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Impacts of REACH restriction and authorisation on substitution in the EU

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Foreword

Replacing substances of concern with safer alternatives and greener technologies is strongly driven by regulation. REACH provides a legislative push for safeguarding health and protecting the environment, as it enables us to gather accurate data on the properties and uses of chemicals, and to develop better safety measures that help to reduce risks. But it also ensures that chemicals that may cause harm are progressively replaced with safer alternatives. Under REACH, two of the main drivers for this substitution are **authorisation** and **restrictions**.

But there is also evidently a pull factor – substituting harmful chemicals and manufacturing processes can be beneficial for companies. Not only can it help to reduce emissions to the environment and lessen the health impact on workers and consumers, it can also have direct reputational benefits as customers are increasingly looking for more sustainable and ecological products and services.

And so substitution should be put in the centre of any business activities of innovative companies with a greener mindset. Within the context of the Green Deal, moving away from harmful substances is becoming an increasingly integral part of corporate policies and the way towards a sustainable and prosperous future.

As part of the second REACH Review in 2017, the European Commission published a report[1] on the overall impacts of REACH authorisation. One of its key findings was that the authorisation process enhances the substitution of substances of very high concern (SVHCs), where it is technically feasible for companies to do so. With this report, we want to follow up on this finding, but have also included the impact of restrictions within its scope – the goal being to understand how both processes impact the substitution of hazardous chemicals in the EU.

We present several case studies and the feedback we have received from stakeholders that are directly affected by authorisation and restriction. The report aims to find out the drivers for substitution, the obstacles companies face, how costly they perceive it to be, how long it takes them to implement, and the challenges and benefits from their point of view.

I hope that through this study we are able to provide a better insight into how REACH restriction and authorisation encourage European companies to substitute to safer chemicals, what the barriers to substitution are and what more can be done to overcome these.

Bjorn Hansen
Executive Director

[1] https://ec.europa.eu/docsroom/documents/26847

Key findings of the study on substitution

- REACH restriction was perceived by respondents as the most effective driver for substitution, followed by authorisation. Furthermore, customer demand and corporate sustainability policies have an impact on companies' substitution activities.
- Some market leading multinational companies had substituted early, driven primarily by corporate sustainability commitments.
- Companies saw little financial incentive and no improvement in competitive advantage associated with substituting to safer alternatives.
- Reduction in emissions to the environment and in worker exposure were perceived as the most important benefits of substitution.
- Companies considered that most of the difficulties they face in substituting were of a technical nature. This was followed by economic and market barriers. Customer specifications were also deemed important.
- Inclusion of a substance in the Candidate List and Authorisation List (REACH Annex XIV) were, besides REACH restriction, the most significant triggers for companies to start their substitution activities. The screening of substances and risk management option analysis (RMOA)[2] also provided incentives.

[2] Screening and risk management option analysis (RMOA) are two distinct but interrelated processes. Some substances screened by ECHA or Member State competent authorities may require a follow-up action on the basis of an identified concern. RMOA is one of the possible follow-up actions for screened substances. Substitution is reported to take place any time after the proposal of screened substance(s) for RMOA, during RMOA, or after the official outcome of RMOA, which may identify the need for regulatory action.

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List of abbreviations

AfA: Application for authorisation

AoA: Analysis of alternatives

BPA: 4,4'-isopropylidenediphenol

DBP: Dibutyl phthalate

DecaBDE: Bis(pentabromophenyl) ether

DEHP: Bis (2-ethylhexyl) phthalate

Diglyme: Bis(2methoxyethyl) ether

DMF: Dimethylfumarate

CMR: Carcinogenic, mutagenic and reprotoxic

CSR: Chemical Safety Report

DU: Downstream user

EC: European Commission

ECHA: European Chemicals Agency

EU: European Union

HBCDD: HexaBromoCycloDoDecane

MS: Member State

NGO: Non-governmental organisation

PBT: Persistent, bioaccumulative and toxic

R&D: Research and development

RAC: Committee for Risk Assessment

REACH: Registration, Evaluation, Authorisation and restriction of Chemicals

RO: Restriction options

RoI: Registry of Intentions

RMM: Risk management measure

RMO: Risk management option

SEA: Socio-economic analysis

SEAC: Socio-Economic Assessment Committee

SVHC: Substance of very high concern

vPvB: very persistent and very bioaccumulative

1. Introduction

The REACH Regulation entered into force on 1 June 2007 with the aim of improving the protection of human health and the environment from the possible risks posed by chemicals, and their free circulation in the internal EU market, while enhancing the competitiveness and innovation of the EU chemicals industry.

For this purpose, two main regulatory risk management measures are available under REACH to address substances that are of the highest concern: *authorisation* and *restriction*. Registrants need to prepare chemical safety assessments and demonstrate that the use of their substances is adequately controlled, and that exposure and emissions are minimised.

Under REACH, there is an obligation to monitor the progress made in achieving the regulation's objectives every five years. In 2017, as part of this review, the European Commission published a study on the overall impacts of the REACH authorisation process in the EU. The main findings of this study indicated that the REACH authorisation system had, among other things, promoted the substitution of substances of very high concern (SVHCs) with safer alternatives.

This report provides the latest information on this, but also includes the impact of restrictions under REACH as part of its scope, with the goal of understanding the impacts of both processes on the substitution of hazardous chemicals in the EU. It presents the results of a survey sent to more than 500 stakeholders including companies affected by authorisation or restriction as well as industry associations, the conclusions reached concerning drivers for substitution, its costs, the time required to implement substitution, and the challenges and benefits from the companies' perspectives. These findings are illustrated with five case studies. Finally, some recommendations for promoting substitution are presented.

Some caveats associated with the study include:

- *Focus on applicants and downstream users*
  - When contacting stakeholders, the focus was centred on applicants for authorisation and downstream users. Therefore, the sample of respondents did not cover all EU industries but a specific subset that had been impacted by REACH regulation. The results need to be interpreted with that in mind.

- *Possible underestimation of innovation as a source and motivation for substitution.*
  - Some of the respondents were applicants for authorisation. This may have contributed to an overemphasis of the need to reduce exposure in the context of substitution in comparison with other factors such as innovation.

- *Possible overestimation of challenges and costs of substitution*
  - Some respondents seemed to express their overall sentiments about the authorisation and restriction processes. This may have resulted in an overestimation of the challenges and costs, while underestimating the benefits of substitution.

2. Methodology

2.1. Data

Data for this study was collected through an online questionnaire (Annex 1) as well as in-depth phone interviews. The questions covered a wide range of issues focusing on the substitution activities of companies in terms of selected alternatives, costs, drivers, challenges and the benefits of substitution.

Tables 1 and 2 illustrate the list of substances and their respective uses within the scope of this study.

Table 1: Substances in the scope of the study - authorisation

Substance	CAS number	Uses
Chromium VI compounds	-	Surface treatment Plating
Trichloroethylene (TCE)	79-01-6	Solvent Degreasing parts in manufacture
Hexabromocyclododecane (HBCDD)	25637-99-4	Flame retardant
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	Plasticiser
Dibutyl phthalate (DBP)	84-74-2	Plasticiser
1,2-dichloroethane	07-06-2	Solvent Swelling agent
Bis(2-methoxyethyl) ether (Diglyme)	111-96-6	Solvent
Arsenic acid	7778-39-4	Treatment of copper foils
Arsenic trioxide	1327-53-3	Processing aid

Table 2: Substances in the scope of the study - restriction

Substance	CAS number	Uses
1, 4-dichlorobenzene	106-46-7	Air fresheners Toilet blocks
Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	214-604-9	Flame retardant
Bisphenol A,4,4'-isopropylidenediphenol	201-245-8	Thermal paper
Dimethylfumarate (DMF)	624-49-7	DMFu in treated articles
Lead and its compounds	7439-92-1	Jewellery Consumer articles
Mercury	7439-97-6	Measuring devices
Bis(2-ethylhexyl) phthalate (DEHP)	117-81-7	Plasticiser

The survey was sent to 554 stakeholders from April to July 2019. These stakeholders included companies affected by an authorisation and/or restriction as well as industry associations. The stakeholders affected by the REACH authorisation process were applicants and downstream users. Relevant stakeholders affected by a restriction were identified through a consultation with the dossier submitter (ECHA or Member State), companies listed in the restriction dossier, companies who participated in past consultations, and companies who have registered a use of a substance.

In addition, ECHA collaborated with various industry associations, who not only encouraged their member organisations to take part in the survey, but also provided information on industry trends. A detailed description of the types of actors and substances is provided in Annex 2.

Based on the answers received through the survey, additional information was collected by conducting interviews with selected stakeholders. The aim of the interviews was to gain an in-depth understanding of companies' substitution activities by exploring points of interest at greater length. The goal was to cover most of the substances in the scope of the study and also to gain valuable insights on industry trends.

2.2. Analytical approach

Both qualitative and quantitative methods were used to analyse the data. In analysing the qualitative data, ECHA mainly used a thematic network[3] analysis method. Thematic network analysis aims to identify the salient themes in the text, and then facilitates the structuring and

[3] https://utsc.utoronto.ca/~kmacd/IDSC10/Readings/Readings/text%20analysis/themes.pdf

representation of these themes.

Quantitative data was analysed descriptively as well as inferentially. Descriptive analysis has been instrumental in transforming the raw data into an understandable, interpretable and representable form, whereas the inferential analysis was used to draw important inferences from the data and make valid predictions whenever necessary.

3. REACH authorisation and restriction

REACH authorisation and restriction are two key regulatory risk management instruments.

Authorisation – in the interests of protecting human health and the environment – ensuring that substances of very high concern (SVHCs) are progressively replaced by less hazardous substances or technologies, where technically and economically feasible alternatives are available is one of three key objectives of the REACH authorisation title. The others are making sure that the risks to human health and the environment are properly controlled and ensuring the good functioning of the internal market.

A substance included in the Authorisation List (Annex XIV) cannot be used or placed on the market after the sunset date[4] unless an authorisation has been obtained for the substance for specific use(s).

Restriction is meant to protect human health and the environment from unacceptable risks posed by chemicals. It may impose a condition for, or prohibition of, the manufacture, use or placing on the market of a substance on its own, in a mixture or in an article.

Both regulatory instruments drive companies to substitute harmful chemicals toward safer alternatives. Given the inherent differences between the two processes, the overall efficacy and the ways in which they lead to substitution varies.

Readers can better familiarise themselves with REACH restriction and REACH authorisation processes and understand their peculiarities and *modus operandi on* ECHA's website.

4. Study results

4.1. Substitution

Substitution is "the replacement or reduction of hazardous substances in products or processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via

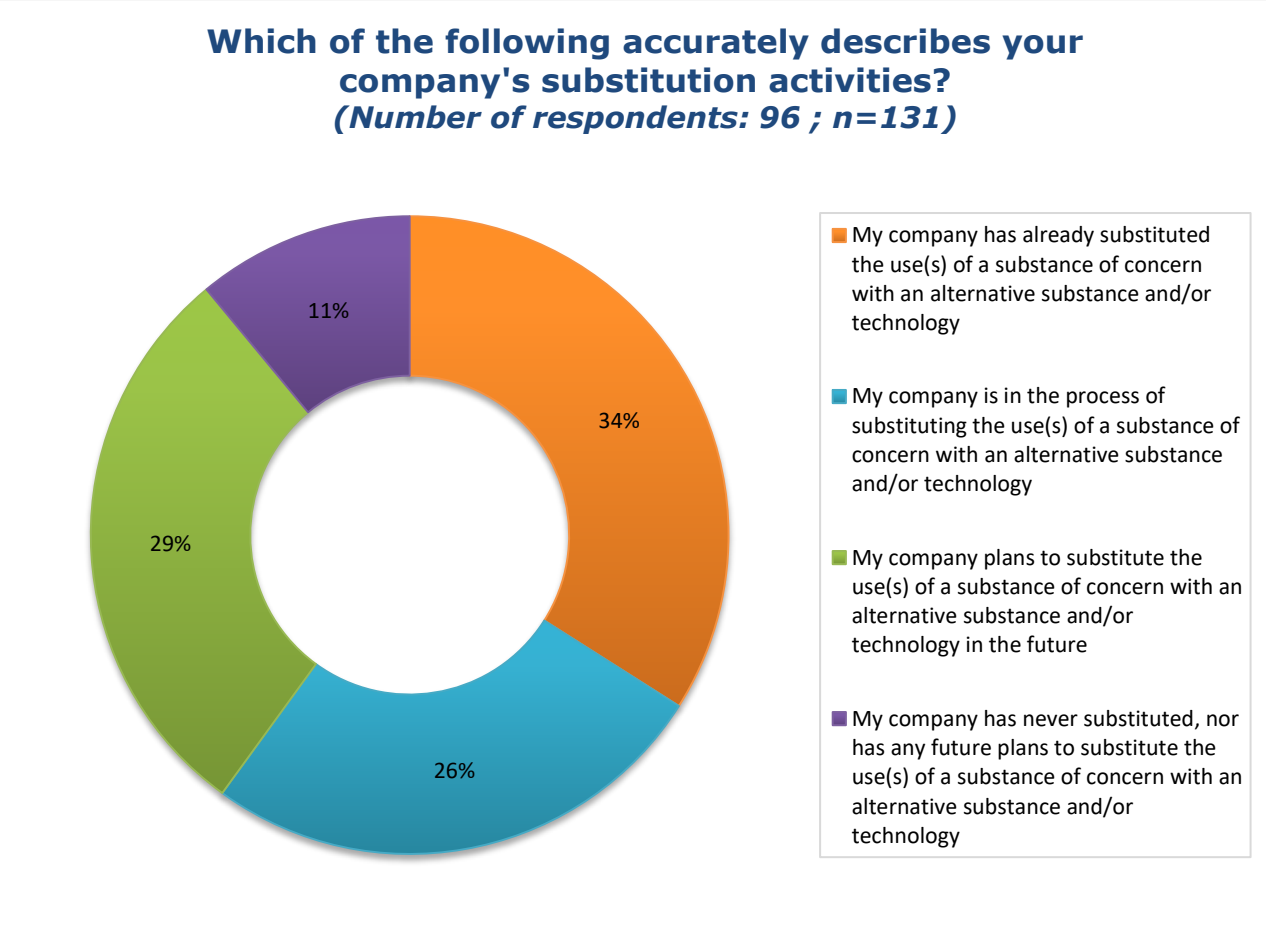
[4] The so-called 'sunset date' is a date after which a substance included in the Authorisation List (Annex XIV) cannot be placed on the market without authorisation for specific use(s).

technological or organisational measures."[5] This definition emphasises the technical function of the substance rather than its physicochemical structure.

The progressive substitution of SVHCs with suitable alternatives is one of the key objectives of authorisation under REACH. Substitution is directly linked with the main objectives of REACH – ensuring a high level of protection for human health and the environment. It also contributes to the overarching EU objectives for a non-toxic environment and a circular economy by progressively replacing harmful substances with more sustainable alternatives.

In total, 96 companies answered the survey. Respondents could select several substances and/or uses at the same time, thereby resulting in a total of 131 answers.

Of the 131 received answers, 34 % (45) indicated that their company had already substituted the use(s) of a substance of concern, while 26 % (34) were in the process of substituting and 29 % (38) had plans to substitute in the future. Finally, 11 % of the respondents (14) indicated that they had no plans to substitute.



[5] Lohse, J., et al. (2003), Substitution of Hazardous Chemicals in Products and Processes. Final Report, Revision 1. Ökopol, Hamburg, March 2003.

Figure 1: Which of the following accurately describes your company's substitution activities?

4.2. Substitution of substances of concern

Figure 2 presents the stage of substitution with respect to the substance of concern. For a few substances (e.g. restriction of BPA in thermal paper), around half of the contacted stakeholders were not concerned by the restriction given that their specific use(s) of the substance did not fall under the scope of the restriction, and therefore answered that they had no immediate plans to substitute.

In total, 96 companies answered the question related to the substitution stage. However, given that respondents had the possibility to select more than one substance, there were a total of 216 answers selected[6].

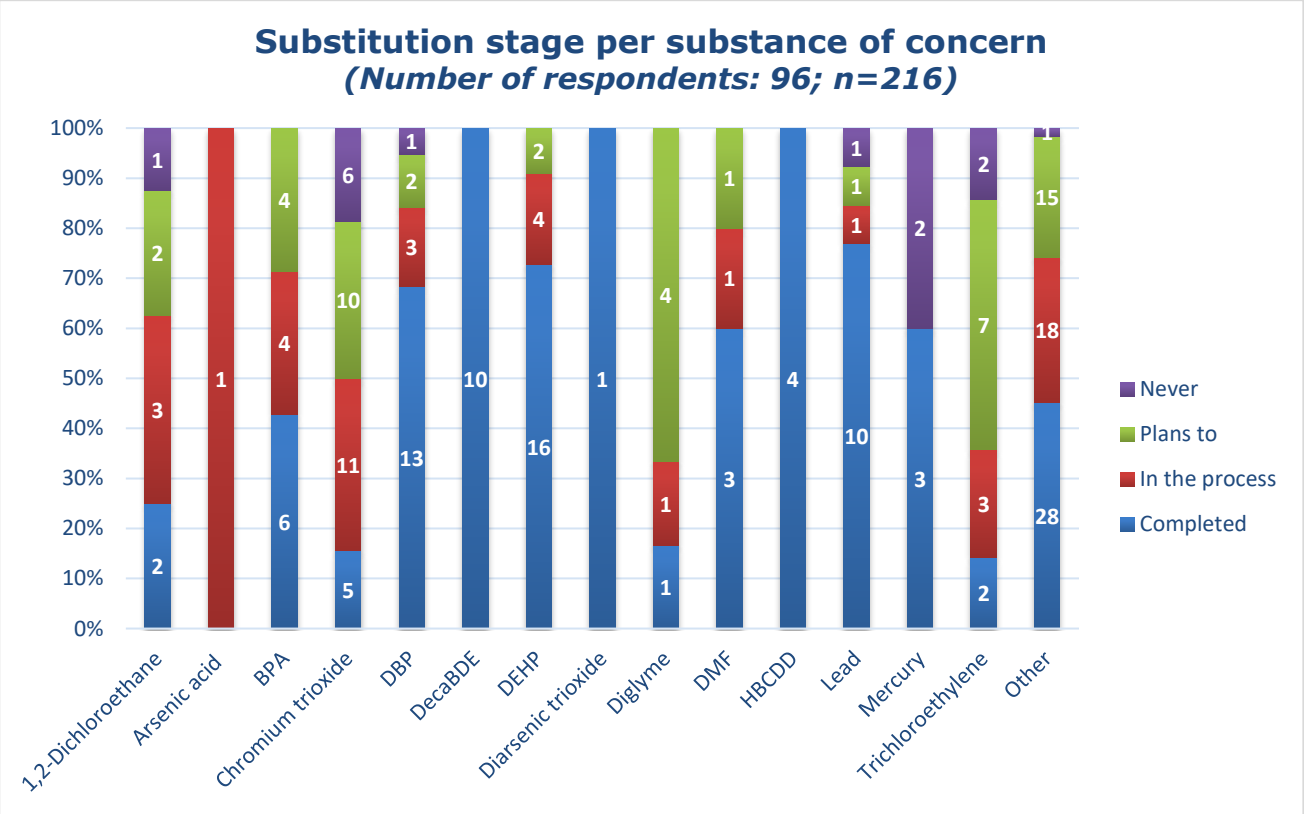


Figure 2: Stage of substitution according to the substance

Based on the survey findings it is possible to build three groups of substances with regard to the

[6] For example, there were a total of 32 responses received for chromium trioxide, of which five responses indicated that the substitution project was completed, 11 substitution projects were still in the process, 10 were planned to be carried out sometime in the future, and six responses suggested that there would be no substitution project undertaken in the future.

stage of substitution.

1. *Substances in the Authorisation List (e.g. HBCDD, DBP, DEHP and diarsenic trioxide) with sunset dates that started more than three years ago and the substances concerned by a restriction (e.g. mercury in measuring devices, lead in jewellery, DecaBDE in flame retardants, and DMFu in treated articles).*

For these substances and the corresponding uses surveyed in this study, substitution in the EU was reported to be either almost completed (more than 70 % of the respondents have already begun to use an alternative) or wholly completed.

Concerning DMFu in treated articles and lead in jewellery, the restrictions entered into force in 2012 and 2015 respectively, and therefore substitution must have been completed before this study. However, the respondents who answered that they are in the process of substitution or planning to substitute in the future, are using these substances for uses not concerned by the restriction.

For mercury in measuring devices, the restriction entered into force in 2014. Therefore, the respondents who answered that they had never substituted:

- have discontinued their uses;
- have exported their uses outside the EU; or
- are using the substance in a way not concerned by the restriction.

Moreover, it is possible that these responses may hint at instances of non-compliance with the conditions of the restriction. In fact, one of the findings of the Forum Enforcement Project (REF-4) [7] was that there was an 88.5 % non-compliance rate in the 392 product checks for measuring devices. Most of the products checked for measuring devices contained mercury above the limit.

2. *Substances in the Authorisation List with a relatively recent sunset date (e.g. chromium trioxide, trichloroethylene, 1,2-dichloroethane, diglyme and arsenic acid).*

For these substances, more than half of the respondents are in the process of substitution or planning to substitute. These results were expected as all the respondents applied for an authorisation for their uses (their own or through an upstream authorisation) in which they have to include a substitution plan. As these substances have a recent sunset date, it is not surprising that the substitution is not yet complete. Less than 25 % of the respondents have completed the substitution.

[7] https://echa.europa.eu/documents/10162/13577/ref_4_report_en.pdf/b53f5cd9-64a4-c120-1953-e9e176b9c282

3. *Substance concerned by a restriction with an entry into force date in the future at the time of the survey (e.g. BPA in thermal paper).*

The restriction of BPA in thermal paper entered into force on 2 January 2020. By mid-2019, 43 % of respondents had substituted away from BPA and 57 % were either in the process or planning to substitute in the immediate future. It is important to note that the respondents planning to substitute were using BPA for other applications than thermal paper.

4.3. Substitution across the supply chain

Each respondent could choose more than one role in the supply chain and was able to describe several substitution activities for several uses/substances. Figure 3 represents the shares of each substitution activity for each type of actor.

According to the survey findings, the completed substitution of at least one substance of concern represents 57 % of the answers selected by distributors, while the substitution in progress represents 29 %. Concerning downstream users and manufacturers, respectively, 42 % and 44 % of the selected answers indicated that the substitution was complete. Moreover, 22 % of selected answers by downstream users and 21 % by manufacturers indicated that they were in the process of substitution. Furthermore, 'planning to substitute' represents 25 % and 19 % of downstream users' and manufacturers' answers, respectively. Distributors did not indicate such plans.

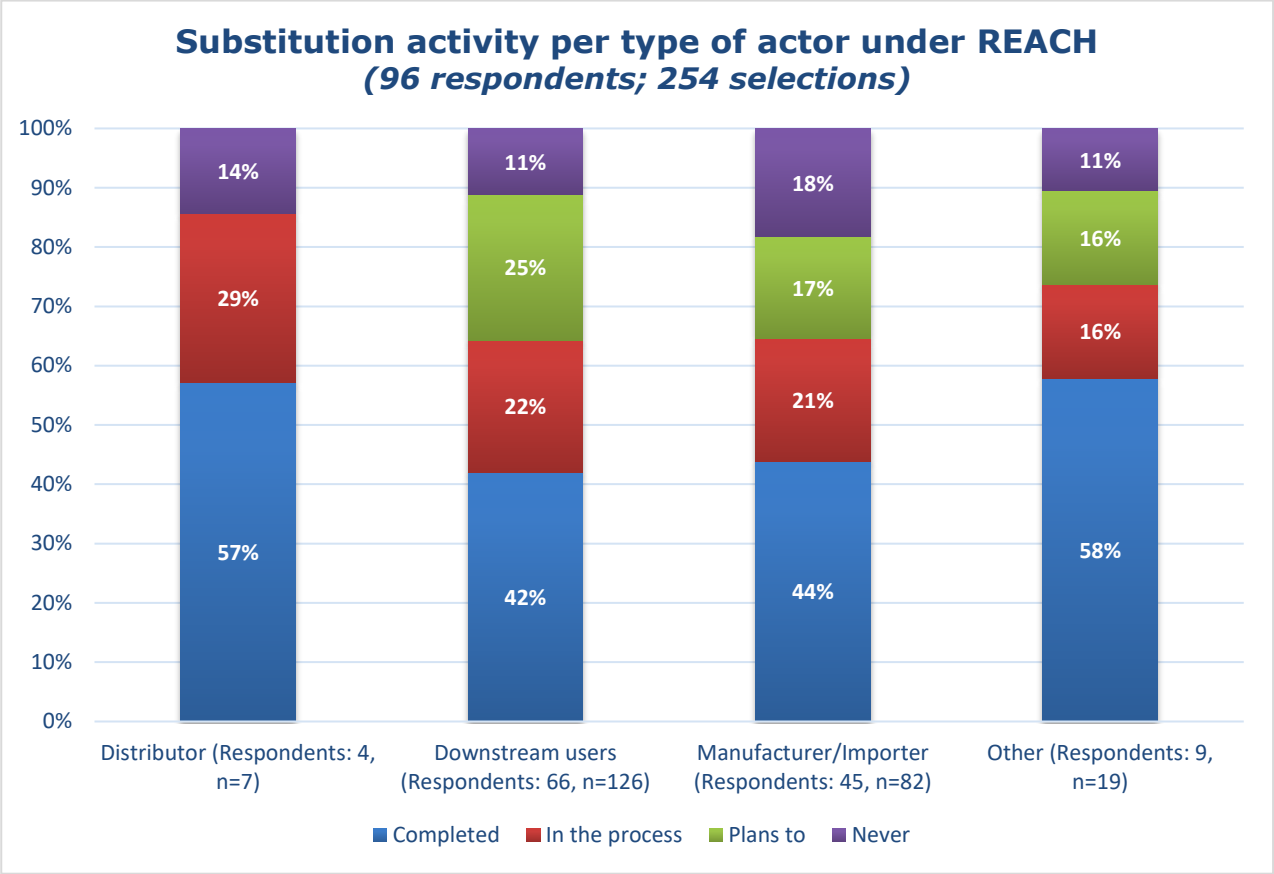


Figure 3: Substitution activity per type of actor under REACH (96 respondents, 254 selections)

4.4. Different regulatory stages at which substitution activities are launched

4.4.1. Authorisations

Out of the 48 answers received from the 36 respondents who said that their substitution was largely brought about by REACH authorisation process, 25 % (12) indicated that companies had started their substitution activities at the time that the substance was included in the *Candidate List*. Approximately the same number of answers (27 %; 13) traced the origin of substitution activities to the inclusion of the substances in the *Authorisation List* (Annex XIV). Five respondents (10 %) indicated the *screening of the substance and risk management option analysis (RMOA)* as the regulatory phase at which companies' substitution activities started.

Furthermore, *applications for authorisation (AfA) and recommendations for inclusion of substance in Authorisation list (Annex XIV)* represented 17 % and 21 % of the total number of answers, respectively.

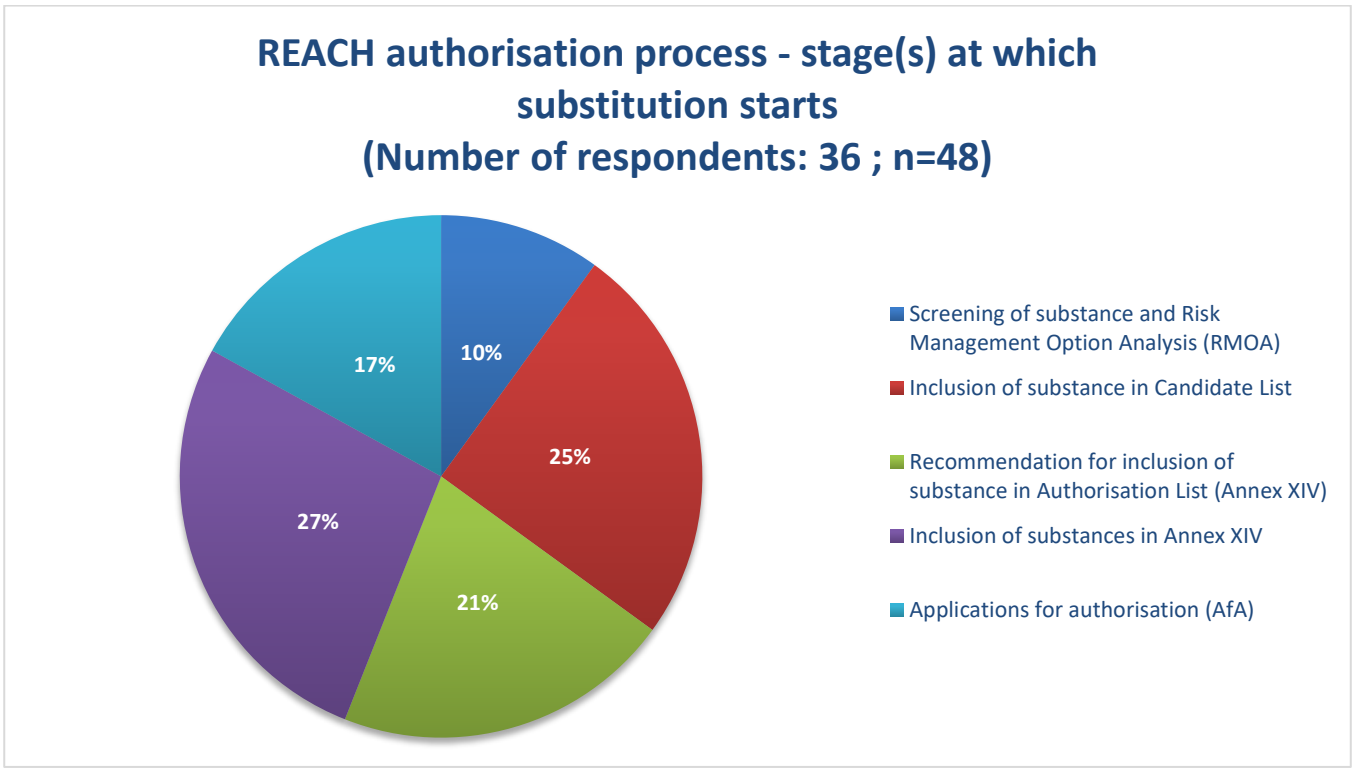


Figure 4: REACH authorisation process - stage(s) at which substitution starts

4.4.2. Restrictions

It appears that most of the companies affected by restriction start their substitution activities at the time when an *intention to prepare a restriction proposal is made public in the registry of intentions* (33 % of the 65 selected answers). Altogether, 30 % of the responses indicated that substitution activities started when the *European Commission decided and amended Annex XVII and published its decision in the Official Journal*. Furthermore, 18 % of the responses traced the origin of the respondents' substitution activities to the issuing of opinions by ECHA's scientific committees, whereas 19 % of answers pinpointed that companies started their substitution projects when *the restriction proposal is prepared and submitted to ECHA's scientific committees*.

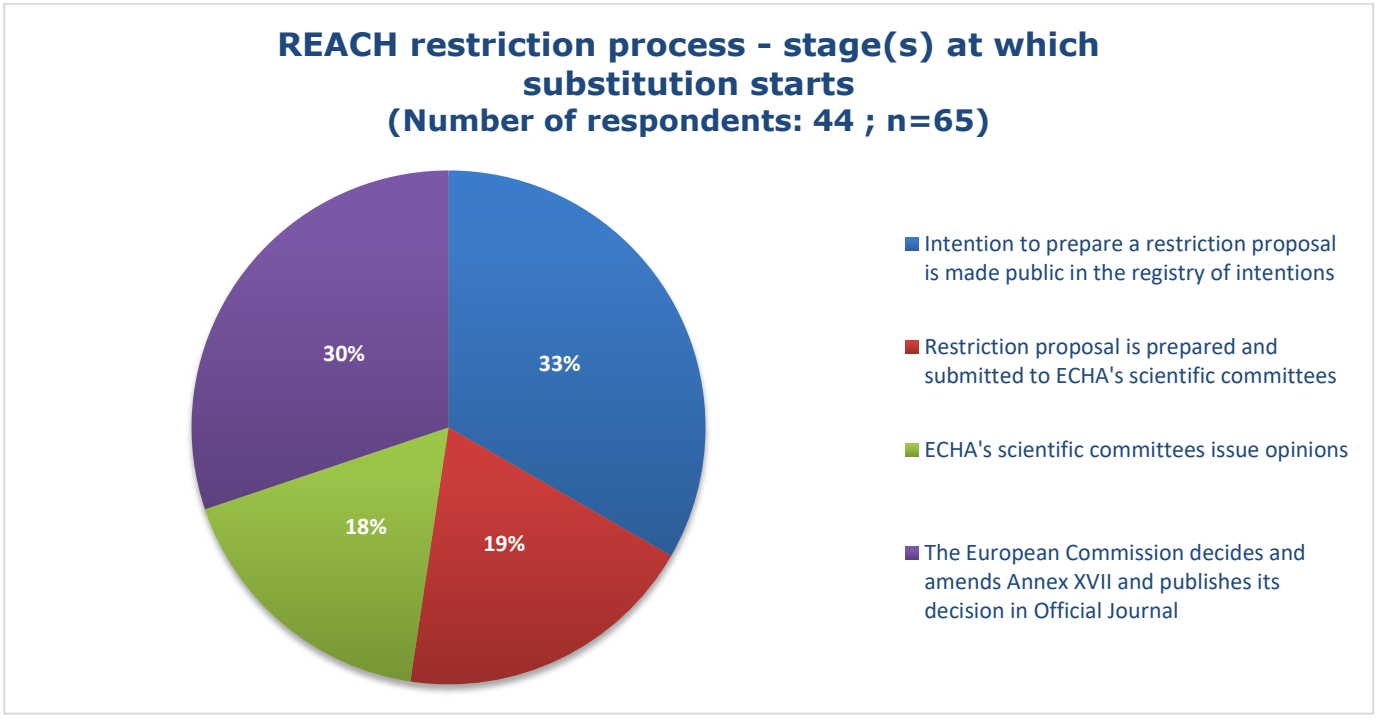


Figure 5: REACH restriction process - stage(s) at which substitution starts

4.5. Drivers for substitution

Figure 6 represents the drivers for substitution. Based on the survey findings, REACH authorisation and restriction processes seem to be the most important drivers for substitution, with 15 % of the respondents selecting the former, and 19 % the latter option.

Other REACH processes and EU regulations play important, but less tangible, roles in driving substitution. Besides the regulatory impetus, companies' substitution activities are to a significant degree driven by *customer demand* (13 %), *own corporate sustainability policy* (13 %), and *public image* (8 %) – noting that these three drivers are inseparably linked with

regulatory incentives.

Finally, 6 % of the respondents indicated *new market opportunities* as their main drivers, whereas *financial benefits associated with alternatives*, *competitors substituting as well*, and *other reasons* were cited by 2 %, 2 % and 9 % of the respondents, respectively.

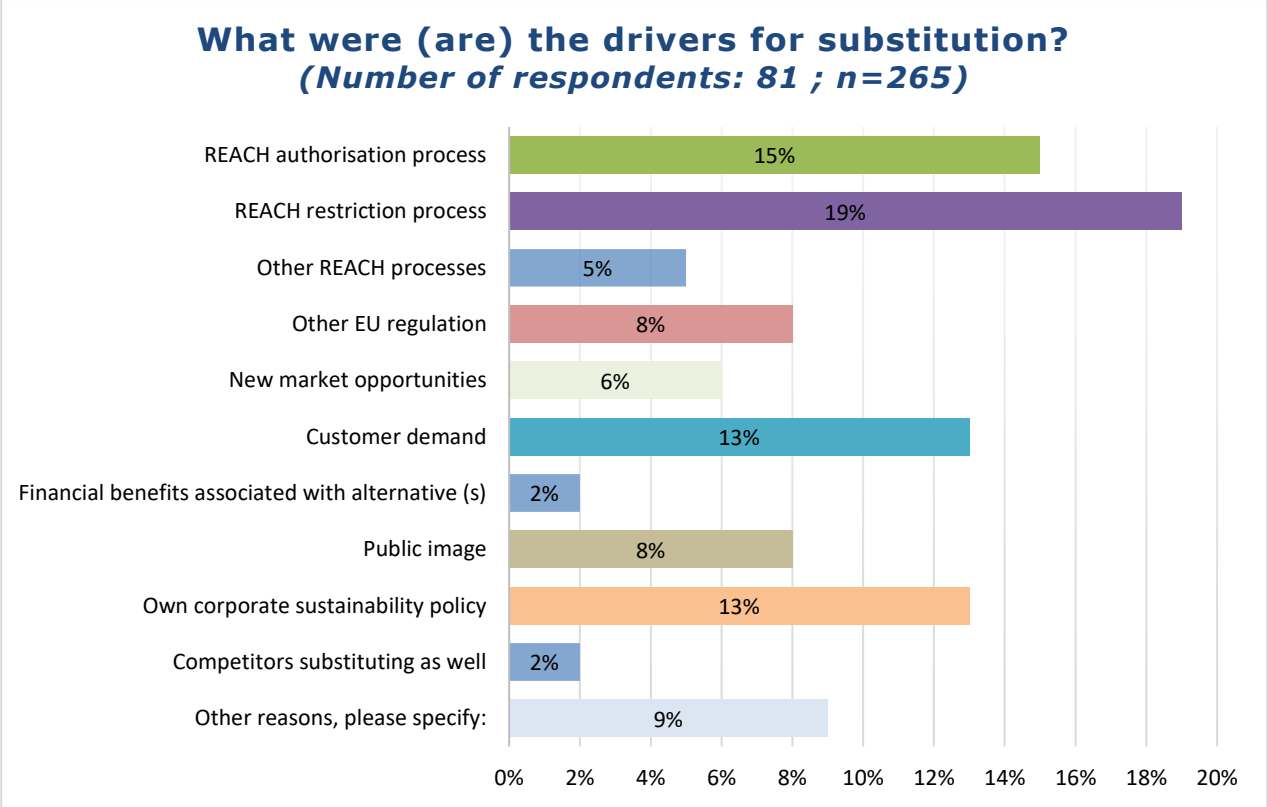


Figure 6: Drivers for substitution

To facilitate an analysis of the findings, the reported drivers were grouped into five larger categories:

- Regulation;
- Financial benefits;
- Market concerns;
- Sustainability concerns and public image; and
- Other.

Each respondent could choose more than one role in the supply chain and could pick several drivers. Figure 7 represents the drivers for substitution per type of actor. Regulation seems to be the pivotal driver across all types of actors as it represented over 40 % of the selected answers. This was followed by market concerns, which were most accentuated in distributors

(27 % of the selected answers) and manufacturers/importers (22 %) and less accentuated in downstream users (20 %) and other actors (21 %).

Sustainability concerns and *public image* were shared by all actors except distributors, albeit to a varying degree. Financial benefits were regarded as an important driver for distributors, whereas their significance was negligible for three other actor types.

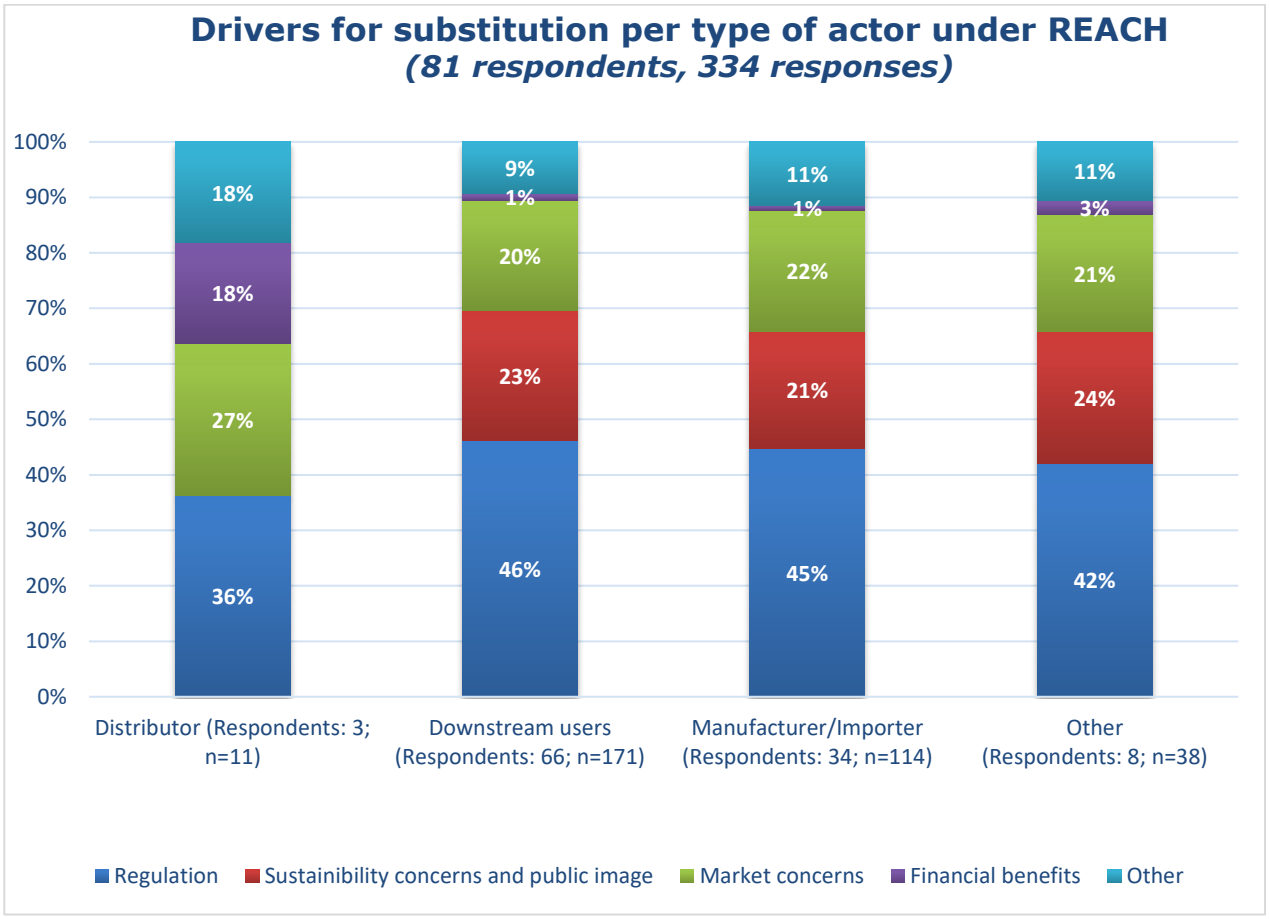


Figure 7: Drivers for substitution according to the type of actor under REACH

4.6. Regulation

Regulation in this survey comprised authorisation, restriction and other processes under REACH as well as other EU regulations. REACH authorisation and restriction processes were by far the most significant drivers for substitution, the former being cited by 15 % of respondents as the key driver and the latter by 19 %.

REACH authorisation and restriction were followed by other REACH processes (5 %) and other EU regulations (8 %). For instance, waste water policy and other non-EU regulations and policy trends, such as the EPA Significant New Use Rule and the Stockholm Convention listing are also highlighted as drivers for substitution.

Based on some of the survey results as well as the interviews, it appeared that regulations often lead to some other non-regulatory considerations that companies are becoming increasingly attentive towards.

4.7. Financial benefits

It was perhaps both surprising and telling that only 2 % of the respondents cited *financial benefits of using an alternative* as a driver for substitution. Financial benefits were here primarily understood as equivalent to an increase in generated revenues. Furthermore, financial benefits of substitution represented 18 % of the answers selected by distributors, whereas the number was close to 1 % for downstream users, manufacturers and other actors.

Given the lack of the existing data, it is hard, if not entirely impossible, to fully explain why the share was so much higher for distributors than for other types of actors. However, given that distributors usually bear the least amount of direct costs as a result of substitution (they primarily incur switching costs from one supplier to another), it is understandable why they may view substitution as less of a financial burden and more of a financial benefit. These types of actor may need to shoulder, at least initially, the costs of substitution, and therefore were less inclined to think of substitution in terms of financial benefits.

4.8. Market concerns

The *market concern* category is composed of three different elements: *New market opportunities*, *customer demand* and *competitors substituting as well*. Figure 8 presents the drivers for substitution related to market concern per type of actor. Out of these, 67 % of the distributors perceived market opportunities in substituting away from hazardous chemicals, whereas only 21 % of downstream users and 28 % of manufacturers substituted for the same reason.

On the other hand, 68 % of downstream users and 60 % of manufacturers concerned by their markets carried out a substitution activity because of customer demand.

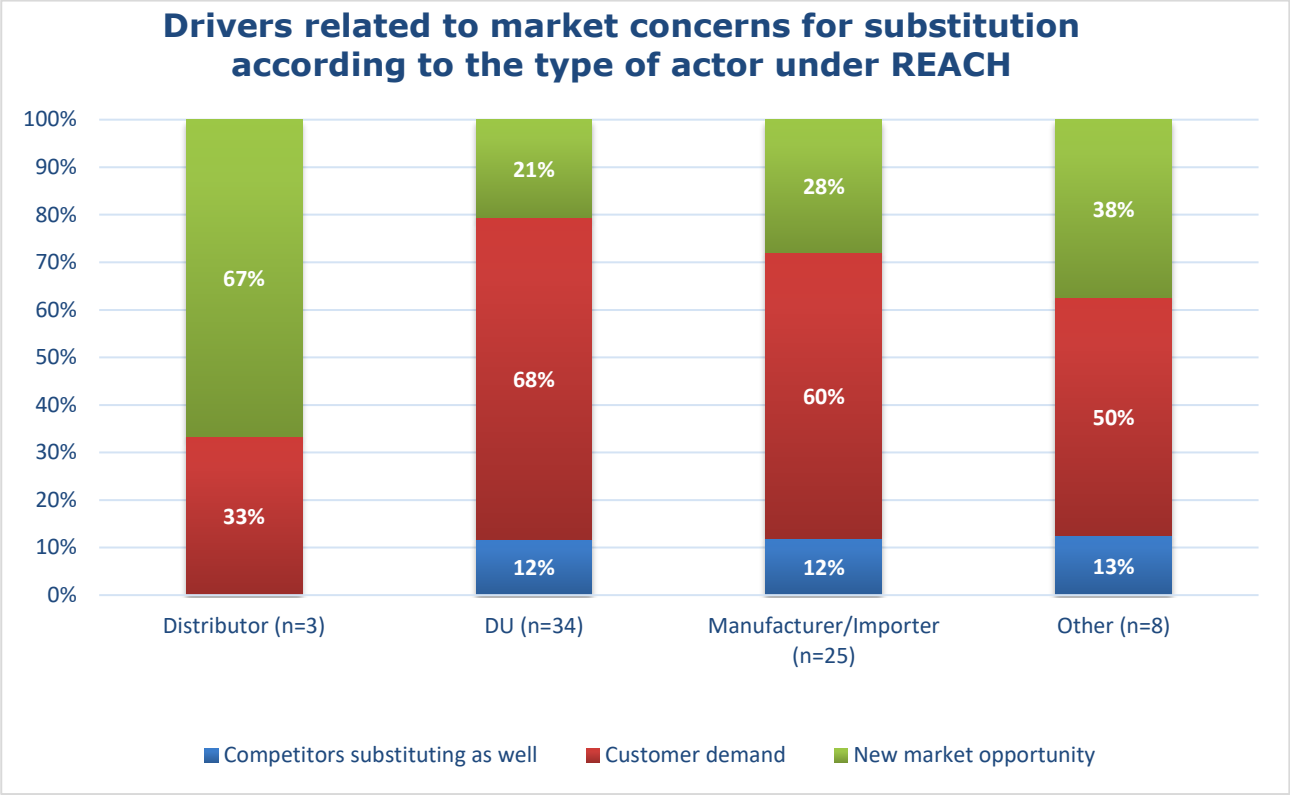


Figure 8: Drivers related to market concerns for substitution according to the type of actor under REACH

Besides regulation, it seems that distributors substituted mostly because they perceived market opportunities and financial benefits associated with using an alternative. On the other hand, manufacturers and downstream users were more concerned by demand from their customers and their own sustainability policies.

As mentioned by several stakeholders during the phone interviews, it is important to note that the drivers were all interconnected. For instance:

- REACH is one of the reasons for changes in the chemicals market: if a substance is restricted, the customer may have to switch to an alternative, which will in turn encourage manufacturers to produce alternative substances.

- Sometimes companies' sustainability policies are related to or stem from regulations. For instance, during phone interviews, some stakeholders claimed that one of the ways they strive to meet the sustainability criteria is by gradually substituting away from substances included in the Candidate List of SVHCs under REACH.

4.9. Sustainability concerns and public image

Environmental sustainability is one of the most defining and prevalent issues facing our society today. Therefore, it is only natural that companies tend to afford heightened attention to it. Companies' sustainability policies are closely linked with their public image in the eyes of various societal stakeholders. *Sustainability concerns and public image* were cited as a driver for substitution by downstream users (23 % of selected answers), manufacturers (21 %), and other stakeholders (24 %), while they were regarded negligible by distributors. It seems, therefore, that substitution is often triggered by companies' general sustainability policies and their desire to have a positive public appeal, which in turn is conducive to bolstering their profitability. This finding is somewhat in contrast with the conclusion of RPA (2017)[8], which stated that "while chemicals management and specific industry initiatives (such as Responsible Care and Global Product Stewardship) contribute to achieving companies' compliance and HSE objectives, these are not directly integrated into sustainability strategies".

4.10. Other drivers

In addition to regulatory drivers, such as REACH authorisation and restriction, respondents also identified other drivers for substitution, among which the most prominent were supply chain disruptions, technical performance constraints of a product and exclusion lists.

Supply chain disruptions were associated with limitations of the market availability of a substance due to supplier withdrawal, formulation obsolescence due to chemical supply disruptions, or supplier business drivers. In that case, companies need to substitute to a substance which is widely available on the market.

Several companies indicated technical performance constraints of a product and its use as a driver for substitution. For instance, in one case the project of substitution was launched in 2002, before REACH came into force.

Finally, trade association exclusion lists, customer-banned and restricted lists, reports on substances of high concern, and supplier demand for a safer alternative, were indicated as drivers for substitution. For instance, in these cases, companies gain a competitive advantage by having a viable alternative and avoiding the use of carcinogenic, mutagenic and reprotoxic (CMR) and persistent, bioaccumulative and toxic (PBT) substances.

[8] "Insights on the impact of REACH & CLP implementation on industry's strategies in the context of sustainability" (2017) available at https://echa.europa.eu/documents/10162/13637/echa_css_report_without_case_studies_en.pdf/a0a6f46f-16c8-fbea-8b41-9ff683aafe5c

Key findings – Drivers

- Regulations (both REACH and other EU regulations) were the primary drivers of substitution in the EU.
- Financial benefits were seldom associated with substitution by REACH actors, with the exception of distributors.
- Market concerns were often spurred by regulatory activities, therefore, they could not be regarded as primary drivers for substitution.
- Companies' sustainability policies were in some instances also linked with regulatory developments.

5. Barriers and costs

The study also investigated underlying factors that determine the time needed for substitution, such as types of barriers, industry-related requirements and certification. It also addresses one-off and annual costs of substitution activities that take more than seven years, from four to six years, and less than three years.

According to the survey findings, 36 % of 81 respondents considered that substitution would take more than seven years, while 20 % indicated four to six years as a sufficient time to complete the substitution activities. On the other hand, 44 % of the respondents could switch to an alternative in less than three years. Figure 9 illustrates the time required for substitution per substance. Among other things, the time required to substitute a given substance depends on its specific function and use.

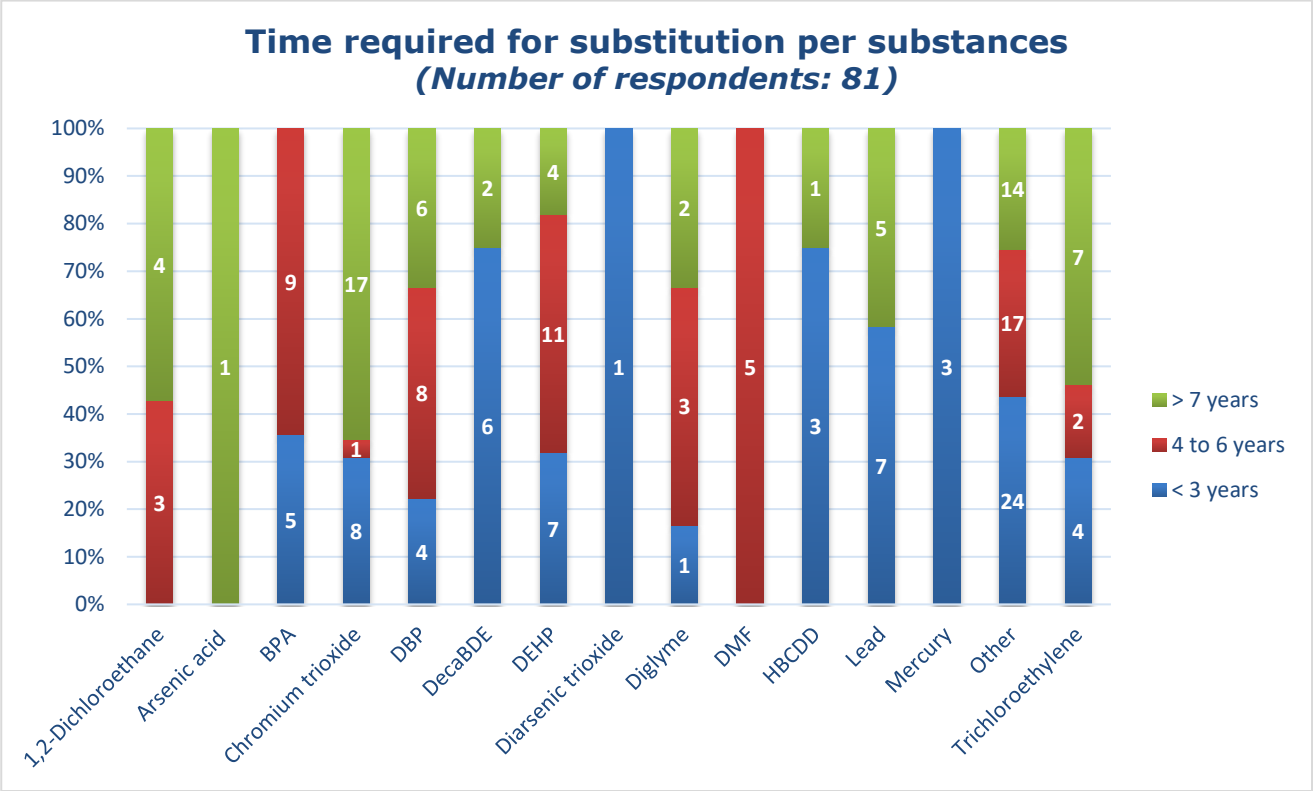


Figure 9: Time required for substitution per substance

5.1. Substitution in more than 7 years

Companies that said they would need more than seven years to substitute **faced similar technical barriers**, including:

- difficulty to identify potential alternatives;
- a lack of available alternatives;
- technical difficulty to test the performance of the identified alternatives (lack of pilot testing capability, research and development (R&D) and available technology); and
- non-availability of technically feasible alternatives that meet customers' requirements (after testing).

These technical barriers were associated with the substitution of the following substances: solvents (1,2-dichloroethane, diglyme and trichloroethylene), plasticisers (DEHP and DBP), flame retardants (HBCDD and DecaBDE), chromium (VI), lead and arsenic acid.

In addition to the technical barriers, companies also face economic and market-related barriers, including:

- non-availability of economically feasible alternatives;
- concerns related to market adoption/approval of the products manufactured with the alternative; and
- reduced competitive advantage in the market as a result of a switch to an alternative.

Companies encountered economic and market-related substitution barriers, for instance: diglyme, trichloroethylene, 1,2-dichloroethane, chromium trioxide, arsenic acid, lead compounds used as stabilisers in PVC, DBP and boric acid. Figure 10 illustrates how companies attempted to overcome the technical, economic and market barriers in substitution activities taking more than seven years.

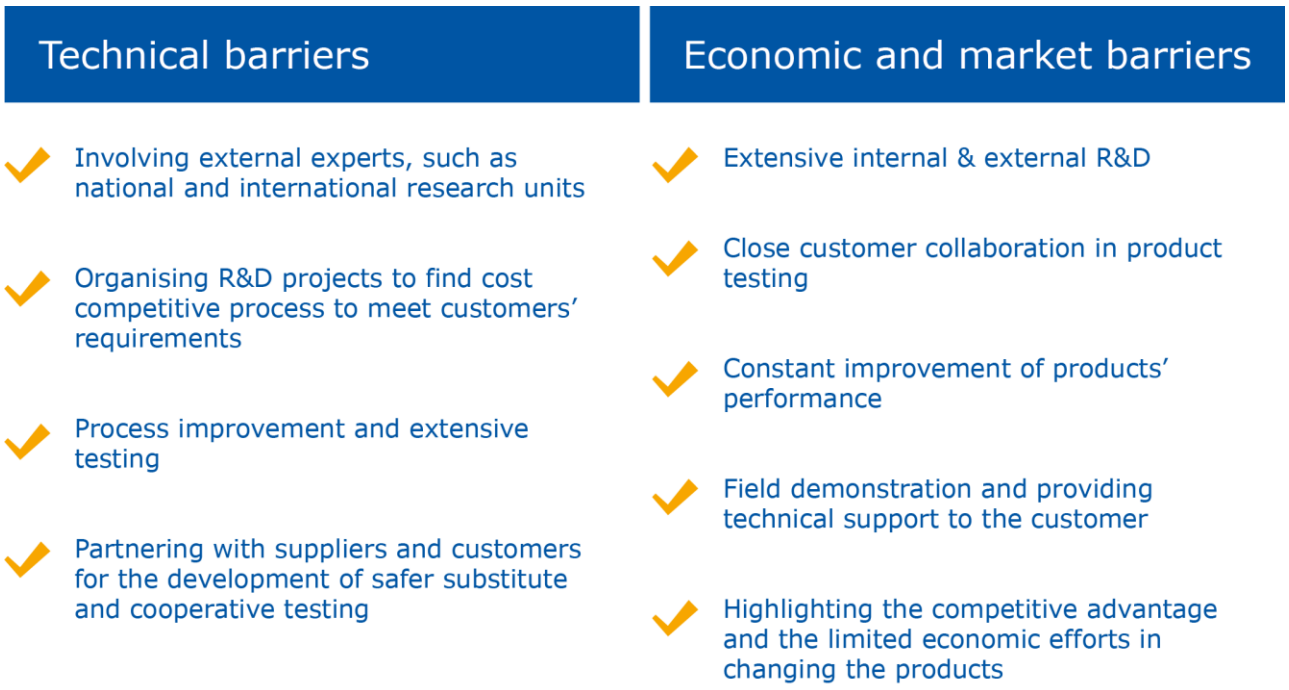


Figure 10: Overcoming the technical, economic and market barriers in substitution >7 years

For instance, in the food packaging industry, concerns related to the market adoption/approval of products formerly manufactured with Chromium (VI), were overcome by global food contact validation and qualifications. The new material manufactured with the alternative was undergoing preliminary qualification testing by customers. This qualification would take five years, as food packaging materials and their final use and characteristics are a sensitive topic.

In certain cases, companies failed to find an acceptable drop-in alternative due to strict industry requirements. Examples of this are found in the pharmaceutical and molecular biology markets concerning end-product specification and performances combined with the unsuitable and non-optimal physical characteristics of any known replacements. In that case, market barriers could be overcome by focusing efforts on a long-term research and development (R&D) project directed at developing a new synthetic pathway and/or technology without the presence of the substance of concern.

Companies' substitution activities taking **more than seven years**, experience the **highest one-off substitution costs,** which may go as high as **€50 million**. For instance, some companies have incurred over €50 million one-off costs in the substitution of diglyme, trichloroethylene, chromium trioxide, DEHP, DBP and HBCDD. These substances were also reported to have one of the highest annual costs, as for most of them, the annual costs are over **€10 million**.

Among the key cost drivers were construction/upgrade of plants and units, R&D, decision and regulatory processes, including conducting environmental impact assessment and acquiring environmental and building permits as well as pilot testing. Other cost drivers related to production development are higher energy and utility consumption, higher raw material costs, higher costs for dedicated safety equipment and technology buy-in. The one-off and recurring costs for substitution activities taking more than seven years are presented in Figures 11 and 12.

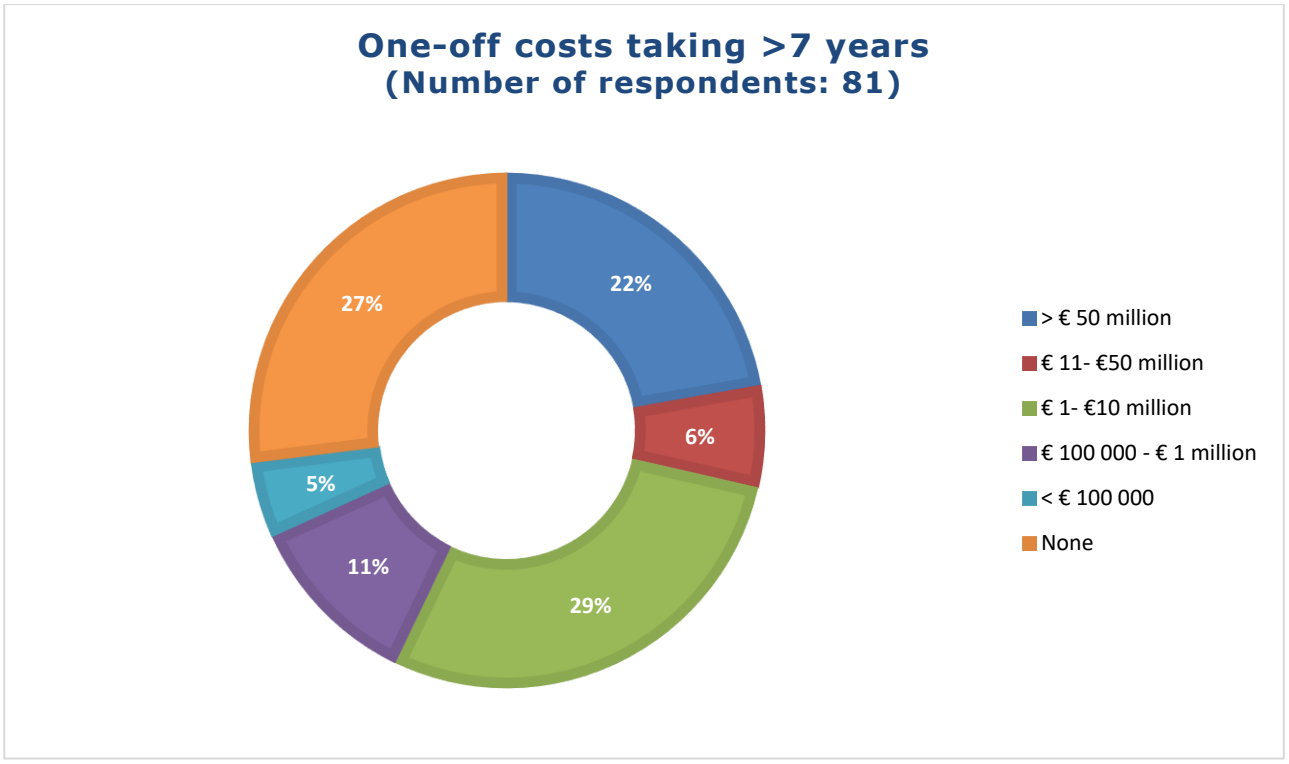


Figure 11: One-off costs for substitution taking >7 years

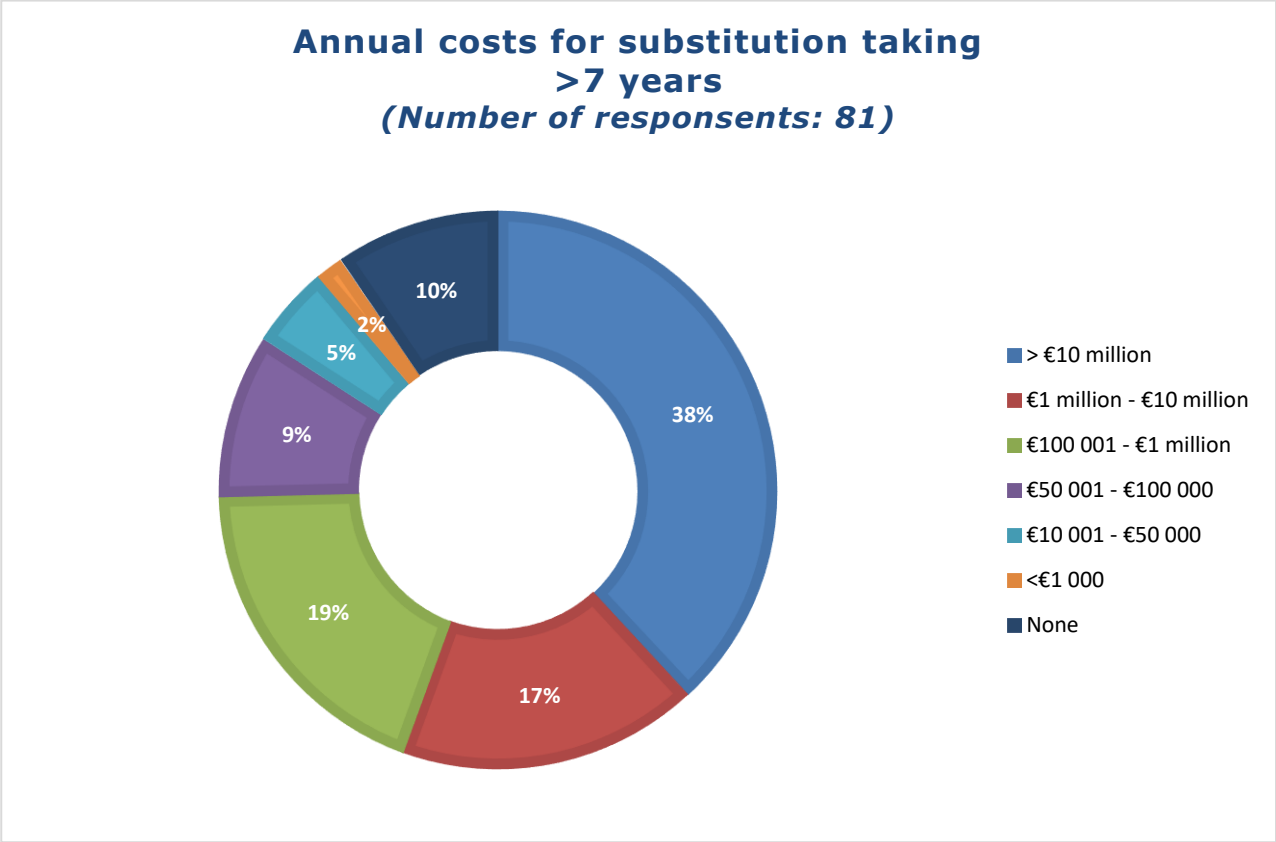


Figure 12: Annual costs for substitution taking >7 years

5.2. Substitution in 4 to 6 years

In addition to the **technical barriers** experienced by the companies requiring more than seven years to substitute, companies substituting in four to six years, experienced constraints on internal R&D and market barriers. These barriers were associated with the substitution of the following substances: solvents (1,2-dichloroethane, diglyme and trichloroethylene), plasticisers (DEHP and DBP), Chromium(VI), BPA and DMF. Figure 13 illustrate how companies attempted to overcome the technical and market barriers for substitution taking four to six years.

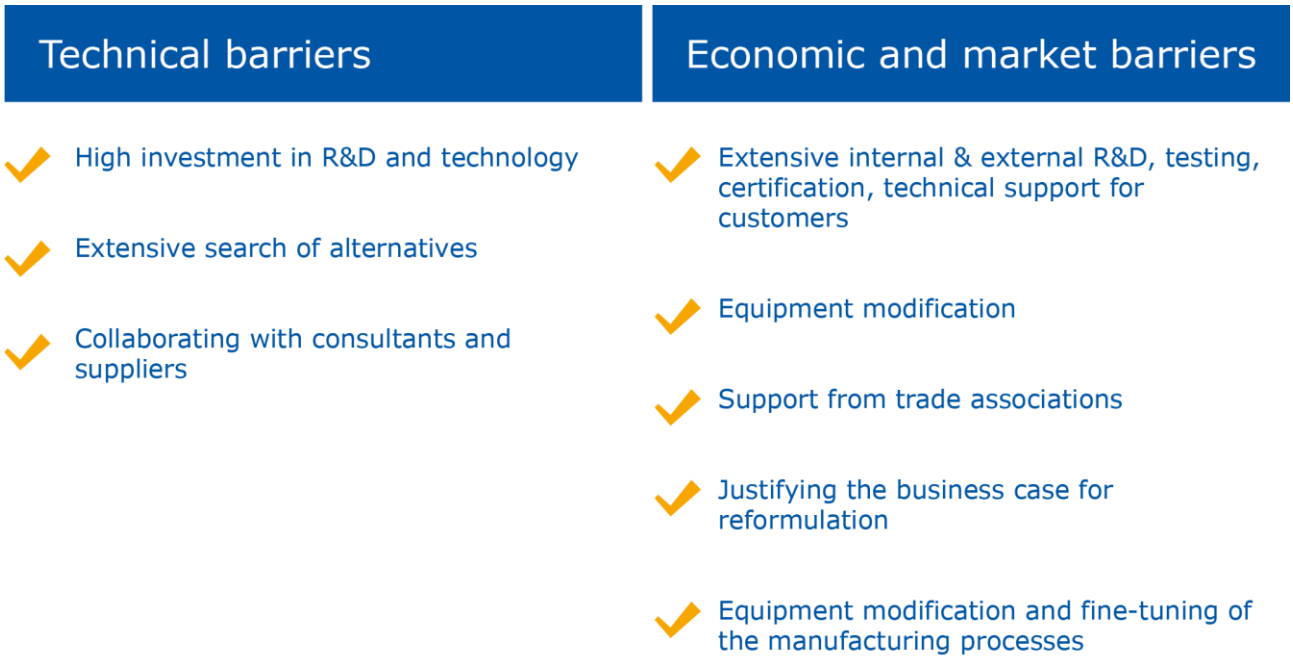


Figure 13: Overcoming technical and market barriers for substitution taking 4 to 6 years

Some of the companies highlighted the need to qualify the alternative material across the full product range, followed by a re-qualification by the customer. Certification with customers across all product lines is time consuming and might take up to six years in some cases. Hence, it is crucially important for companies to start the certification process and engage in communication with customers as early as possible.

Another way to overcome the barrier of market adoption/approval is by equipment modification and fine-tuning of the manufacturing processes to ensure functional robustness and equivalency of products after substitution. Fine-tuning includes multiple and very costly recursions of manufacturing trials and validation test procedures. Despite efforts made by companies to modify industrial tooling and processes, in certain cases, finding a technically feasible alternative that meets the customer's requirements (after testing) was not possible.

As such, substitution activities were deemed unsuccessful and this led to a closure of production. Another approach companies undertake to overcome the market adoption/approval barrier was conducting various tests and analysis with regard to the performance of the products manufactured with the alternative and providing technical support for customers.

Of the companies substituting to an alternative **in four to six years,** 46 % have incurred **one-off** costs in the range of **€1–10 million** for substituting 1,2-dichloroethane, BPA, DBP, and DEHP. These substances also have high annual substitution costs. According to the survey findings, for 57 % of the uses of **1,2-dichloroethane and BPA**, the **annual substitution costs**

indicated are in the range of **€1–10 million**. Main cost drivers are R&D, change of technology, testing, regulatory costs for *in vitro* diagnostic and pharma regulation, and customer approval processes. On the other hand, for **DBP and DEHP**, annual substitution costs could go well beyond **€10 million**. The main cost drivers indicated are R&D, search and screening for suitable substitution in high technology manufacturing processes, high costs of raw material, testing, functional validation of the product, customer approval processes, stockpiling, and warehousing. The one-off and annual costs for substitution activities taking four to six years are presented in Figures 14 and 15.

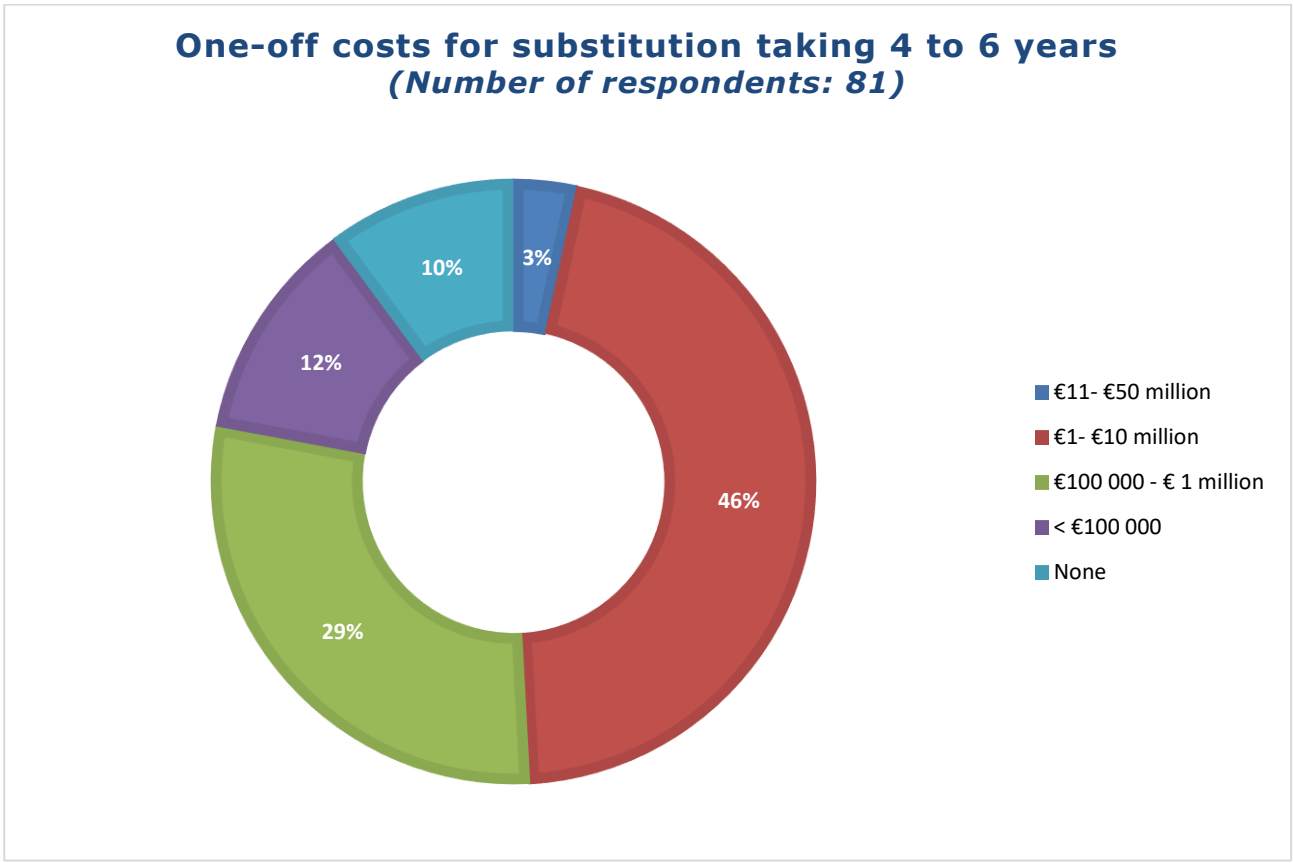


Figure 14: One-off costs for substitution taking 4 to 6 years

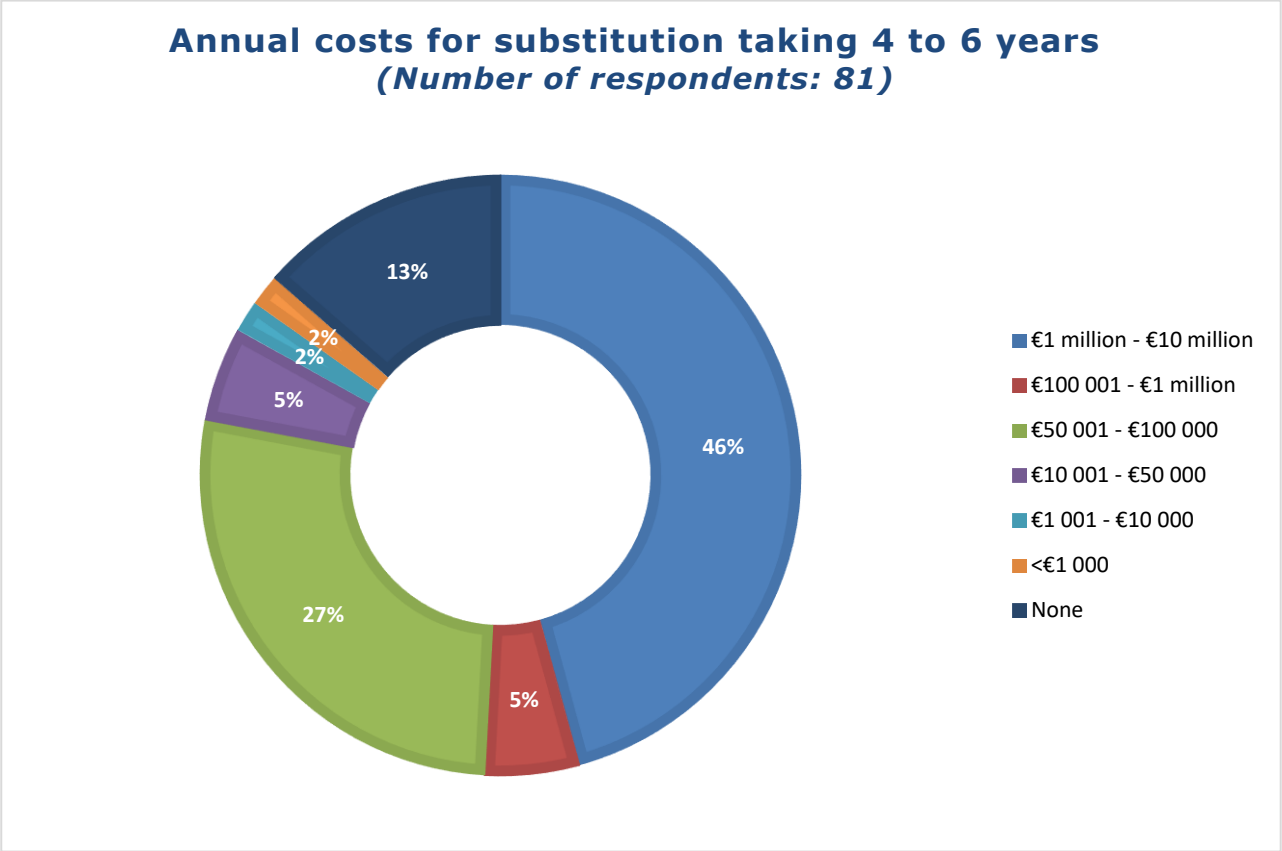


Figure 15 - Annual costs for substitution taking 4 to 6 years

5.3. Substitution in less than 3 years

Companies substituting in **less than three years** had already identified a first list of alternatives. The only **technical barriers** they encounter are technical difficulties to test the performance of the identified alternatives, e.g. due to a lack of pilot testing capability and non-availability of technically feasible alternative that meet the customer's requirements (after testing).

These two technical barriers were associated with the substitution of **trichloroethylene, DBP, BPA as a plasticiser, chromium trioxide, HBCDD, and DecaBDE**. Many companies substituting in less than three years emphasised that they are facing **economic barriers**, including a **lack of financial resources** to carry out an analysis of alternatives, testing or any other necessary substitution-related activity and **non-availability of economically feasible alternatives**. Companies concerned by these economic barriers were engaged in the substitution of **DBP, DEHP, chromium trioxide, HBCDD, DecaBDE and diarsenic trioxide**.

Substitution in less than three years for BPA, DBP, HBCDD and chromium trioxide is also associated with **market barriers**, including concerns related to market adoption/approval of the products manufactured with the alternative, insufficient quantities of the alternative on the

market and a reduced competitive advantage as a result of the substitution. Figure 16 illustrates how companies substituting in less than three years attempted to overcome the technical, economic and market barriers.

Figure 16: Overcoming technical, economic and market barriers for substitution activities taking <3 years

Some companies highlighted the importance of active interaction with customers, for instance, reaching an agreement for conducting intensive tests under their conditions or sending sample parts for testing to overcome the market approval barrier.

Others emphasised the importance of engaging with actors along the supply chain, including brand owners and leading industry trade bodies to showcase the progress on substitution and achieve full market awareness of the viability of the company's technology. With regard to the substitution of BPA in thermal paper, it was highlighted that the main barrier and cause of delay of substitution was not only the higher cost of the alternatives, but also their availability on the market. Even for BPS, it is believed that the market would have problems in getting high volumes; as for the rest of the alternatives, it was reported that it is difficult to find volumes

above 1 000 tonnes. Finally, the reduced competitive advantage on the market experienced by some of the respondents, for instance related to the substitution of DBP and DEHP, was overcome by increased sales and marketing activities.

Companies requiring **less than three years to substitute, experience the lowest one-off and annual substitution costs.** For 39 % of the uses of substances of concern, respondents indicated one-off costs of less than €100 000, whereas for 38 % there is no one-off substitution cost. On the other hand, for over 60 % of the uses, annual costs were reported to be below €100 000. Substances for which substitution takes less than three years include DBP, DEHP, BPA, diarsenic trioxide, trichloroethylene and chromium trioxide. The main cost drivers are R&D, testing, patents, technology, equipment, qualification and upgrade of processes, environmental and medical monitoring, and more maintenance due to the substitution. The one-off and annual costs for substitution activities taking less than three years are presented in Figures 17 and 18.

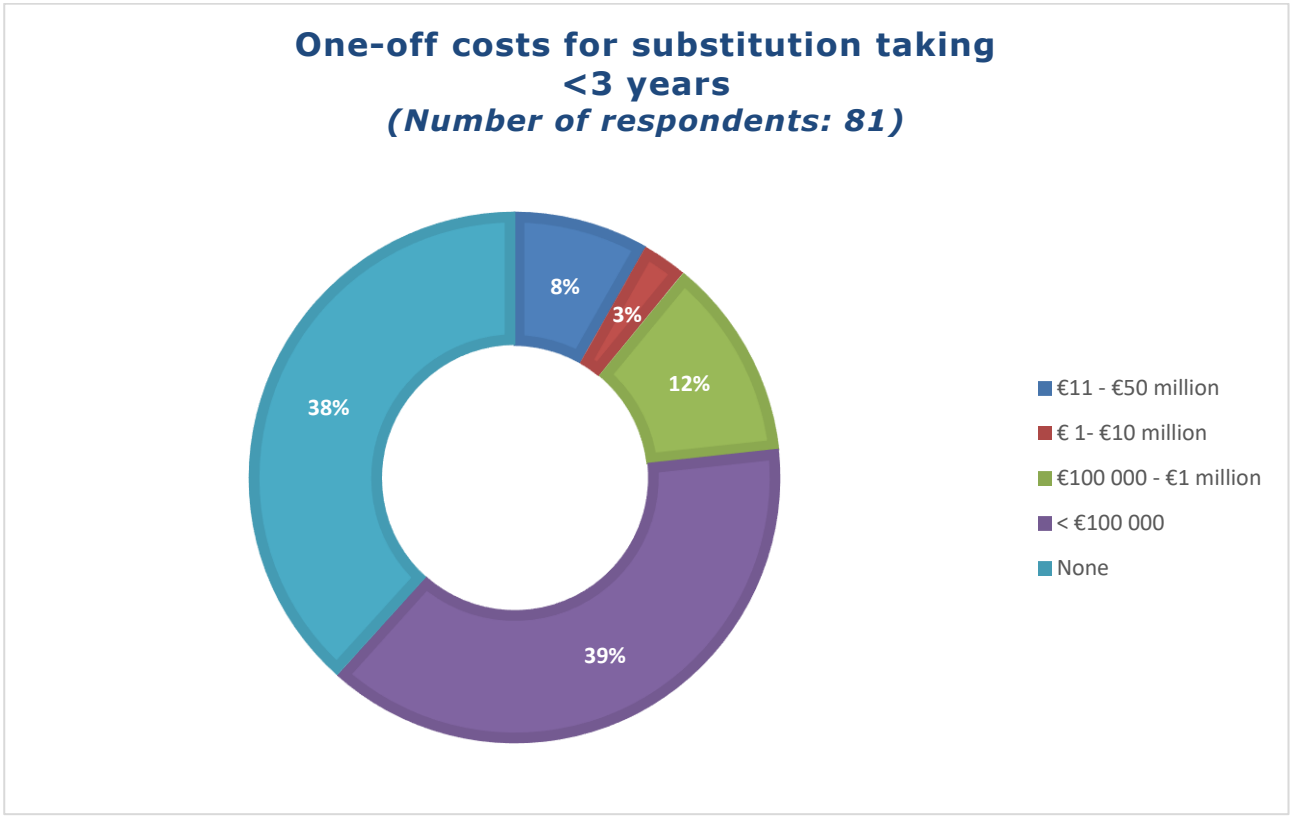


Figure 17: One-off costs for substitution taking <3 years

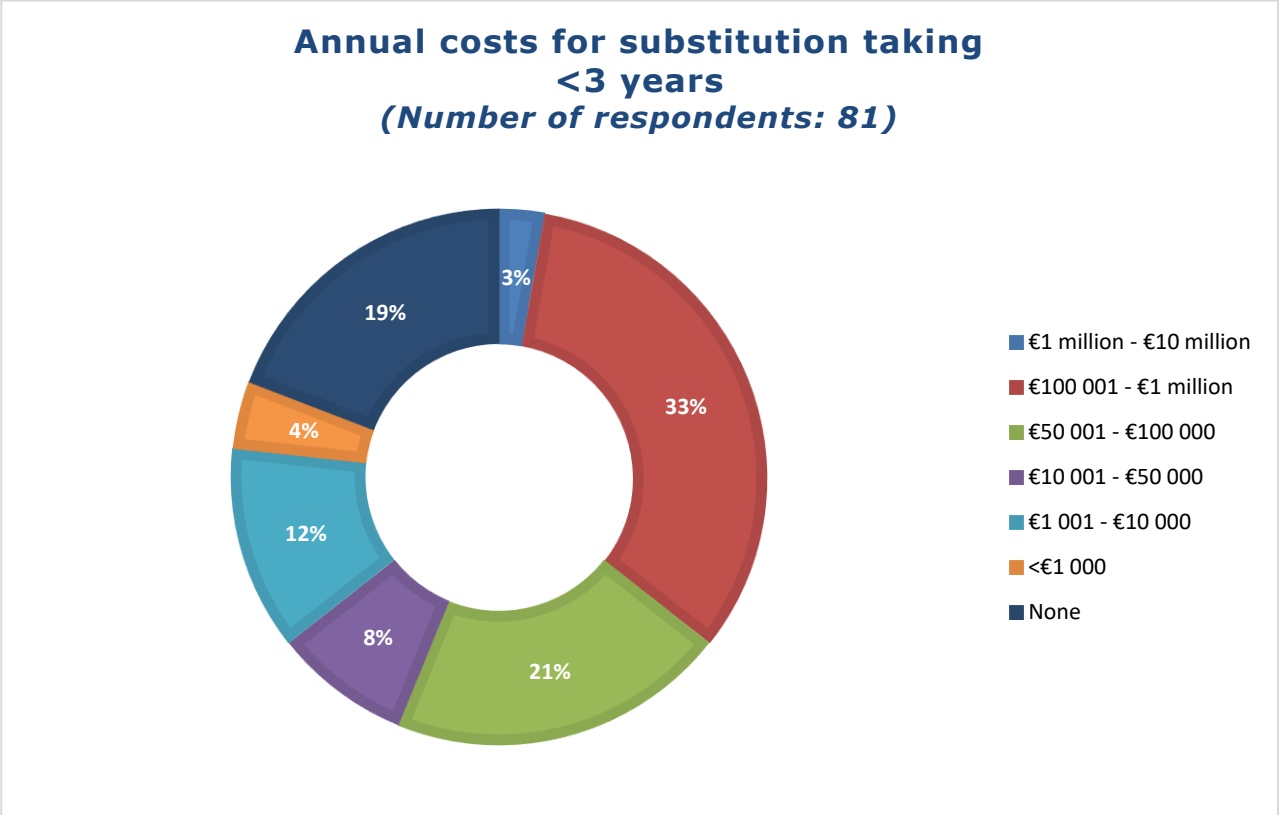


Figure 18: Annual costs for substitution taking <3 years

5.4. Industry perspective on barriers and costs of substitution

Existing industry standards and requirements often play an important role in shaping the barriers and costs of substitution. Both the survey and the interviews conducted with companies and industry associations provided insights on the barriers and costs of substitution in the **pharmaceutical and diagnostic, aeronautic and plasticiser industries.**

Industry standards and requirements are **key cost drivers in the pharmaceutical and diagnostic industry**. For companies using solvents, such as trichloroethylene and diglyme, substitution often involves disruptive technology change. Due to the high requirements and strict regulations for processes and products in the medical device and pharmaceutical industry, companies report that they need **four to six years** to complete the substitution process.

Barriers were attempted to be overcome by high investment in research and development, change of technology, testing, regulatory costs for *in vitro* diagnostics and pharma regulation. For instance, changing of a product or an instrument has an effect on a company's global portfolio as any change will consequently trigger a new registration or approval in different countries. This is very time consuming, as the company needs to adjust hundreds of market authorisations that their products hold around the world.

On the other hand, companies in the **aeronautic industry** experienced high substitution costs as a result of extensive testing to obtain an aeronautic certification, which proves that the properties of the new product are equal or better than properties of the former. Each component has to meet many safety requirements, which leads to additional testing. Furthermore, materials used in the aeronautic sector consist of hundreds of niche formulations, with demanding performance requirements and extensive supplier testing before shipping materials to the original equipment manufacturers (OEMs). Due to the extremely low volume compared to other industrial sectors and demanding requirements, the unit cost of formulations can be very high. Furthermore, companies in the aerospace industry do not have complete visibility of all costs associated with developing alternatives for substances in all materials, equipment, components, and parts used throughout a typical aerospace product's lifecycle as some of these are designed and controlled by the suppliers. For instance, even after alternatives are identified, suppliers may incur high implementation costs.

In terms of barriers, the findings of the survey indicated that customers' preferences could prevent substitution, as is the case for chromium-plated components, which are part of the undercarriages in aircraft. Even though the company plating the components understands the benefits associated with moving to an alternative, and has moved to tartaric sulphuric acid iodising for the rest of their processes, their biggest customer has strict requirements, insisting that components must be chromium-plated. This is an evident example of customer-driven use of SVHCs, even though an alternative is both technically and economically feasible.

With regard to substitution in the **plasticisers industry**, a large manufacturer of an alternative to DEHP emphasised that the substitution was hindered as the alternative they produce, **DINP**, was undergoing several hazard assessments to determine whether it has reprotoxic properties or not. In addition, the company reported that it was losing market share due to imports of another alternative produced in Asia, which was not being assessed under REACH. To overcome these barriers, the manufacturer of DINP said that it was working with the regulatory bodies in the EU. Another perspective on the substitution of DEHP is provided by the European Federation of Precision Mechanical and Optical Industries **(EUROM 1)**. After consulting with key industry players, EUROM 1 emphasised that the substitution of DEHP takes one to three years and key cost drivers are R&D, testing and processes modifications. The key barriers identified were a lack of financial resources to carry out an analysis of alternatives, testing or any other necessary substitution-related activity and constraints on internal R&D to carry out assessment. Thus, it was concluded that since the eyewear industry uses small quantities of DEHP, it needed to rely on alternatives that had already been developed by other industries.

Key findings – Barriers

Companies required more time to substitute in cases where technically or economically feasible alternatives were not available or when high industry requirements with regard to product specification were present.

- Barriers were overcome by investing in R&D, process improvement and extensive testing, receiving support from external experts and customer collaboration.

6. Benefits of substitution

Figure 19 summarises the benefits of substitution. Of the respondents, 81 were able to pick several benefits and gave 246 selected answers. The majority of them (44 %) related to reduced worker exposure and emissions to the environment. Other important benefits that were cited by the respondents are *improved consumer perception of the company's environmental and social sustainability* (15 %), *avoided administrative burden and uncertainty in applying for an authorisation and respecting the imposed conditions* (14 %), and *increase in competitive advantage in the market* (9 %). On the other hand, the respondents cited *increase in revenues from alternative substance(s) or technology* (4 %) and *increase in the number of people employed* (2 %), as the least important benefits associated with substitution. 7 % of the respondents selected the "*Other"* option, which, *inter alia*, included:

- Avoided supply chain disruptions;
- Enhanced relationships with local authorities in removing substances of concern from the

product portfolio for the benefit of both employees and the environment;

- Reduced consumer exposure;
- Enhanced end-user satisfaction arising from improved performance of a substitute;
- No benefits at all.

Key findings – Benefits of substitution

- Companies reported that the main benefit of substitution was the reduction of emissions of hazardous chemicals. It was also a way for them to improve their public image.

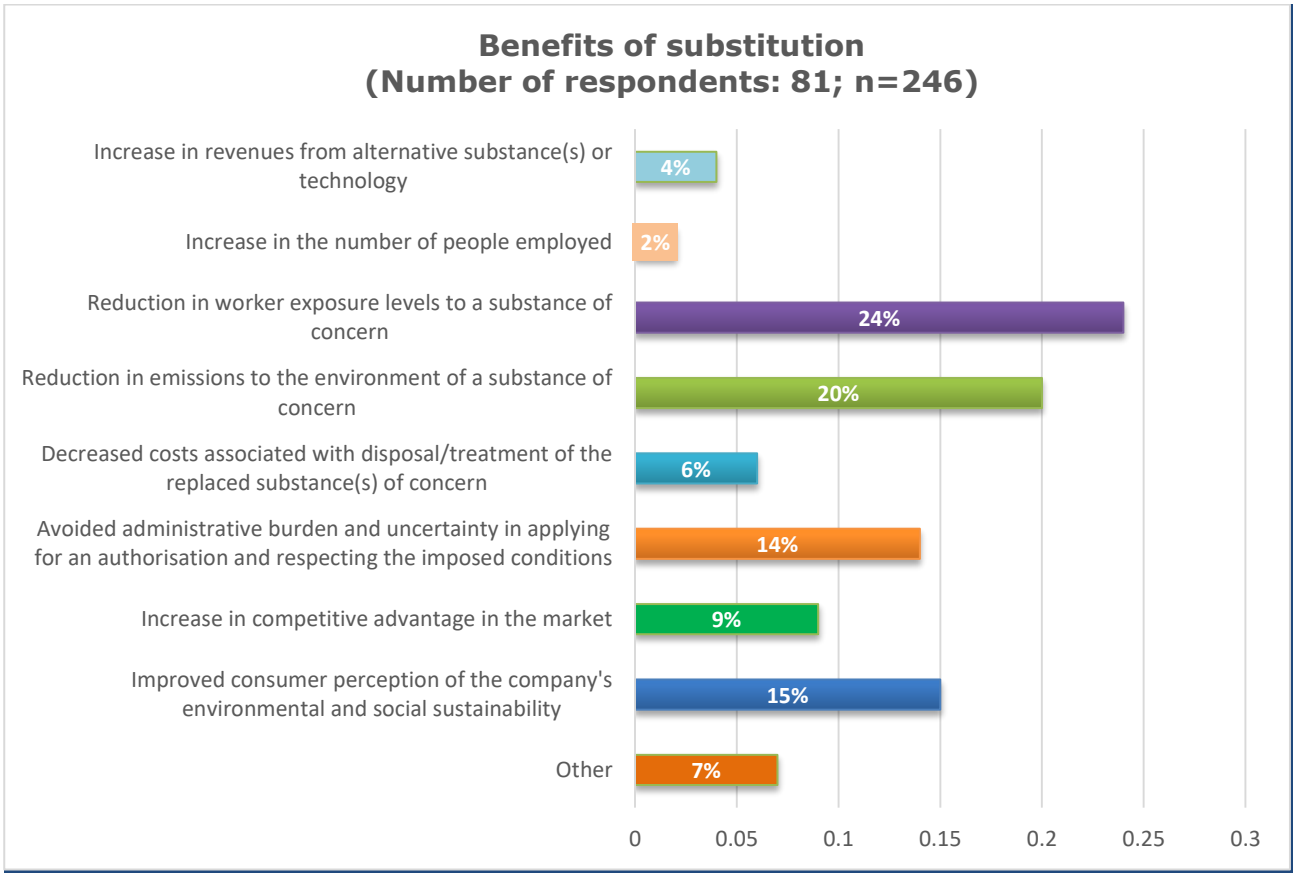


Figure 19: Benefits of substitution

7. Different cases of substitution

7.1. No substitution

In a few cases, respondents indicated that they have neither substituted nor have any future plans to substitute. This case study aims to understand why some companies choose not to substitute and the focus falls on three companies. The first company stated that substituting 1,2-Dichloroethane with an alternative would require a capital expenditure of over €98 million. Furthermore, even if the company made such an investment, the energy efficiency of the plants would worsen and operating costs would rise considerably (estimated at ca. €12 million per year). In addition, the new technology would be associated with a poorer quality end product and a more limited range of products. As a result of a potential substitution, this company would face technical, economic and market barriers.

Another company, operating in the aerospace business, uses chromium trioxide for a heavy-lift launch vehicle. It did not substitute, as the conducted trials were unsuccessful considering the specificity of their products and industrial processes. Furthermore, the company decided to terminate its activities on the launcher by the end of 2020, therefore removing the need for substitution. However, the company did not specify whether the technical barriers to substitution influenced the decision to terminate the activities.

A third company included in this case study is a small family business using chromium trioxide for vintage car restoration. Substituting to an alternative, for instance Cr(III), would be significantly more expensive, yet the final result would not meet their customers' expectations. Therefore, the company highlighted that the anticipated serious market approval barrier will lead to the closing of their business if authorisation was not granted.

7.2. Early stage substitution

Out of all respondents, four companies stood out with their ambitious substitution strategies, including ongoing and planned activities. These companies had substitutes, were in the process or planned to substitute numerous substances of high concern in the future.

The primary drivers they highlighted were their own corporate sustainability policies, customer demand and improving public image, while as secondary drivers they have indicated REACH authorisation and restriction and other EU regulations.

One of these companies is a multinational, operating worldwide in the pharmaceutical and diagnostics industries. It has publicly committed to phasing out any SVHC worldwide within 10 years after their entry into the Candidate List. Exemptions are permitted only if the substitution is not technically feasible. Currently, 29 SVHCs are used across the company's global operations

and all of them are subject to the company's ambitious phase-out plan. The company's commitment to sustainability was indicated as a sufficient driver for substitution even in the absence of regulatory drivers.

The largest benefits as a result of substitution are improved customer perception of the company's environmental and social sustainability, avoidance of supply chain disruption and an increased competitive advantage in the market. The company stressed that in the pharmaceutical and *in vitro* diagnostics industries, not only the technological change of the process or product is a challenge, but also accompanying regulatory measures, such as "re-registration". The innovation unfriendly and the highly regulated environment were indicated as a barrier related to the search for alternative substances and technologies. Being a market leader in biotech and *in vitro* diagnostics, the company has a Chemical Legislation Unit providing guidance documents for developers – as the underlying aim is safe-by-design products – who are involved in the selection of substances for products and processes. Moreover, the company has a Green Chemistry working group, which supports chemists with the dissemination of the newest ideas and benchmarking opportunities and organises seminars in collaboration with academia.

Other innovation-driven companies include a multinational company primarily producing crystal jewellery and accessories, which considers substitution as early as a substance is included in the Candidate List or a Recommendation for inclusion of a substance in the Authorisation List is made. On the other hand, a global multinational clothing-retail company and a global supplier of paints, coatings, and specialty materials, respectively, both start substitution activities when an intention to prepare a restriction proposal is made public in the registry of intentions. The former company does not allow any SVHCs in amounts of more than 0.1 % w/w in any of their products. Both companies indicated that the REACH Regulation as well as their own corporate sustainability policies, customer demand and public image were key drivers.

The company in the jewellery sector overcame the technical and economic barriers through research, testing, acquiring additional resources for substitution and waiting for suppliers to develop alternatives. On the other hand, the company in the clothing sector has a large product portfolio and takes on substitution activities per product: one at a time, having developed an internal routine for phase out projects e.g. Screened Chemistry or finding other ways to work with the best available chemistry.

Finally, the supplier of paints is overcoming the technical and market barriers through continuous work, trade association's support and defining and justifying the business case to reformulate products in order to continue in the market.

7.3. No substitution because of customer demand

During phone interviews, two respondents informed that they could not substitute because of their customers' demand. Both companies were using chromium trioxide for electroplating of parts used in the aeronautical sector and both are running a business based on customer demand. Therefore, they produced parts according to received orders and agreements with their customers.

One company was in the process of substituting chromium trioxide. It was working with manufacturers to look for potential alternatives and they are carrying out R&D projects to propose parts made with a potential safer alternative that has superior technical and functional properties, thus exceeding their clients' requirements. For this company, the major cost was linked to the organisation of a new production line without chromium trioxide. However, it stated that their clients in the aeronautical sector did not wish to use parts without chromium trioxide. Indeed, any new parts made with a potential alternative must get a new certification which requires several testings to ensure that it meets all the technical requirements. Hence, this company applied for authorisation to be able to continue producing parts made with chromium trioxide so they could keep their clients. They stated that if they had not applied for authorisation, their clients would switch to their competitors.

The second company did not plan to substitute their use of chromium trioxide as they are using it for only one customer in the aeronautical sector who claimed that they cannot phase chromium trioxide out. Therefore, the use of chromium trioxide of this company was entirely driven by their customer's demand.

7.4. Regulation-driven substitution

Based on the survey findings, approximatively one-third of the respondents stated that they start to look for a substitute when a substance is included in the Authorisation List or listed for restriction in Annex XVII to REACH. During a phone interview, a manufacturer of flame retardants said that substitution required an investment of tens of millions of euros, so they preferred to wait until a definitive regulatory decision was in place to take actions.

These companies look for alternatives based on their own R&D programme and on consultations with their suppliers and customers. Some of these respondents are still in the process of substituting a substance of concern whereas some other respondents from the same sector have already phased out the initial substance. For instance, one manufacturer of a plasticiser was still producing DBP and DEHP, while others had already substituted them.

7.5. Market-driven substitution

During a phone interview, one respondent stated they had started substitution activities because they perceived market opportunities in doing so. This small company acted as a distributor of an alternative to chromium trioxide for printing and packaging applications.

For this company, the main driver for substitution was the financial benefits associated with the alternative. Indeed, as this solution was thought to have superior technical and functional properties, substitution actually allowed them to increase their competitive advantage in the market.

During the development of their alternative, they successfully applied for a Horizon 2020 TI Pilot research grant of €3million to overcome the financial barriers linked to investments for the new capital equipment. They were actively engaged with two industry trade bodies for printing and packaging and with multiple parties along the supply chain to ensure full market awareness about the viability of their new technology.

8. Summary and conclusions

According to the survey findings, REACH authorisation and restriction are the main drivers for substitution and often lead to a series of other, secondary drivers, such as customer demand and company image. For instance, for many respondents, substitution of hazardous chemicals in their activities was part of their own sustainability policy and these companies claimed that they aim to phase out all substances identified as SVHCs.

As REACH helps these stakeholders to identify substances which are hazardous for human health and/or the environment, it is difficult to tell whether or not such substitution would happen if specific regulatory risk management actions under REACH had not been taken. .

The technical, economic and market barriers, which are typically associated with the substitution process, are illustrated in Figure 20.

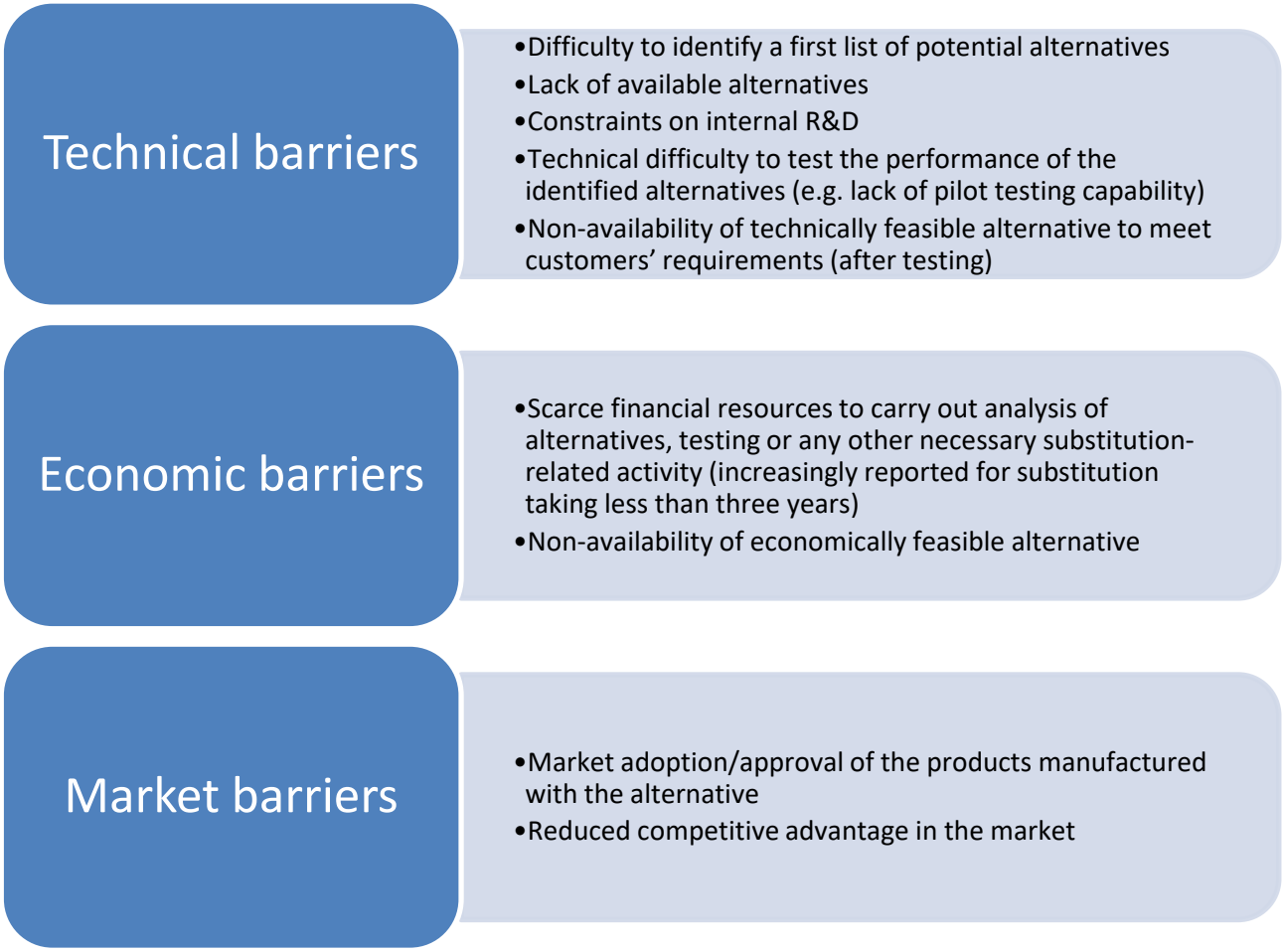


Figure 20: Barriers to substitution

Technical barriers were reported to account for between 55 % and 70 % of all barriers. Companies substituting in **more than seven years** were mostly constrained by the technical barriers, while companies substituting in **four to six years** were mostly affected by constraints on internal R&D. Companies elaborated on the key technical barriers to substitution by providing a brief description of the most prominent ones:

- A list of potential alternatives and a drop-in alternative did not exist.
- Substitution would require changing the whole process and/or technology, which in most cases involved construction of a new production plant or purchase of new equipment.
- If the end-product is subject to other regulations, the requirements that the alternative must fulfil were more severe, hence companies would incur great technical difficulties to find a feasible substitute.

Figure 21 illustrates how companies attempted to overcome the technical, economic and market barriers. If stakeholders cannot overcome these barriers, they would need to apply for an

authorisation (if the substance is in the Authorisation List), to relocate the use of the substance outside of the EU or to cease their operation to use the substance in the EU.

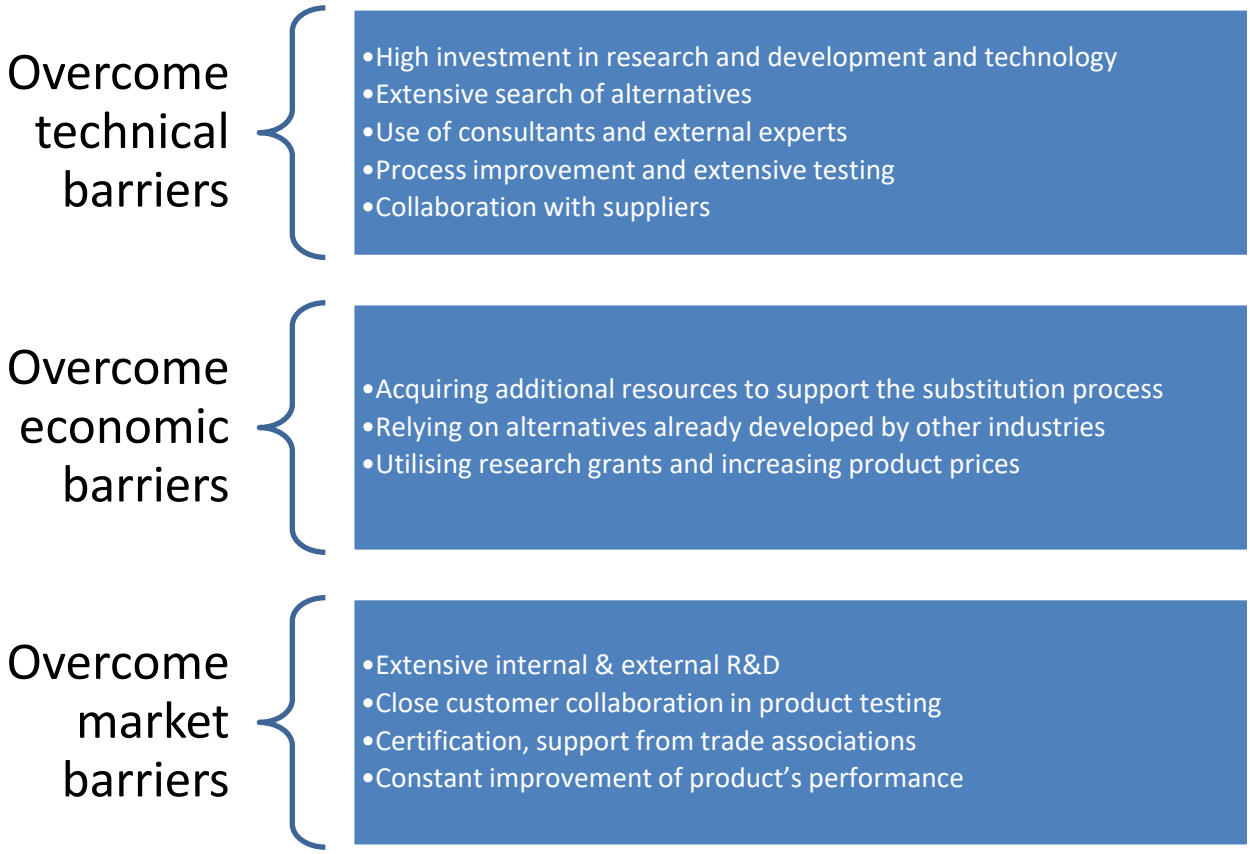


Figure 21: Overcoming barriers to substitution

Companies affected by REACH authorisation and restriction incurred various one-off substitution costs. In 10 % of the substitution activities, respondents have incurred a one-off cost over €50 million. In **two-thirds of the cases** analysed, the **one-off** investment costs did not exceed €1 million. According to the survey findings, as a result of the substitution, 36 % reported annual costs of up to €50 000, 41 % incurred **annual costs** in the ranges of €50 000 – €1 million, and 24 % indicated that their recurring costs are in the range of €1-10 million or more.

The most significant cost drivers identified by the respondents were testing, R&D and changes to the production equipment and processes to enable the use of an alternative substance or technology. One-off and annual substitution costs were case-specific, depending on the substance of concern, availability of alternatives and the need for developing new manufacturing processes or the purchase of equipment. The highest one-off and annual costs were prevalent for substitution activities taking more than seven years, with the main cost drivers highlighted being extensive R&D, testing and construction and/or upgrade of plants and

units. In contrast, substitution activities completed in shorter periods, such as in less than three years, were the least costly both in terms of one-off and annual costs. For instance, in only 23% of substitution activities respondents have indicated one-off costs exceeding €100 000.

Key findings – Costs

- Companies requiring more time to substitute experienced higher substitution costs, mostly driven by extensive R&D, testing and construction and/or upgrade of existing plants and units.
- In most cases analysed, the one-off substitution cost did not exceed €1 million, but could exceed €50 million in rare cases.

Based on the results, the main benefit of substitution for companies is a decrease of worker exposure to a hazardous substance and/or a decrease of emissions of the hazardous substance to the environment. For the majority of respondents, substitution was also a way for them to improve the consumer perception of their environmental and social sustainability.

9. Recommendations

Based on the results from this study the following recommendations are made to facilitate the substitution process:

- Trade associations and regulators could facilitate knowledge-sharing by organising and promoting events where companies share experience and best practice on substitution.
- Using a 'grouping approach', chemically similar alternatives should be systematically analysed in restriction dossiers. Likewise it could also be considered to include groups of substances into the Authorisation List. This would encourage the use of less hazardous and sustainable alternatives, and specifically help avoid regrettable substitution.
- Industry and regulators could establish collaborative networks across the supply chain. These could comprise actors with potential technological solutions, to help in identifying and overcoming barriers to substitution, clarifying and achieving end-user requirements and identifying crucial R&D areas.
- Research and innovation activities could be accelerated by providing funding opportunities for research institutes for screening and testing alternatives. This could be done at national or EU level to help companies overcome the technical barriers to substitution they are currently facing and even set them on the path of a safe-by-

design approach when developing new products.

Based on the findings of this study, early stage substitution is observed for some multinational companies, which are market leaders in their industry and substitution seems to be driven primarily by corporate sustainability commitments.

Annexes

Annex 1 - Survey questions

Q1. Type of actor under REACH? (Multiselection)
- Manufacturer/Importer/Only representative of a substance of concern
- Manufacturer/Importer/Only representative of an alternative substance and/or technology to a substance of concern
- Downstream user of a substance of concern
- Downstream user of alternative substance and/or technology to a substance of concern
- Distributor of a substance of concern
- Distributor of an alternative substance and/or technology to a substance of concern
- Other actor, please specify:

Q2. Which of the following describes accurately your company's substitution activities? (Multiselection)
- My company has already substituted the use (s) of a substance of concern with an alternative substance and/or technology
- My company is in the process of substituting the use (s) of a substance of concern with an alternative substance and/or technology
- My company plans to substitute the use (s) of a substance of concern with an alternative substance and/or technology in the future
- My company has never substituted, nor has any future plans to substitute the use (s) of a substance of concern with an alternative substance and/or technology

Q3. What substance (s) of concern and for what use (s) have you substituted away from? (Open ended)

Q4. What substance (s) of concern and for what use (s) are you in the process of substituting away from? (Open ended)

Q5. What substance (s) of concern and for what use (s) do you plan to substitute away from in the future? (Open ended)

Q6. What alternative substance (s) or technology (ies) have you substituted to? (Open ended)

Q7. What alternative substance (s) or technology (ies) are you in the process of substituting to? (Open ended)

Q8. What alternative substance (s) or technology (ies) do you plan to substitute to in the future? (Open ended)

Q9. What were (are) the drivers for substitution? (Multiselection)
- REACH authorisation process
- REACH restriction process
- Other REACH processes
- Other EU regulation
- New market opportunities
- Customer demand
- Financial benefits associated with alternative (s)
- Public image
- Own corporate sustainability policy
- Competitors substituting as well

- Other reasons, please specify:

Q10. If substitution was triggered by the REACH Authorisation process, at what stage(s) did you decide to substitute? (Multiselection)
- Screening of substance and Risk Management Option Analysis (RMOA)
- Inclusion of substance in Candidate List
- Recommendation for inclusion of substance in Authorisation List (Annex XIV)
- Inclusion of substances in Annex XIV
- Applications for authorisation (AfA)

Q11. If substitution was triggered by the REACH Restriction process, at what stage(s) did you decide to substitute? (Multiselection)
- Intention to prepare a restriction proposal is made public in the registry of intentions
- Restriction proposal is prepared and submitted to ECHA's scientific committees
- ECHA's scientific committees issue opinions
- The European Commission decides and amends Annex XVII and publishes its decision in Official Journal

Q12. Estimated one-off investments into substituting a substance?
- < €100 000
- > €100 000 but < € 1 million
- €1- 10 million
- €11- 50 million
- > €50 million
- None

Q13. Estimated annual costs of implementing substitution activities?
- < €1 000
- €1 001 - € 10 000
- €10 001 - € 50 000
- €50 001 - € 100 000
- €100 001 - € 1 million
- €1-€ 10 million
- > €10 million
- None

Q14. What are the main cost drivers in substitution? (Open ended)

Q15. Estimated time required to switch to alternative substance or technology?

- < 1 Year
- 1 to 3 years
- 4 to 6 years
- > 7 years

Q16. Main reasons for substitution taking this much time: (Open ended)

Q17. What were the main barriers/challenges to substitution? (Multiselection)
- Difficulty to identify a first list of potential alternatives
- Technical difficulty to test the performance of the identified alternatives, e.g. due to a lack of pilot testing capability (please explain)
- Non-availability of technically feasible alternative to meet customer's requirements (after testing)
- Non-availability of economically feasible alternative
- Lack of financial resources to carry out analysis of alternatives, testing or any other necessary substitution-related activity
- Concerns related to market adoption/approval of the products manufactured with the

alternative
- Lack of available alternatives
- Reduced competitive advantage in the market as a result of a switch to alternative
- Constraints on internal R&D to carry out assessment
- Other

Q18. How did you overcome or intend to overcome the barrier (s)? (Open ended)

Q19. Benefits of substitution
- Increase in revenues from alternative substance (s) or technology
- Increase in the number of people employed
- Reduction in worker exposure levels to a substance of concern
- Reduction in emissions to the environment of a substance of concern
- Decreased costs associated with disposal/treatment of the replaced substance (s) of concern
- Avoided administrative burden and uncertainty in applying for an authorisation and respecting the imposed conditions
- Increase in competitive advantage in the market
- Improved consumer perception of the company's environmental and social sustainability
- Other

Q20. Do you think your company would benefit from a "safe-by-design" approach when developing new products instead of having to fix issues at a later stage when they arise? (Open ended)

Annex 2 – Consulted stakeholders

The applicants for authorisation

The first type of relevant stakeholders were companies who have applied for authorisation for the use of substance(s). Once the relevant applicants were identified, all the relevant case-specific information was collected for each application. In parallel, internal consultations were held with colleagues in charge of handling the application(s) with the intention of gathering information on applicants as well as understanding the key details of the case. Applicants' contact details were obtained using internal databases (e.g. REACH IT).

Downstream users

According to Article 66 of REACH, if a downstream user is covered by an upstream application, they must notify ECHA of their use of an SVHC. All these notifications (called DU66 notifications) have been registered in one file since 2015. Using the existing DU66 notifications registry, downstream users were contacted directly.

Stakeholders relevant for restrictions

During the preparation of a restriction dossier, the dossier submitters usually contact relevant stakeholders to find out the volume of the substance used and the potential alternatives. These contacted stakeholders are listed in the restriction dossier (Annex: Stakeholder information).

In parallel, internal consultations with ECHA colleagues involved in developing those dossiers were conducted to get an insight about the most important stakeholders for each substance. When ECHA was not the dossier submitter, the relevant Member State was consulted, usually by phone.

Stakeholders who have participated in past consultations

ECHA also made a note of the stakeholders who had participated in the consultations for relevant restriction dossiers. The contact details of the participants in consultations could be obtained from the internal registry.

European industry associations

On the basis of consultations as well as internal consultations, it has been possible to identify some EU industry associations that were assumed to have useful information for this project. Those associations have been contacted and asked to share the online survey with their members.

Companies who have registered a use of the substances

Under REACH, companies in the European Union have the responsibility to collect information on the properties and uses of the substances they manufacture or import above one tonne a year and communicate this information to ECHA through a *registration dossier*. All these registrations, as well as contact details of registrants, are available to ECHA.

For some substances (for instance, lead and BPA), the restriction is covering only a limited part of the possible uses of the substance. Therefore, the companies that have been contacted from the registration list have not been necessarily concerned by the restriction.

Annex 3 - Methodology

This chapter provides an overview of methods applied in the study and defines the processes used. It will be broken down into the following four major phases:

1. Planning and design

ECHA developed a framework for carrying out the research, defined the scope and objectives of the research and assessed appropriateness of different methodologies in meeting these objectives. Once the study outline was completed and its objectives clearly defined, it was decided that the mixed method of research – integrating quantitative and qualitative data collection and analysis – would be the most effective way of moving forward.

2. Data collection

The following actions were undertaken at the data collection phase:

Preparing a survey

ECHA developed an online questionnaire consisting of 20 questions covering a wide range of issues focusing on the substitution activities of companies in terms of selected alternatives, costs, drivers, challenges and benefits of substitution.

The online survey was prepared using the online application tool Webropol 3.0.

Consultation and engagement with external stakeholders

ECHA contacted external stakeholders and consulted them in order to receive information on several subjects relevant for the project. Among the consulted stakeholders were consulting firms, non-governmental organisations (NGOs) and industry.

Compiling a list of relevant stakeholders to contact

Once the online survey was ready, ECHA proceeded with compiling a list of stakeholders that may have been impacted by authorisation or restriction requirements.

Table 3: Total number of contacted stakeholders

Table 3: Total number of contacted stakeholders	
Type of stakeholders	**Numbers**
Applicants	66
Downstream users	217
Companies concerned by a restriction	271
TOTAL	**554**

Launching an online survey

Once the survey was fully prepared and the stakeholder contacts created, ECHA sent tailored emails to specific groups of stakeholders asking them to respond to the survey online as well as to inform ECHA about their willingness to take part in in-depth telephone interviews. Whenever it was deemed necessary, reminders were sent out to encourage participation in the survey.

Follow-up

After receiving the responses and analysing them, ECHA contacted selected stakeholders for further consultation. This was done particularly in those cases when some key data were thought to be missing from the response or when further corroboration and/or in-depth investigation was thought to be necessary.

Telephone interviews

Targeted telephone interviews were arranged with identified stakeholders to get better and more in-depth insights. Discussed topics, although largely similar, varied from stakeholder to stakeholder, given their different positions in the supply chain and other specificities. The interviews lasted between 30 minutes and one hour. Table 4 provides an overview of the number of interviews per substance, application/ industry and type of actor.

Table 4: Stakeholder interviews

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Substances	**Application/Industry**	**Type of actor**
1,2-dichloroethane	Swelling agents in the Pharmaceutical and diagnostics industry	DU of a substance of concern
1,2-dichloroethane; diglyme	Solvent; Beads covered by biomolecules used in diagnostics	DU of a substance of concern
Arsenic acid and chromium trioxide	Production of copper foils	DU of a substance of concern
BPA	Thermal paper	Manufacturer/ Importer/ Only representative of an alternative substance and/or technology to a substance of concern; Downstream user of a substance of concern
Chromium trioxide	Surface treatment of components for aeronautic, defence and electronic industries	DU of a substance of concern
Chromium trioxide	Functional chrome plating and surface treatment in the aeronautics industry	Manufacturer/ Importer/ Only representative of an alternative substance and/or technology to a substance of concern; DU of a substance of concern
Chromium trioxide	Old vintage car restorations	DU of a substance of concern
Chromium trioxide	Printing and packaging	Distributor of an alternative substance and/or technology to a substance of concern
Chromium trioxide	Functional chrome plating of components for the aeronautics industry	DU of a substance of concern
DEHP	Safety blocks for used needles; plasticizer in ion selective electrodes; bags containing chemical solutions used for analysis purposes	DU of a substance of concern
DEHP, DHP	-	Manufacturer/ Importer/ Only representative of a substance of concern
Phthalate plasticisers	Aerospace and automotive industry	Manufacturer/ Importer/ Only representative of a substance of concern/ alternative substance and/or technology to a

		substance of concern; DU
Lead	Recycling of metal	Recycler
Lead	-	Association
Lead; DEHP	Optical industries	Association
Trichloroethylene	Process solvent in the manufacture of polyethylene separators for lead acid batteries	DU of a substance of concern
DecaBDE, HBCDD	Alternatives	Association
DEHP, DBP	-	Manufacturer of alternatives

Data validation

ECHA verified the completeness and accuracy of the received responses before proceeding to the data analysis stage.

3. Data analysis

Qualitative data analysis

Some of the following tools have been useful in facilitating the qualitative data analysis:

- *Webropol text mining* – a quick and reliable way to process open-ended answers. It helps in identifying key themes, grouping and classifying answers and analysing them in relation to other answers.
- *Excel* – various Excel data analysis tools (e.g. pivot tables) were deployed to make sense of the vast amounts of data.

Quantitative data analysis

These tools have served the purpose of analysing the quantitative data as listed below:

- *Webropol professional statistics* – an easy-to-use tool designed for analysing quantitative data by means of quick imports of data, and the automated creation of interactive result tables and graphs.
- *Webropol Insight* – a predictive analysis tool based on methods of statistical analysis.
- *Excel* – a number of Excel tools were used to conduct a quantitative data analysis (e.g. charts, pivot tables, data analysis ToolPak).

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