefits of the policy scenarios in case (ii) i.e., ‘low’ costs of industrial transformation and ‘medium’ environmental benefits

Policy Scenario	Costs	Benefits		Benefit: Cost Ratio	
		Option A (EU Commission evidence)	Option B (Broader scientific evidence)	Option A (EU Commission evidence)	Option B (Broader scientific evidence)
PS1 – Annex B listing broad exemptions	-0.5	+0.5	<+0.5	0.6	0.3
PS2 – Annex B acceptable purpose exemption	-1.0	+0.5	<+0.5	0.6	0.2
PS3 – Annex A prohibition	-2.5	+1.0	<+0.5	0.3	0.1

Source: Ricardo analysis based on the evidence presented in this Study.

Further, a third case was developed which combined the ‘low’ costs of industrial transformation with the higher bound environmental benefits on quality of natural resources and biodiversity. This would be even more unlikely to occur, as the evidence suggests that large investments and energy intensive activities would be required to achieve these environmental benefits.

The qualitative impact ratings for the underlying impact categories are set out in the table below.

Table _A 27 Qualitative economic, social and environmental impact ratings in case (iii) i.e., 'low' costs of industrial transformation and 'high' environmental benefits

Broad category	Evidence base Option	PS1	PS2	PS3
Conduct of businesses and administrative burden, functioning of the internal market, sustainable production, and position of SMEs	N/A	-0.5	-1.0	-2.5
Innovation and research	N/A	+0.5	+0.5	+0.5
Sectoral competitiveness, trade and investment flows and third countries	N/A	-0.5	-0.5	-1.0
Employment	N/A	0	-0.5	-1.5
Consumers and households	N/A	0	0	-0.5
Technological development and the digital economy	N/A	-0.5	-0.5	-1.5
Quality of natural resources (water, soil, air), including Option A and Option B	Option A (EU Commission evidence)	+1.0	+1.5	+2.0
	Option B (broader scientific evidence)	0	0	0
Biodiversity, including Option A and Option B	Option A (EU Commission evidence)	+0.5	+1.0	+1.0
	Option B (broader scientific evidence)	0	0	0
Waste production, generation and recycling	N/A	-0.5	-0.5	-0.5
Resources, transport, energy and climate	N/A	-0.5	-0.5	-1.5

Source: Ricardo analysis based on the evidence presented in this Study.

As expected, based on this, the overall economic and social impacts remain negative and the overall environmental impact remains positive. However, the overall societal benefits are still observed to be lower than the overall societal costs, even though the balance of costs and benefits becomes less negative (i.e., benefit: cost ratio for Option A assessment remains lower than 1, albeit closer to 1). This means that even if industry found ways to achieve even higher emissions reductions with lower costs, the estimated benefits to society from the policies under consideration would still be outweighed by the adjustment costs. These estimates are presented in the Table below.

Table _A 28 Costs and benefits of the policy scenarios in case (ii) i.e., 'low' costs of industrial transformation and 'medium' environmental benefits

Policy Scenario	Costs	Benefits		Benefit: Cost Ratio	
		Option A (EU Commission evidence)	Option B (Broader scientific evidence)	Option A (EU Commission evidence)	Option B (Broader scientific evidence)
PS1 – Annex B listing broad exemptions	-0.5	+0.5	<+0.5	0.8	0.3
PS2 – Annex B acceptable purpose exemption	-1.0	+1.0	<+0.5	0.8	0.2
PS3 – Annex A prohibition	-2.5	+1.0	<+0.5	0.4	0.1

Source: Ricardo analysis based on the evidence presented in this Study.

In conclusion, **for all these possible but unlikely scenarios (in which lower bound industrial costs are compared against lower to upper bound environmental benefits on the quality of natural resources and biodiversity), the sensitivity analysis concluded that overall societal benefits remain lower than overall costs (i.e., benefit: cost ratio remains lower than 1).** This demonstrates that the overall conclusions in this Study are not sensitive to the multiple and complex ways in which the policies under consideration will impact the EU chemicals sector, wider society and the environment. This is aligned with the conclusions reached through the cost-effectiveness analysis presented in Section 5.1, which concludes that even lower bound estimates of adjustment costs per kg of D4, D5, and D6 emissions reductions are higher than the 'accepted' costs of any other action undertaken in the past to restrict the use and/or reduce emissions of other persistent substances (or these substances in other applications, such as cosmetics).

T: +44 (0) 1235 75 3000

E: enquiry@ricardo.com

W: ee.ricardo.com