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Study on the impacts of the 2018 REACH registration deadline

Final report

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Unit F.1 – REACH

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Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Study on the impacts of the REACH 2018 registration deadline

Final report

Wood EIS GmbH – May 2021

Report for

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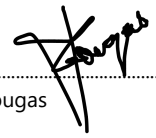

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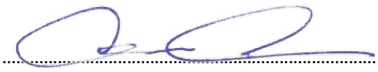

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Abstract

Under REACH, manufacturers and importers of chemicals are required to submit information on the properties and uses of the substances they manufacture or import above 1 tonne per year. The third and final registration deadline, 31 May 2018, required registration for substances between 1 and 100 tonnes. This report assesses and, where possible, quantifies the impact on economic operators of registrations submitted for the 2018 registration deadline. Total costs of registration in 2018 were estimated as €1,290 million for the 10-100t range and €960 million for the 1-10t range. Results of the study survey (covering around 5% of total registrations) suggest that the average costs of registration per substance for the 10-100t range were in reasonable agreement with those predicted, but average costs per substance for the 1-10t substances were around seven times those originally predicted. The study also explores communication obligations in the supply chain, SIEF and consortia, resources, benefits and effects on the chemicals market.

Contents

List of abbreviations

AOP	Adverse Outcome Pathway
CLP	Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008)
COM	European Commission
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DCG	Directors Contact Group
ECHA	European Chemicals Agency
EEA	European Economic Area
ES	Exposure scenario
EU	European Union
FTE	Full Time Equivalent
GDP	Gross Domestic Product
IUCLID	Software application for use to register chemicals and update information
LoA	Letter of Access
MISA	Metals and Inorganics Sectoral Approach
NACE	Statistical Classification of Economic Activities in the European Community
NGO	Non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
OFI	Opportunity for improvement
PBT	Persistent, bio accumulative and toxic
PPORD	Product and Process Oriented Research and Development
QSAR	Quantitative structure–activity relationship
RAAF	Read-Across Assessment Framework
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheets
SIEF	Substance information exchange forum
SME	Small and medium enterprises
SVHC	Substance of very high concern
UK	United Kingdom
UVCB	Substance of Unknown or Variable composition
vPvT	Very persistent very toxic
XML	Extensible Mark-up Language

Executive summary

This report is provided to support the European Commission in assessing the impacts on economic operators from the REACH 2018 registration deadline. The information gathered in this study relies on an extensive review of the literature, as well as a survey, interviews and webinars involving numerous experts in the field, from industry, trade associations, EU institutions, national authorities, consultancies, NGOs and other experts. The report explores a series of topics such as the costs and benefits of the 2018 registration deadline on economic operators; SIEFs and registration consortia; communication obligations for downstream users; use of resources and consultants; and effects on the EU market.

Context

REACH is the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force in 2007 and its main objectives are to ensure a high level of protection for human health and the environment; the promotion of test methods not involving vertebrate animals; the free circulation of substances on the internal market; and the enhancement of competitiveness and innovation.

Under the REACH registration process, manufacturers and importers of chemical substances are required to gather and submit information on the properties and uses of the substances they manufacture or import above 1 tonne per year. Three deadlines for registration were set, based on tonnage and hazard:

- 2010 (>1000t per year, substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2 above 1t per year, and substances classified as very toxic to aquatic organisms above1t per year);
- 2013 (>100t per year); and
- 2018 (>1t per year). For the 2018 deadline, by 31 May 2018, a total of 33,363 registrations had been submitted by 5,478 registrants.

Approach taken

A combination of consultation tools was used to collect the necessary evidence, including an online survey, in-depth interviews and online webinars. The online survey elicited a total of 296 responses, from business operators, trade and business associations, sector representatives, consortia, and other stakeholders. In addition, 32 interviews were carried out. Two webinars were held to present, test and validate initial findings, inviting reflections, feedback and corrections and to ensure that the most relevant available data had been used. Triangulation was used to compare perceptions (from interviews), observations (from the survey) and documentation (written evidence from the literature), using transversal analysis and expert judgement.

Estimates and responses from the survey's respondents were considered to be reasonably representative of the wider population of registrants, including for the estimates of costs from registration. The survey for the present study covered 8% of registrations submitted for the 2018 deadline and 6% of companies registering 1-10t substances. It covered 11% of registrations and 3% of companies registering 10-100t substances.

In estimating the total costs of registration, the **average cost per substance registration** was the primary data point used from the survey. Companies that provided such data included:

- 105 companies that provided data for substances registered at 1-10t. This covered 928 substances, or 4% of the 21,986 registrations submitted.
- 101 companies that provided data for substances registered at 10-100t. This covered 668 substances, or 5% of the 12,781 registrations submitted.

There does not appear to be any particular geographical bias in the responses received. Of the companies that provided data on costs of registration, around one third did not specify the member state that they are located in. Of the remainder, 26% were located in Germany, 19% in Italy, 14% in Spain, 8% in France and 7% in the UK. For comparison, 26% of all registrations in 2018 were from companies in Germany, with 14% from the UK, 11% from France, 9% from Italy and 8% from each of the Netherlands and Spain.

Similarly, there does not appear to be any particular bias in the size of companies responding to the survey compared to those that registered substances overall. Of those companies that provided data on costs of registration "per registration" (as used in the estimates of total costs), 51% were large enterprises, 16% medium, 21% small and 12% micro enterprises. Based on ECHA's registration statistics, of the 5314 companies that registered substances for the 2018 deadline, 75% were large companies, 10% medium, 9% small and 6% micro-sized companies.

Nevertheless, it was not possible to ensure representativeness of the responses in every potential sub-category of data (e.g. by type of operator, by sector, etc.), due to the large population sizes and the range of actors and geographies to be represented, as well as the lack of responses from certain stakeholder categories.

Costs of the 2018 registration deadline, including costs of updates

The average costs of registration per substance and per company were collated through survey responses. The estimates of costs of registration per substance and per registration are based on the results of the survey of companies that registered substances in 2018. Companies were asked to provide estimates of the costs of registration in the following ways: numbers of substances registered; average cost per substance registration; total costs of all registrations submitted by the company (for all substances registered); costs of key components of registration (e.g. preparing the registration dossier, testing costs, costs of read-across, etc.). This data was used in combination with the data on numbers of registrations provided by ECHA based on the registrations actually received, to estimate the total costs of registration for the 2018 deadline.

For the 1-10 tonnage band, the average costs per registration (per company) was around €44,000 and the average costs per substance registered was around €95,000, while for the 10-100 tonnage band, the average costs per registration (per company) was around €101,000 and the average costs per substance registered was around €280,000.

The study investigated several components of the costs of registration, such as the costs of preparing a dossier and the costs of undertaking tests. Based on survey responses, the costs of preparing a registration dossier (including drafting, finalising a technical registration dossier and submitting it, including administrative data and producing summaries for REACH annexes) was high for both the 1-10t substances (average of €18,000) and 10-100t substances (average of €39,000). This is an important finding as these costs were incurred by all registrants.

In addition, there were substantial costs of undertaking tests to obtain the necessary information for submission. The costs of tests for all of the endpoints under REACH Annex VII (1-10t substances) are around €60-€70,000; the costs of testing for 10-100t substances is much higher, particularly for toxicological and ecotoxicological tests. However, note that not all these tests were necessary, not all companies had to undertake those tests, and some companies obtained the results by paying for a letter of access. However, a large proportion (35-41%) did not know if tests were used and only a small proportion (16-19% indicated that they were used for more than 50% of information requirements.

The study also highlights issues with lack of justification in some cases for the use of read-across, and a lack of certainty as to what read-across will be accepted by ECHA. Consultation for the current study highlighted that further guidance on read-across and sameness would be beneficial for the future. Testing was reported as particularly expensive for complex substances such as UVCBs compared to basic chemicals. The majority of survey respondents that provided an informed response indicated that read-across and QSARs were used for

at least some endpoints. The costs of changes to company systems and of legal support was also reported as significant in some cases; however, there was only a small number of responses on this cost components.

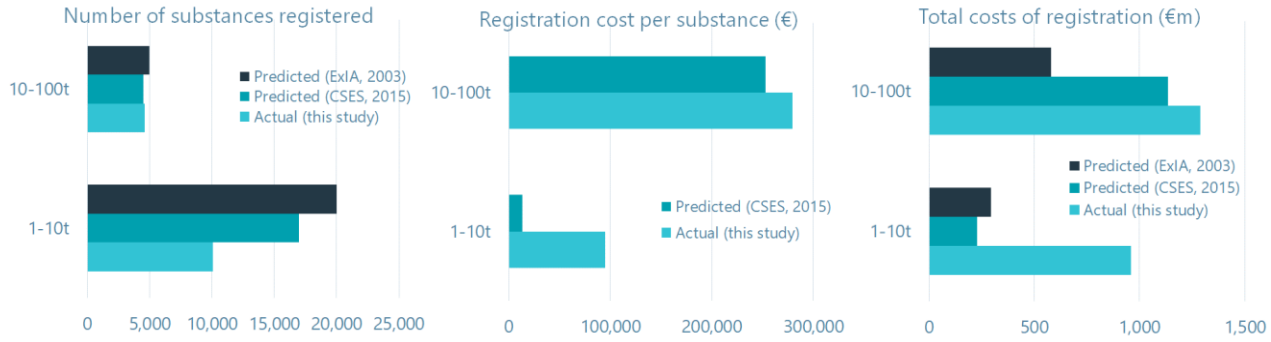
Table 0.1 Summary of average costs per registration per company, and costs of key components

Cost component	1-10t	10-100t	N (1-10t)	N (10-100t)
1. Average costs per substance registration	€43,699	€100,929	105	101
2. Cost for preparing the Registration Dossier [Note 1]	€18,225	€39,484	116	115
3. Physicochemical requirement study costs [Note 2]	€10,463	€13,125	81	80
4. Toxicological requirement study costs [Note 2]	€14,197	€104,911	56	56
5. Ecotoxicological requirement study costs [Note 2]	€11,760	€26,293	54	58
6. Costs of read-across and QSARs	€3,577	€6,019	11	13
7. Costs for a chemical safety assessment / report	-	€14,801	-	41
8. Costs of letter of access [Note 2]	€16,986	€30,626	107	108
9. Cost of legal support	€12,559	€12,590	26	23
10. Costs of training or changes to company systems	€3,314	€3,998	21	23

Notes:
1) See section 4.8.4 for details of the different elements included in this component. 2) For cost components 3, 4, 5 and 8, respondents provided data in the survey in ranges of costs. In these cases, the average costs were taken by assuming that on average, costs were in the midpoint of the range, and a weighted average cost was calculated accordingly (i.e. by summing the numbers of companies responding in each range by the cost for that range, and then dividing the total by the total number of responses. For all other cost components, the cost is the mean average of all responses provided. 3) The number of responses used in calculation of each cost component is provided in the final two columns.

Based on the above cost estimates from the survey results (particularly average costs per substance registration) and on data on the actual numbers of substances/registrations from ECHA, the total costs of registration were estimated as €1,290 million for the 10-100t substances (range €860 to €1,580 million) and €960 million for the 1-10t substances (range €700 to €1,120 million), giving €2,250 million in total (range €1,560 to €2,700 million). The total cost across all three deadlines, taking into account these uncertainty ranges is estimated as between €3.1 to €7.3 billion (with €4.8 billion as a central estimate).

The three charts below highlight some of the key conclusions on the costs of registration and a comparison with the previous ex-ante estimates. The charts reflect that the actual number of substances registered at 10-100t was in line with expectations before the 2018 deadline; however, the number registered at 1-10t was a bit more than half of the number predicted. The average costs of registration per substance for the 10-100t range were in reasonable agreement with those predicted (around 10% higher), but the average costs per substance for the 1-10t substances were around seven times those originally predicted. In terms of total costs per registration, these were based on the same cost elements as the ex-ante assessment. It should be noted that the estimates of costs and numbers of substances expected to be registered for the 2018 deadline were considered to be one of the most uncertain parts of the cost estimates in the original impact assessment. The cost estimates for the current study are likewise subject to uncertainty but, as noted above, the number of responses received gives a reasonable degree of confidence that the results are representative of the wider pool of registrations.



Costs of updates

REACH requires that registration dossiers be reviewed on a regular basis and updated as new information becomes available. Companies interviewed indicated that they often wait for ECHA to request an update to be made, e.g. through compliance checks, evaluations or dossiers being considered incomplete; otherwise, the main reasons why companies did not update registrations was because it was not perceived as required or because there was no new information available.

In terms of costs of updating registrations, companies most frequently incurred costs in the range €1,000 to €10,000 for all tonnage bands, although costs were lower for lower tonnage-band substances. The costs of updates do not appear to be related to the size of a company and the costs to update were, overall, considered affordable by SMEs. Testing costs and the Letter of Access were reported as the main drivers to the costs of updates.

A key challenge with updating registration reported by companies relates to the frequent changes to IUCLID software and information requirements. IUCLID version upgrades and changes by ECHA were frequently reported to have been an issue in updating dossiers, as well as changes being made to the guidelines which then change the requirements for companies. Overall, encoding information in IUCLID was reported as a main task outsourced by companies to consultants, reflecting the complexity perceived by businesses. Other issues in updating registrations include problems related to data-sharing, cost sharing and communication, which were encountered by about half of respondents to the survey. Companies also faced difficulties complying with deadlines for updates that were close to the 2018 registration deadline, given the limited capacity of laboratories, which were reportedly overwhelmed with requests for analysis.

SIEF and registration consortia

The approximate costs associated with joint registration (including joint registration and SIEF administrative costs, costs of liaising with other parties and other costs involved with the SIEF per company; excluding Letter of Access costs), for the 1-10 tonnage band vary between less than €1,000 to more than €20,000, with about half of respondents having had costs between €1,000 and €10,000. For the 10-100 tonnage band, about 40% of respondents also reported costs of above €20,000. Many registrants faced issues regarding disputes over pricing policies, cost sharing, prices of data or unexpected costs for SIEFs. There were mixed views on whether the Implementing Regulation (EU) 2016/9 on joint submission of data has been successful or not with most respondents finding that the regulation brought some improvements related to the transparency and fairness of costs. However, other companies reported that issues related to data sharing and joint registration raised for the previous registration deadlines (as mentioned in the 2018 REACH review) remained.

Communication obligations for downstream users

Article 31 of REACH covers communication obligations between downstream users and suppliers to ensure that relevant information is passed through the supply chain. In this context, manufacturers and importers of substances must provide their customers with a safety data sheet (SDS). SDSs include information on the properties and hazards of the substance or mixture; instructions for handling, disposal and transport of the substance; and exposure control measures; information on how to control exposure of workers, consumers and the environment. When receiving a safety data sheet, downstream users must apply adequate measures to control the risks linked to the substance, and check whether the exposure scenario covers their use of the substance. If not, they may make their use known to their supplier and request an updated exposure scenario. Downstream users must also provide information on safe use to their customers, when necessary.

REACH has led to an increase in costs of managing information exchange along the supply chain. The costs of preparing extended safety data sheets are considered a more substantial burden for smaller companies. As the result of the many factors that can influence the costs of communicating in the supply chain, very varied ranges of costs of preparing an SDS have been provided in the literature and in the survey carried out for this study. In the survey, respondents indicated that costs of preparing SDS ranged between €200 to €50,000. Several companies mentioned during the second webinar that the low cost of €200 was likely the cost to prepare a single SDS, and higher costs represented the cost to prepare SDS for a portfolio of substances, as it was reported that the time and cost to prepare an SDS highly depended on the number of products in a portfolio. Key challenges in communication in the supply chain included, among others, complex data requirements, low awareness of some small downstream users, or non-EU manufacturers, etc. The extended safety data sheets (and in particular exposure scenarios) were often considered lengthy, complex and too technical for the audience they are addressed to. Similar shortcomings and challenges had already been identified in the 2018 REACH review.

Resources and consultants

For the 2018 registration deadline (and compared to the previous deadlines), companies were less likely to have a dedicated REACH unit/manager within their organisations and in particular, SMEs were more likely to outsource some or all of the registration activities to consultants. Key reasons to outsource the registration activities included limited internal human resources as well as the lack of both technical and regulatory expertise in-house, in particular, for those companies registering chemicals for the first time. The main tasks outsourced cover the overall preparation of the dossiers; encoding the information in the software tools used for submission (IUCLID); as well as substance information exchange fora and consortia management; and technical support (e.g. monitoring and technical studies).

While consultants providing services of management and coordination related to SIEFs and consortia were available, there were insufficient consultants/laboratories with in-depth technical and scientific knowledge specific to certain (groups of) substances being registered, especially complex substances. Overall, the quality of consultants was considered satisfactory, but the costs of services provided by external consultants were considered high by a majority of respondents (although they noted that these costs depended on the type of consultancy). Several suggestions for technical training and support were made during the study consultation activities. These included the simplification of IUCLID, as well as step-by-step instructions to access and input information; tutorials (including videos) on steps to register; webinars on read-across; and clarity on future compliance requirements.

Benefits to companies from the 2018 registration deadline

Companies generally found it difficult to identify direct benefits to their businesses from REACH registration. Those that did identify benefits highlighted that REACH registration could be considered as a competitive advantage and that it increased the transparency of the market. Companies considered the availability of information on substances and the dissemination of information on safe use through the supply chain as a

significant benefit from REACH registration, as it has had a positive effect on the risk management practices of companies. Thereby, increased information on substances seems to encourage companies to reduce the use of hazardous chemicals, although results are less clear cut on this issue.

Effects on the EU market

The overall growth in world chemicals sales is predicted to continue, increasing from €3.7 trillion in 2019 to €6.2 trillion in 2030. The EU leads in speciality chemicals, with an expected continued increase in production value of speciality chemicals, of which many will be 1-10 tonne and 10-100 tonne substances: in 2019, the EU27 and the UK had a speciality chemical production value of €260.9 billion, which is expected to reach €323.8 billion by 2030. However, the EU's share of world markets has declined in the last 20 years, with emerging market growth, in particular China, which is now top of the global sales ranking. The analysis highlights that there has been no discernible impact on the overall market as a result of the REACH 2018 deadline, to date. However, the available data do not provide information on whether the REACH 2018 registration deadline may have had an impact on the level of growth of the EU market.

Most companies reported absorbing the 2018 REACH registration costs by reducing their profit margins, and therefore, have not passed on the cost of registration to their supply chain: for some companies, this, in turn, resulted in substantial pressure on prices from very competitive markets, in particular those for which the majority of competitors are located outside the EU. The analysis notes that other market dynamics and economic cycles also affect product prices, substance withdrawals and other commercial decisions around substances. Finally, only limited change has been reported as regards the levels of research and development as a result of the 2018 REACH registration deadline.

Next steps and the wider policy context

The registration of chemical substances is only the first step of a series of processes set out in REACH to assess and manage the risks from chemicals being placed on the EU market. ECHA is responsible for checking the compliance of registrations with the requirements set out under REACH: by the end of 2020, 19.2% of registration dossiers in the 10-100 tonnage band were checked for compliance and 13.8% of registration dossiers in the 1-10 tonnage band. Based on this evaluation, substances may be proposed as candidates for further regulatory processes, such as Authorisation (through recommendations for the Authorisation List and applications for Authorisation) or Restriction (e.g. limit or ban). Therefore, a good understanding of the costs and benefits in the first step of registration (as well as the drivers for those and potential hurdles) is critical to assess the wider impacts from REACH incurred by economic operators.

In addition, in 2020, the European Commission presented its Chemicals Strategy for Sustainability, setting out areas where it wants to make greater progress, along with concrete objectives and actions. Along with other ex-post studies such as the 2018 REACH review, the present report informs the European Commission in a series of impact assessment processes to further improve chemicals legislation, by building on existing evidence and feedback from stakeholders. It is expected that the outcome and findings of the present report can feed into several actions to be undertaken by the European Commission in the future, such as the further extension of the duty of registration under REACH to substances not under scope, e.g. certain polymers, or improving the availability of data on chemicals by updating information requirements under REACH.

Résumé exécutif

Ce rapport a pour objectif d'aider la Commission européenne à quantifier l'impact des enregistrements REACH avant la date limite d'enregistrement 2018 sur les opérateurs économiques. Les informations rassemblées dans cette étude reposent sur une revue approfondie de la littérature, ainsi que sur une enquête, des entretiens et des webinaires impliquant de nombreux experts dans le domaine, issus de l'industrie, d'associations professionnelles, d'institutions européennes, d'autorités nationales, de consultants, d'ONG et d'autres experts. Le rapport explore une série de sujets tels que les coûts et les avantages de la date limite d'enregistrement de 2018 pour les opérateurs économiques; les SIEFs et les consortia; les obligations de communication pour les utilisateurs en aval; utilisation des ressources et des consultants; et effets sur le marché de l'Union Européenne (UE).

Le contexte

REACH est le règlement de l'UE sur l'enregistrement, l'évaluation, l'autorisation et la restriction des produits chimiques. Il est entré en vigueur en 2007 et ses principaux objectifs sont d'assurer un niveau élevé de protection de la santé humaine et de l'environnement; la promotion de méthodes d'essai n'impliquant pas d'animaux vertébrés; la libre circulation des substances sur le marché intérieur; et le renforcement de la compétitivité et de l'innovation.

Dans le cadre du processus d'enregistrement REACH, les fabricants et les importateurs de substances chimiques sont tenus de collecter et de soumettre des informations sur les propriétés et les utilisations des substances qu'ils fabriquent ou importent au-delà d'une tonne par an. Trois dates limites d'enregistrement ont été fixées, en fonction du tonnage et du danger: 2010 (> 1000 tonnes par an, substances classées cancérigènes, mutagènes ou toxiques pour la reproduction, catégorie 1 ou 2 au-dessus de 1 tonne par an, et substances classées comme très toxiques pour les organismes aquatiques au-dessus de 1 tonne par an); 2013 (> 100 tonnes par an); et 2018 (> 1 tonne par an). Pour la date limite d'enregistrement 2018, au 31 mai 2018, un total de 33,363 inscriptions avaient été soumises par 5,478 inscrits.

Approche

Une combinaison d'outils de consultation a été utilisée pour recueillir les preuves nécessaires, notamment une enquête en ligne, des entretiens et des webinaires en ligne. L'enquête en ligne a suscité un total de 296 réponses, et couvre des opérateurs économiques, des associations commerciales, des représentants de secteur, des consortiums et d'autres parties prenantes. En outre, 32 entretiens ont été réalisés. Deux webinaires ont été organisés pour présenter, tester et valider les premiers résultats, susciter des réflexions, des commentaires et des corrections et pour s'assurer que les données disponibles les plus pertinentes avaient été utilisées. La triangulation a été utilisée pour comparer les perceptions (issues des entretiens), les observations (issues de l'enquête) et la documentation (informations issues la littérature), en utilisant une analyse transversale et un jugement d'expert.

Les estimations et les réponses des répondants à l'enquête ont été considérées comme raisonnablement représentatives de l'ensemble de la population des entreprises enregistrant sous REACH, y compris pour les estimations des coûts de cet enregistrement. L'enquête de la présente étude a couvert 8% des enregistrements soumis pour la date limite de 2018 et 6% des entreprises enregistrant des substances entre 1-10 tonnes. Il couvrait 11% des enregistrements et 3% des entreprises enregistrant 10 à 100 tonnes de substances.

Pour estimer les coûts totaux d'enregistrement, le coût moyen par enregistrement de substance était le principal point de données utilisé à partir de l'enquête. Les entreprises qui ont fourni de telles données comprenaient:

- 105 entreprises qui ont fourni des données pour des substances enregistrées à 1-10t. Cela couvrait 928 substances, soit 4% des 21,986 enregistrements soumis.
- 101 entreprises qui ont fourni des données pour des substances enregistrées à 10-100 t. Cela couvrait 668 substances, soit 5% des 12,781 enregistrements soumis.

Il ne semble pas y avoir de biais géographique particulier dans les réponses reçues. Parmi les entreprises qui ont fourni des données sur les coûts d'enregistrement, environ un tiers n'ont pas précisé l'État membre dans lequel elles se trouvent. Sur le reste, 26% se trouvaient en Allemagne, 19% en Italie, 14% en Espagne, 8% en France et 7% au Royaume-Uni. À titre de comparaison, 26% de toutes les immatriculations en 2018 provenaient d'entreprises en Allemagne, 14% du Royaume-Uni, 11% de France, 9% d'Italie, 8% des Pays-Bas et 8% de l'Espagne.

De même, il ne semble pas y avoir de biais particulier dans la taille des entreprises ayant répondu à l'enquête par rapport à celles qui ont enregistré des substances. Parmi les entreprises qui ont fourni des données sur les coûts d'enregistrement « par enregistrement » (telles qu'utilisées dans les estimations des coûts totaux), 51% étaient de grandes entreprises, 16% des moyennes, 21% des petites et 12% des microentreprises. Sur la base des statistiques d'enregistrement de l'ECHA, sur les 5,314 entreprises qui ont enregistré des substances pour la date limite de 2018, 75% étaient de grandes entreprises, 10% des moyennes, 9% des petites et 6% des micro-entreprises.

Néanmoins, il n'a pas été possible d'assurer la représentativité des réponses dans chaque sous-catégorie potentielle de données (par exemple par type d'opérateur, par secteur, etc.), en raison de la grande taille de la population et de l'éventail d'acteurs et de géographies à représenter, ainsi que le manque de réponses de certaines catégories de parties prenantes.

Coûts de la date limite d'enregistrement 2018

Les estimations des coûts d'enregistrement par substance et par enregistrement sont basées sur les résultats de l'enquête auprès des entreprises qui ont enregistré des substances en 2018. Les entreprises ont été invitées à fournir des estimations des coûts d'enregistrement en fournissant les éléments suivants: nombre de substances enregistrées; coût moyen par enregistrement de substance; les coûts totaux de tous les enregistrements soumis par l'entreprise (pour toutes les substances enregistrées); les coûts des éléments clés de l'enregistrement (par exemple, la préparation du dossier d'enregistrement, les coûts des tests, les coûts d'utilisation de méthodes par références croisées, etc.). Ces données ont été utilisées en combinaison avec les données sur le nombre d'enregistrements fournies par l'ECHA sur la base des enregistrements effectivement reçus, pour estimer les coûts totaux d'enregistrement pour la date limite de 2018.

Pour la fourchette de quantité 1-10 tonnes par an, le coût moyen par enregistrement (par entreprise) était d'environ 44,000 € et le coût moyen par substance enregistrée était d'environ 95,000 €, tandis que pour la fourchette de quantité 10-100 tonnes par an, les coûts moyens par enregistrement (par entreprise)) était d'environ 101,000 € et le coût moyen par substance enregistrée était d'environ 280,000 €.

L'étude a examiné plusieurs éléments des coûts d'enregistrement, tels que les coûts de préparation d'un dossier et les coûts de réalisation des tests. Sur la base des réponses à l'enquête, les coûts de préparation d'un dossier d'enregistrement (y compris la rédaction, la finalisation d'un dossier d'enregistrement technique et sa soumission, y compris les données administratives et la production de résumés pour les annexes REACH) étaient élevés pour les deux fourchettes de quantité, c'est-à-dire de 1 à 10 tonnes par an (moyenne de 18,000 €) et 10 à 100 tonnes par an (moyenne de 39,000 €). Il s'agit d'une constatation importante car ces coûts ont été supportés par tous les déclarants.

En outre, les coûts des tests pour obtenir les informations nécessaires à la soumission sont jugés importants. Les coûts des tests nécessaires pour l'annexe VII de REACH (substances pour la fourchette de 1 à 10 tonnes par an) sont d'environ 60 à 70,000 €; le coût des tests pour les substances dans la fourchette 10 à 100 tonnes

par an est beaucoup plus élevé, en particulier pour les tests toxicologiques et écotoxicologiques. Cependant, tous ces tests n'étaient pas nécessaires, toutes les entreprises n'étaient pas obligées de procéder à ces tests et certaines entreprises ont obtenu les résultats en payant une lettre d'accès. Cependant, une grande proportion des répondants a l'enquête (35-41%) ne savait pas si des tests étaient utilisés et seulement une petite proportion (16-19%) ont indiqué qu'ils étaient utilisés pour plus de 50% des besoins d'information.

L'étude met également en évidence des problèmes liés au manque de justification dans certains cas de l'utilisation de méthodes de références croisées et à un manque de certitude quant aux méthodes de références croisées qui seront acceptées par l'ECHA. La consultation pour l'étude en cours a souligné que des orientations supplémentaires sur les méthodes de références croisées seraient bénéfiques pour l'avenir. Les tests ont été signalés comme particulièrement coûteux pour les substances complexes telles que les substances de composition inconnue ou variable, par rapport aux produits chimiques de base. La majorité des répondants au sondage qui ont fourni une réponse ont indiqué que les méthodes de références croisées et de relation quantitative structure à activité ont été utilisées pour au moins certains paramètres. Les coûts des modifications des systèmes de l'entreprise et du soutien juridique ont également été signalés comme étant importants dans certains cas; cependant, il n'y a eu qu'un petit nombre de réponses sur ces éléments de coût.

Table 0.2 Récapitulatif des coûts moyens par enregistrement par entreprise et des coûts des composants clés

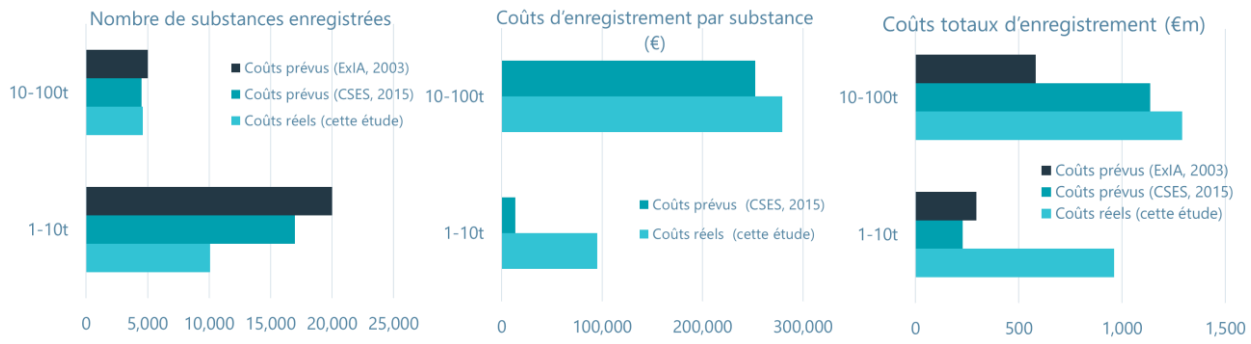
Type de coûts	1-10t	10-100t	N (1-10t)	N (10-100t)
1. Coûts moyens par enregistrement de substance	€43,699	€100,929	105	101
2. Coût de la préparation du dossier d'enregistrement [Note 1]	€18,225	€39,484	116	115
3. Coûts des études sur les critères physico-chimiques [Note 2]	€10,463	€13,125	81	80
4. Coûts des études toxicologiques [Note 2]	€14,197	€104,911	56	56
5. Coûts des études écotoxicologiques [Note 2]	€11,760	€26,293	54	58
6. Coûts des lectures croisées et des QSAR	€3,577	€6,019	11	13
7. Coûts de l'évaluation et du rapport sur la sécurité chimique	-	€14,801	-	41
8. Frais de lettre d'accès [Note 2]	€16,986	€30,626	107	108
9. Coût de l'assistance juridique	€12,559	€12,590	26	23
10. Coûts de formation ou modifications des systèmes de l'entreprise	€3,314	€3,998	21	23

Remarques:
1) Voir la section 4.8.4 pour plus de détails sur les différents éléments inclus. 2) Pour les composantes de coût 3, 4, 5 et 8, les répondants ont fourni des données de l'enquête en fourchettes de coûts. Dans ces cas, les coûts moyens ont été pris en supposant qu'en moyenne, les coûts se situaient au milieu de la fourchette, et un coût moyen pondéré a été calculé en conséquence (c'est-à-dire en additionnant le nombre d'entreprises répondant dans chaque fourchette par le coût de cette fourchette, puis en divisant le total par le nombre total de réponses. Pour tous les autres éléments de coût, le coût correspond à la moyenne de toutes les réponses fournies. 3) Le nombre de réponses utilisées dans le calcul de chaque élément de coût est indiqué dans les deux dernières colonnes.

Sur la base des estimations de coûts ci-dessus tirées des résultats de l'enquête (en particulier les coûts moyens par enregistrement de substance) et des données sur le nombre réel de substances / enregistrements de l'ECHA, les coûts totaux d'enregistrement ont été estimés à 1,290 millions d'euros pour

les substances de 10 à 100 tonnes (dans une fourchette allant de 860 € millions à 1,580 € millions) et 960 millions € pour les substances de 1 à 10 tonnes (fourchette de 700 à 1,120 millions €), soit 2 250 millions € au total (fourchette de 1,560 € à 2,700 millions €). Le coût total pour les trois échéances, compte tenu de ces fourchettes d'incertitude, est estimé entre 3,1 et 7,3 milliards d'euros (dont 4,8 milliards d'euros comme estimation centrale).

Les trois graphiques ci-dessous mettent en évidence certaines des principales conclusions sur les coûts d'enregistrement et une comparaison avec les estimations ex ante précédentes. Les graphiques montrent que le nombre réel de substances enregistrées entre 10 et 100 tonnes par an était conforme aux attentes avant la date limite de 2018; cependant, le nombre enregistré à 1-10 tonnes par an était d'un peu plus de la moitié du nombre prévu. Les coûts moyens d'enregistrement par substance pour la fourchette 10-100 tonnes par an étaient en accord avec ceux prévus (environ 10% plus élevés), mais les coûts moyens par substance pour les substances dans la fourchette 1-10 tonnes étaient environ sept fois plus élevés que ceux initialement prévus. Les coûts totaux par enregistrement dans l'étude présente sont basés sur les mêmes éléments de coût que l'évaluation ex ante. Il convient de noter que les estimations des coûts et du nombre de substances qui devraient être enregistrées pour la date limite de 2018 ont été considérées comme l'une des parties les plus incertaines des estimations de coûts dans l'analyse d'impact initiale. Les estimations des coûts de la présente étude sont également sujettes à l'incertitude, mais, comme indiqué ci-dessus, le nombre de réponses reçues donne un degré raisonnable de confiance dans le fait que les résultats sont représentatifs de l'ensemble des enregistrements.



Coûts des mises à jour

REACH exige que les dossiers d'enregistrement soient examinés régulièrement et mis à jour au fur et à mesure que de nouvelles informations deviennent disponibles. Les entreprises interrogées ont indiqué qu'elles attendent souvent que l'ECHA demande une mise à jour, par ex. par des contrôles de conformité, des évaluations ou des dossiers jugés incomplets; sinon, les principales raisons pour lesquelles les entreprises n'ont pas mis à jour les enregistrements étaient parce qu'elles n'étaient pas perçues comme nécessaires ou parce qu'aucune nouvelle information n'était disponible.

En ce qui concerne les coûts de mise à jour des enregistrements, les entreprises ont le plus souvent encouru des coûts de l'ordre de 1,000 à 10,000 euros pour toutes les fourchettes de quantité, bien que les coûts soient inférieurs pour les substances à fourchette de quantité inférieure. Les coûts des mises à jour ne semblent pas être liés à la taille d'une entreprise et les coûts de mise à jour étaient, dans l'ensemble, considérés comme abordables par les PME. Les coûts des tests et la lettre d'accès ont été signalés comme les principaux facteurs expliquant les coûts des mises à jour.

Un défi majeur lié à la mise à jour des enregistrements signalés par les entreprises est lié aux changements fréquents apportés au logiciel IUCLID et aux exigences en matière d'information. Les mises à niveau et les changements de version d'IUCLID par l'ECHA ont souvent été signalés comme ayant posé problème lors de la mise à jour des dossiers, ainsi que des modifications apportées aux lignes directrices qui modifient ensuite les exigences pour les entreprises. Dans l'ensemble, l'encodage des informations dans IUCLID a été signalé

comme une tâche principale sous-traitée par les entreprises à des consultants, reflétant la complexité perçue par les entreprises. Parmi les autres problèmes liés à la mise à jour des enregistrements figurent les problèmes liés au partage des données, au partage des coûts et à la communication, qui ont été rencontrés par environ la moitié des répondants à l'enquête. Les entreprises ont également eu du mal à respecter les délais de mise à jour proches de la date limite d'enregistrement de 2018, compte tenu de la capacité limitée des laboratoires, qui auraient été submergés de demandes d'analyse.

SIEF et consortiums d'enregistrement

Les coûts approximatifs associés à la soumission conjointe de données (y compris l'enregistrement conjoint et les coûts administratifs du SIEF, les coûts de liaison avec d'autres parties et les autres coûts liés au SIEF par entreprise; à l'exclusion des coûts de la lettre d'accès) pour la fourchette de quantité 1-10 tonnes par an varient entre moins de 1,000 € à plus de 20,000 €, environ la moitié des répondants ayant eu des coûts compris entre 1,000 et 10,000 €. Pour la fourchette de 10 à 100 tonnes par an, environ 40% des répondants ont également signalé des coûts supérieurs à 20,000 €. De nombreux déclarants ont été confrontés à des problèmes liés à des litiges concernant les politiques de tarification, le partage des coûts, les prix des données ou des coûts imprévus pour les FEIS. Les avis étaient partagés sur la question de savoir si le règlement d'exécution (UE) 2016/9 sur la soumission conjointe de données a été couronné de succès ou non, la plupart des répondants estimant que le règlement apportait certaines améliorations liées à la transparence et à l'équité des coûts. Cependant, d'autres entreprises ont signalé que les problèmes liés au partage de données et à l'enregistrement conjoint soulevés pour les dates limites d'enregistrement précédentes (comme mentionné dans l'examen REACH 2018) subsistaient.

Obligations de communication pour les utilisateurs en aval

L'article 31 de REACH couvre les obligations de communication entre les utilisateurs en aval et les fournisseurs afin de garantir que les informations pertinentes sont transmises tout au long de la chaîne d'approvisionnement. Dans ce contexte, les fabricants et importateurs de substances doivent fournir à leurs clients une fiche de données de sécurité (FDS). Les FDS contiennent des informations sur les propriétés et les dangers de la substance ou du mélange; instructions pour la manipulation, l'élimination et le transport de la substance; les mesures de contrôle de l'exposition; et des informations sur la manière de contrôler l'exposition des travailleurs, des consommateurs et de l'environnement. Lors de la réception d'une fiche de données de sécurité, les utilisateurs en aval doivent appliquer des mesures adéquates pour maîtriser les risques liés à la substance et vérifier si le scénario d'exposition couvre leur utilisation de la substance. Dans le cas contraire, ils peuvent faire connaître leur utilisation à leur fournisseur et demander un scénario d'exposition mis à jour. Les utilisateurs en aval doivent également fournir des informations sur l'utilisation en toute sécurité à leurs clients, si nécessaire.

REACH a entraîné une augmentation des coûts de gestion de l'échange d'informations tout au long de la chaîne d'approvisionnement. Les coûts de préparation des fiches de données de sécurité étendues sont considérés comme une charge plus importante pour les petites entreprises. En raison des nombreux facteurs qui peuvent influencer les coûts de communication dans la chaîne d'approvisionnement, des fourchettes très variées de coûts de préparation d'une FDS ont été fournies dans la littérature et dans l'enquête réalisée pour cette étude. Dans l'enquête, les répondants ont indiqué que les coûts de préparation de la FDS variaient entre 200 € et 50,000 €. Plusieurs entreprises ont mentionné au cours du deuxième webinaire que le faible coût de 200 € était probablement le coût de préparation d'une seule FDS, et que les coûts plus élevés représentaient le coût de préparation de la FDS pour un portefeuille de substances, car il a été signalé que le temps et le coût de préparation une FDS dépendait fortement du nombre de produits dans un portefeuille. Les principaux défis de la communication dans la chaîne d'approvisionnement comprenaient, entre autres, des exigences complexes en matière de données, une faible sensibilisation de certains petits utilisateurs en aval, ou des fabricants non européens, etc. Les fiches de données de sécurité étendues (et en particulier les scénarios d'exposition) étaient souvent considérées comme longues, complexe et trop technique pour le

public auquel ils s'adressent. Des lacunes et des défis similaires avaient déjà été identifiés dans l'examen REACH de 2018.

Ressources et consultants

Pour la date limite d'inscription de 2018 (et par rapport aux dates limites précédentes), les entreprises étaient moins susceptibles d'avoir une unité / un responsable REACH dédié au sein de leur organisation et, en particulier, les PME étaient plus susceptibles d'externaliser une partie ou la totalité des activités d'enregistrement à des consultants. Les principales raisons d'externaliser les activités d'enregistrement comprenaient des ressources humaines internes limitées ainsi que le manque d'expertise technique et réglementaire en interne, en particulier pour les entreprises qui enregistrent des produits chimiques pour la première fois. Les principales tâches externalisées couvrent la préparation globale des dossiers; encodage des informations dans les outils logiciels utilisés pour la soumission (IUCLID); ainsi que les forums d'échange d'informations sur les substances et la gestion des consortiums; et soutien technique (par exemple suivi et études techniques).

Bien que des consultants fournissant des services de gestion et de coordination liés aux FEIS et aux consortiums aient été disponibles, il n'y avait pas suffisamment de consultants / laboratoires possédant des connaissances techniques et scientifiques approfondies spécifiques à certaines (groupes de) substances enregistrées, en particulier les substances complexes. Dans l'ensemble, la qualité des consultants a été jugée satisfaisante, mais les coûts des services fournis par des consultants externes ont été jugés élevés par une majorité de répondants (bien qu'ils aient noté que ces coûts dépendaient du type de conseil). Plusieurs suggestions de formation technique et de soutien ont été faites au cours des activités de consultation de l'étude. Celles-ci comprenaient la simplification d'IUCLID, ainsi que des instructions étape par étape pour accéder aux informations et les saisir; des tutoriels (y compris des vidéos) sur les étapes à suivre pour s'inscrire; webinaires sur les lectures croisées; et la clarté des futures exigences de conformité.

Avantages pour les entreprises à partir de la date limite d'inscription 2018

Les entreprises ont généralement eu du mal à identifier les avantages directs pour leurs entreprises de l'enregistrement REACH. Ceux qui ont identifié des avantages ont souligné que l'enregistrement REACH pouvait être considéré comme un avantage concurrentiel et qu'il augmentait la transparence du marché. Les entreprises ont considéré la disponibilité d'informations sur les substances et la diffusion d'informations sur une utilisation sûre tout au long de la chaîne d'approvisionnement comme un avantage significatif de l'enregistrement REACH, car cela a eu un effet positif sur les pratiques de gestion des risques des entreprises. Ainsi, une information accrue sur les substances semble encourager les entreprises à réduire l'utilisation de produits chimiques dangereux, bien que les résultats soient moins clairs sur cette question.

Effets sur le marché de l'UE

La croissance globale des ventes mondiales de produits chimiques devrait se poursuivre, passant de 3,7 billions d'euros en 2019 à 6,2 billions d'euros en 2030. L'UE est en tête des produits chimiques de spécialité, avec une augmentation continue attendue de la valeur de la production de produits chimiques de spécialité, dont beaucoup seront dans les fourchettes 1 à 10 tonnes et 10 à 100 tonnes de substances par an: en 2019, l'UE27 et le Royaume-Uni avaient une valeur de production de produits chimiques de spécialité de 260,9 milliards d'euros, qui devrait atteindre 323,8 milliards d'euros d'ici 2030. Cependant, la part de l'UE sur les marchés mondiaux a diminué au cours des 20 dernières années, avec la croissance des marchés émergents, en particulier la Chine, qui occupe désormais la première place du classement mondial des ventes. L'analyse met en évidence qu'à ce jour, il n'y a eu aucun impact perceptible sur le marché global en raison de l'échéance REACH 2018. Cependant, les données disponibles ne permettent pas de savoir si la date limite d'enregistrement de REACH 2018 a pu avoir un impact sur le niveau de croissance du marché de l'UE.

La plupart des entreprises ont déclaré avoir absorbé les coûts d'enregistrement REACH 2018 en réduisant leurs marges bénéficiaires et n'ont donc pas répercuté les coûts d'enregistrement sur leur chaîne d'approvisionnement: pour certaines entreprises, cela a entraîné une pression substantielle sur les prix de la part de marchés très concurrentiels, en particulier ceux pour lesquels la majorité des concurrents sont situés en dehors de l'UE. L'analyse note que d'autres dynamiques de marché et cycles économiques affectent également les prix des produits, les retraits de substances et d'autres décisions commerciales concernant les substances. Enfin, seuls des changements limités ont été signalés en ce qui concerne les niveaux de recherche et développement à la suite de la date limite d'enregistrement REACH 2018.

Prochaines étapes et contexte politique plus large

L'enregistrement des substances chimiques n'est que la première étape d'une série de processus définis dans REACH pour évaluer et gérer les risques liés à la mise sur le marché de produits chimiques de l'UE. L'ECHA est chargée de vérifier la conformité des enregistrements avec les exigences énoncées dans REACH: à la fin de 2020, 19,2% des dossiers d'enregistrement dans la fourchette de 10 à 100 tonnages ont fait l'objet d'un contrôle de conformité et 13,8% des dossiers d'enregistrement dans la fourchette de quantité les 1 à 10 tonnes. Sur la base de cette évaluation, des substances peuvent être proposées comme candidates pour d'autres processus réglementaires, tels que l'autorisation (par le biais de recommandations pour la liste d'autorisation et les demandes d'autorisation) ou de restriction (par exemple, limite ou interdiction). Par conséquent, une bonne compréhension des coûts et des avantages lors de la première étape de l'enregistrement (ainsi que des moteurs de ceux-ci et des obstacles potentiels) est essentielle pour évaluer les impacts plus larges de REACH encourus par les opérateurs économiques.

En outre, en 2020, la Commission européenne a présenté sa stratégie pour des produits chimiques durables, définissant les domaines dans lesquels elle souhaite progresser davantage, ainsi que des objectifs et des actions concrets. Parallèlement à d'autres études ex post telles que la revue REACH 2018, le présent rapport informe la Commission européenne d'une série de processus d'évaluation d'impact afin d'améliorer davantage la législation sur les produits chimiques, en s'appuyant sur les preuves existantes et les commentaires des parties prenantes. Les résultats et les conclusions du présent rapport pourront alimenter plusieurs actions à entreprendre par la Commission européenne à l'avenir, telles que l'extension des obligations d'enregistrement sous REACH aux substances non couvertes par le champ d'application, par exemple certains polymères, ou en améliorant la disponibilité des données sur les produits chimiques en mettant à jour les exigences d'information au titre de REACH.

1. Introduction

1.1 Purpose of this report

This is the **final report** for the contract on 'impacts from REACH 2018 registration deadline on economic operators'. **Wood E&IS GmbH** (hereafter 'Wood'), together with **Milieu Consulting Sprl** and **PFA-Brussels** were contracted by the European Commission (DG GROW Unit D1) to:

- Develop a methodology to assess the impacts from the REACH 2018 deadline (Task 1).
- Identify and review all relevant existing information for this assessment and gather new data (Task 2).
- Analyse that data and provide conclusions (Task 3).
- Discuss preliminary results in an ad-hoc workshop (Task 4).
- Present the final study (Task 5).

In addition, specific objectives outlined in the tender specifications of the study were to:

- Quantify the direct costs of the registration exercise in 2018, (where possible) by cost component, volume ranges, by cost category, and comparing these costs to initial cost estimates made in previous impact assessments
- Identify and evaluate structural changes from the 2018 registration on the EU chemicals market, inter alia, on price, supply stability and availability of substances, by size of company, type of sector, and role under REACH.
- Quantify costs for updating registrations and extended safety data sheets, assessing the main drivers behind costs, as well as key challenges and difficulties met by economic operators.
- Describe the pricing policies of the substance information exchange fora (SIEF) and consortia, including their affordability.
- Evaluate the main effects and cost drivers for communication obligations for downstream users, and how this impacts communication across supply chains, and what the major concerns are around this.
- Assess the resources spent on adaptation to REACH, including the availability of adequately qualified persons to deal with REACH within the company or resorting to outsourced staff, e.g. consultants, including potential constraints for SMEs to acquire such qualified staff.
- Evaluate benefits from the 2018 registration deadline.

1.2 Scope

The scope of this study is as follows:

- Legislation and timing: this study focuses on the impacts from REACH registration. It considers impacts occurring from the latest (2018) registration exercise only.
- Analysis: the consultation and the analysis focused on impacts (costs and benefits) to economic operators (i.e. businesses). Economic operators include manufacturers from the chemical industry, importers, only representatives (ORs) as well as downstream industries affected by the 2018 registration requirements. Other stakeholders have been consulted to gather further insight on impacts upon economic operators. For example, these stakeholders include the European Chemicals Agency (ECHA), consultants and non-governmental organisations (NGOs).
- Geography: the study scope is the EU27 and the UK, which was a Member State at the time of the registration deadline.

The study started in January 2020 and ran for a period of 15 months.

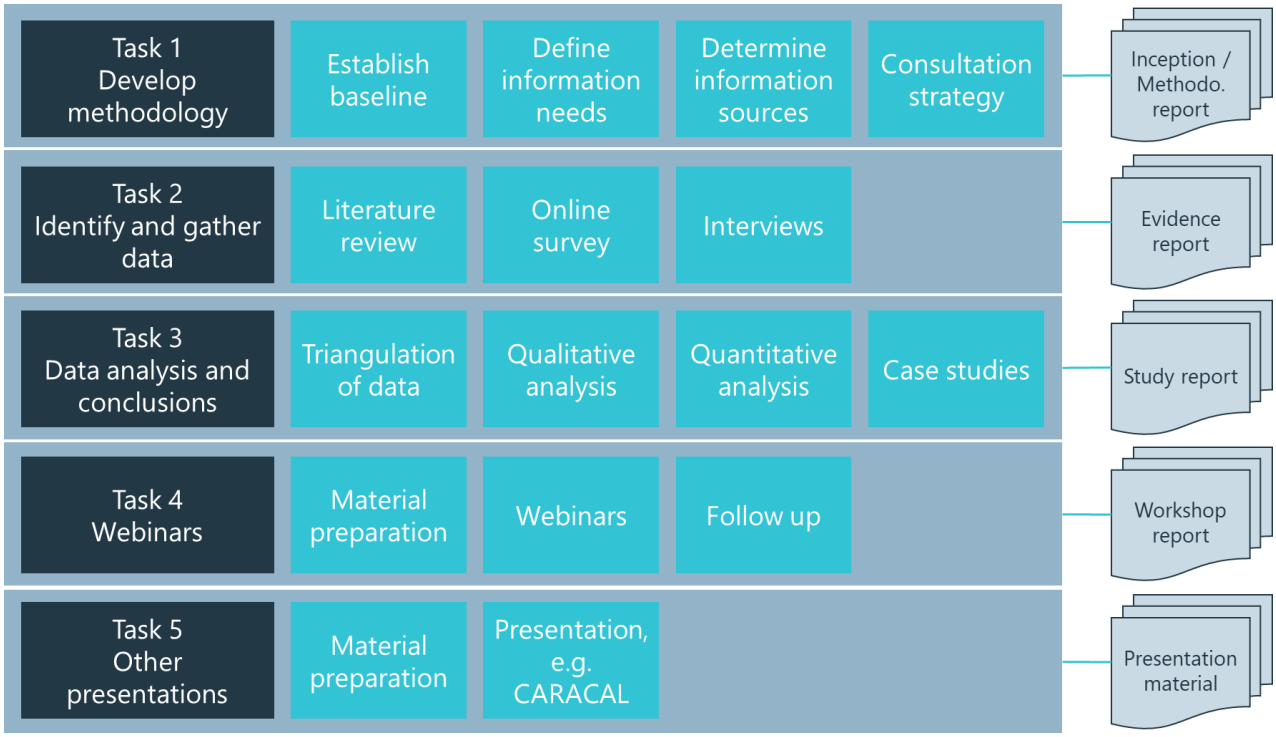
2. Methodology

This section aims to present the methodology used for the study. This includes the analytical framework, the literature review, the consultation strategy and analysis.

2.1 Overview

The project team developed a methodological framework to present the data and information needs for the successful development of key methods and messages in the project and the proposed approaches at collecting and verifying that data as well as the methods for the analysis. The figure below provides an overview of the project steps and sub-steps, as well as all deliverables.

Figure 2.1 Overview of methodology



2.2 Literature review

A review of existing literature has been undertaken. The purpose was twofold: firstly, to identify and collate existing secondary data; and secondly to identify key information gaps. This was intended to ensure that the questionnaire survey was short and focussed on filling the gaps.

The literature review was carried out to summarise baseline data, identifying cost estimates made in previous assessments. This step in the methodology was also useful to avoid, mitigate or acknowledge any identified weaknesses in previous methodologies and compare methods and scope between the current study and previous assessments, and ensure consistency. The project team carried out a literature review through web-based search covering policy reports and studies; grey literature (e.g. industry association briefings, consultancy reports); and proceedings of conferences, symposia and meetings. A complete list of sources used in the literature review can be found in the bibliography.

2.3 Consultations and evidence base (Synopsis Report)

This section summarises the consultation activities undertaken as part of the study on the impacts of the REACH 2018 registration deadline. The consultation was carried out as a means to collect the necessary evidence from various groups of stakeholders, compare these and analyse them in order to draw conclusions regarding the impacts of the REACH 2018 registration deadline, mainly on economic operators.

A combination of consultation tools was used to collect the necessary evidence. These included:

- An online survey, targeting key stakeholders. A total of 296 replies were collected mainly from economic operators and sector representatives as well as some consultants and trade associations.
- 32 In-depth and "gap filler" interviews to further discuss some of the issues with survey respondents, as well as other stakeholders who did not participate in the online survey. Interviews were conducted mainly with economic operators and EU-wide industry associations, as well as with the EU Commission and ECHA, consultants, one NGO, etc.
- Two online webinars, to present, test, and validate findings with 60 and 73 participants.

2.3.1 Online survey

For the online survey, a questionnaire was developed with different questions for different types of stakeholders. The main questionnaire targeted registrants under the 2018 registration deadline (i.e. economic operators). In addition, competent authorities, NGOs, trade associations and other stakeholders were sent a shorter version, asking for reflections and/or suggested improvements. The detailed responses are in Appendix A.

The survey was uploaded to the EU Survey tool[1] by the project team on 19 May 2020 and was available for a period of 12 weeks, until 11 August 2020. The online survey was made available in English, French, German, Spanish, Italian and Polish. Responses were monitored on a weekly basis, and follow-up emails to specific stakeholder groups were sent in order to ensure good coverage of data. Stakeholders were invited to take part in the survey via an email from the project team on 20 May 2020. Subsequently, stakeholders were sent reminder e-mails from the project team on 28 and 29 July. ECHA also invited stakeholders to take part in the survey via email on 3 June 2020, with reminders posted on ECHA's social media platforms.

Table 2.1 Dissemination channels used for the consultation

Dissemination channel	Purpose
Sectoral and national trade associations	The project team contacted various sectoral and national trade associations in order to reach out to their business and non-business members.
REACH public consultation contacts	154 businesses agreed with ECHA to provide their name and contact details in the REACH review public consultation and were further contacted to take part in the survey.
DG GROW / ECHA and their networks	ECHA disseminated the online survey through their database of registrants. The Commission's (DG GROW) communication department promoted the survey on a regular basis on Twitter and LinkedIn. ECHA provided visual material to support communications.
SME-specific channels	SME United (former UEAPME) and Business Europe were asked to disseminate the survey via their memberships.

[1] https://ec.europa.eu/eusurvey/home/welcome

Dissemination channel	Purpose
Project team's networks	Target extensive networks from Wood, PFA and Milieu.

More than 500 stakeholders were contacted for the online survey. These included business operators, trade and business associations, sector representatives, consortia, NGOs, and public authorities including EU institutions as well as consultants that provide support with REACH registrations. Business and industrial operators included small and medium enterprises, manufacturers from the chemical industry, importers, only representatives as well as downstream industries affected by the 2018 registration requirements. National industry and trade associations were also contacted to provide feedback on the impacts of the 2018 REACH registration deadline, as well as competent authorities in charge of chemical regulation from all EU member states and the UK.

A general 'cleaning' of the data was undertaken to enable the results for analysis. This included removing duplicate responses, test responses and empty responses. The ECB exchange rate[2] was applied to figures (costs in currencies other than Euro), where required. Quantitative responses were 'cleaned' and presented in the same format to enable analysis, with data processed in Microsoft Excel. Respondents' also completed the survey in several different languages (DE, FR, IT, ES, PL, CZ, EN). Translations of answers to the survey were carried out using an online translator and were then reviewed by native speakers in the project team.

The consultation elicited a total of 296 responses: 295 responses were received through the online portal and an additional response was provided by email. A detailed breakdown of the type of respondents is provided in the table below.

Responses were received from most Member States. Just under a fifth of the responses were from Germany (52 responses – 19% of the total EU responses); over a tenth were from Italy (33 responses – 12% of the EU responses) and from Spain (30 responses – 11% of EU responses); 5% (15) were from France, followed by the UK (12 responses - 4%). Fewer than 10 responses were received from each of the remaining Member States. A total of 36 respondents were from non-EU areas located in Hong Kong, India, Japan, South Korea, Malaysia, Mexico, the USA, South Africa, Peru, Norway and Switzerland.

Neither NGOs, nor national helpdesks responded to the survey. It is thought that (based on follow-up consultation) that this was because they had not undertaken registration themselves.

Table 2.2 Type of respondents involved in the consultation

Type of respondent	Number of respondents	Percentage of respondents
Business > 250 employees	117	39%
Business > 50 employees	56	19%
Business > 10 employees	61	20%
Business < 10 employees	27	9%
Business (unknown size)	11	4%
Subtotal – Total businesses	272	
Trade associations	5	2%

[2] ECB exchange rate average from 1 June 2013 to 31 May 2018: https://www.ecb.europa.eu/stats/policy_and_exchange_rates/euro_reference_exchange_rates/html/index.en.html

Type of respondent	Number of respondents	Percentage of respondents
NGOs	0	-
Public authorities	0	-
Consultants	15	5%
Other (self-employed, representatives)	4	2%
Total	296	100%

2.3.2 Interviews

The survey was supplemented with telephone interviews between 24 August 2020 and 15 January 2021 to further investigate and validate initial findings from the open public consultation and collect more detailed, qualitative information on the impacts of the REACH registration deadline. The interviews involved both:

- Survey respondents whom the project team wanted to ask more in-depth questions of, based on their input to the survey, so-called 'in-depth interviews'.
- Additional stakeholders who had not taken part in the online survey, but from whom the project team thought it could gather relevant/key feedback, so-called 'gap-filler' interviews.

In total, 61 organisations were invited to take part in a telephone interview and 32 interviews (including one written response) were carried out. Interview guides were developed based on the type of stakeholder and separate questions were asked of NGOs, trade associations, consortia, etc. These were sent to stakeholders prior to the interviews for the interviewees to obtain an overview of the key points which would be tackled during the discussion. The interviews were summarised in minutes by the interviewers. A detailed breakdown of the type of respondents is provided in the table below.

Table 2.3 Interviews

Type of stakeholders	Interviews undertaken	Type of interviewees
EU-wide and/or national industry associations	9	7 EU-wide associations and 2 national associations
Companies	15 (incl. one written response)	6 large, 9 SMEs
EU Commission and agencies	4	
Environmental Groups, NGOs	1	1 EU-wide
Consortia/SIEF Managers	1	
Consultants	2	
Total	**32**	

Despite being encouraged to do so, most NGOs and national helpdesks invited declined and indicated that they had few insights into the impacts from the REACH 2018 deadline on economic operators as they have not undertaken registration themselves. In addition, several consortium managers suggested talking to companies to obtain feedback on consortia and so were not able to provide input themselves.

2.3.3 Webinars

The study specifications included a one-day workshop with a limit of 60 participants. However, due to COVID 19 restrictions, it was agreed with the Commission that this would be replaced by two online webinars. 73 stakeholders attended the webinar on 14 October 2020, and 40 attended the webinar on 21 October. Stakeholders included economic operators, trade associations and public authorities.

The purpose of the webinars was to present, test and validate findings inviting reflections, feedback and corrections and to ensure that the most relevant available data had been used. Furthermore, the workshop aimed to highlight outstanding gaps/barriers in knowledge, enrich existing data on participants' reflections and experiences as well as understand and explore changes over time, lessons learned, and policy implications, including challenges for SMEs in particular.

Topics covered included direct costs of registration and costs of updates, resourcing (including consultants), participation in SIEFs and consortia, benefits from 2018 registration for companies, effects on chemicals markets, including benefits for the industry and communication obligations with the supply chain/downstream users. **Microsoft Teams** was used as a platform to host participants.

Table 2.4 Webinars – topics covered

#	Webinar	Topics covered (from study specific objectives)	Dates
1	**Week 12/10/2020** Impacts from the 2018 registration deadline **on companies**	• Direct costs of registration and costs of updates. • Resourcing and consultants. • Participation in SIEFs and consortia. • Benefits from 2018 registration for companies.	• Wednesday 14/10, 09.00 – 11.00 CET.
2	**Week 19/10/2020** Impacts from the 2018 registration deadline **on the chemical market and across supply chains**	• Effects on chemicals markets, including benefits for the industry. • Communication obligations with the supply chain/downstream users.	• Wednesday 21/10, 09.00 – 11.00 CET.

A copy of the workshop report can be found in Appendix C: this document provides a summary of the content and outcomes of two online webinars.

2.4 Analysis

2.4.1 Triangulation of primary and secondary data

Triangulation was used to compare perceptions (from interviews), observations (from the survey) and documentation (written evidence from the literature), using transversal analysis and expert judgement. Feedback received during the consultation was reviewed and responses collected were cross-referenced in order to assess their quality and identify any possible trends and patterns or highlight inconsistencies.

2.4.2 Statistical analysis, including cost assessment

The analysis of the online survey data started with a data cleaning process to ensure that data values were correct (i.e. they lie within an expected range, spelling and sense check etc). The data cleaning process also included coding open questions. A record was kept of all steps taken to ensure that the analysis was as transparent as possible.

Several of the specific objectives required an assessment of the cost impacts, including direct costs of registration, costs of updates, etc. The main source of data for this assessment was from the online survey

with economic operators and trade associations, as well as the interviews. The information collected from published secondary sources (e.g. the REACH review) and unpublished reports (e.g. two reports carried out by ECHA on the 2018 deadline) also fed into the assessment of costs and benefits[3].

The online survey provided results differentiated by:

- Type of respondent: company, trade association, business association or sector group representative, consultants, EU institution, international organisation, national/local public authority, non-governmental organisation, academia or think tank.
- The role of respondent in the supply chain: manufacturer of substances, only representative, importers of substances or mixtures, distributor/wholesaler/retailer of chemical substances or mixtures, suppliers of articles (manufacturer/importer/distributor of articles), downstream users, formulators, end user, provider of advice or technical support.
- Geographies: within EU (by Member State) and beyond EU.
- Sector: see Appendix D – several of these sub sectors were aggregated in the survey to make it easier for respondents to answer.
- Size of company: micro, small, medium and large according to thresholds[4] based on number of employees, turnover and/or balance sheet.

2.4.3 Presentation of data

A series of figures, tables and graphs are presented throughout the report to illustrate some of the key findings gathered from the online survey. The rules below apply to all data presented in the report:

- Where applicable, outlier values were removed from the underlying data, e.g. costs of registration equal to €0 or €1. These costs were not considered when calculating e.g. average values.
- Not every question from the survey received a total of 296 responses (the number responding overall). Some questions only targeted certain stakeholder categories. For example, graphs covering the costs of registration per substance per company only present the responses from companies and trade associations.
- Responses to the online survey that a question was 'not applicable to the organisation' or 'do not know' were not included in the figures presented in the report to facilitate readability and avoid biased estimates.
- Companies that did not specify a size were excluded from the figures, tables and graphs that split the responses by size of company but were not excluded from other statistics.
- Averages presented in the report are based on the individual contributions from respondents. Note, however, that despite guidance on the scope of each question in the survey, some responses included or excluded certain specific cost items, when reported by the respondent.

[3] A study from CEPS and Economisti Associati identifies three main categories of cost forming a typology of regulatory costs further included in the Better Regulatory Toolbox: direct, indirect and enforcement costs. **Direct costs** directly incurred due to the legislation and include monetary obligations, substantive obligations (capital expenditures and operating expenditures) and administrative burden; **Indirect costs** can also be generated as a result of legislative requirements including those related to opportunity costs due to the substitution of raw materials/ products and the loss of markets and those incurred by general public and other companies upstream in the value chain and passed on to companies through the price of inputs. ***Note a third category - Enforcement costs*** *- concern the public administration and designated competent authorities responsible for the enforcement of the Directives (this is out of the scope of this study).* http://ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

[4] European Commission, SME definition, https://ec.europa.eu/growth/smes/sme-definition_en

2.4.4 Case studies

The project team carried out **four case studies**, to allow for in-depth understanding of certain topics outlined below:

- Challenges and best practice with the use of read-across in dossier preparation.
- Complexity of dealing with substances of unknown variable composition, complex reaction products or biological materials (UVCBs) in dossier preparation.
- Improved communication through the supply chain through Safety Data Sheets (SDS).
- The issue of 'free-riders' in registration.

2.5 Limitations and gaps

Table 2.5 Overview of limitations

Limitations
The methodology used to assess costs and benefits draws on previous similar exercises and it did not involve testing for statistical significance of results. Instead, it provides an estimate of the order of magnitude of costs incurred by economic operators in the 2018 REACH registration deadline.
It was not possible to ensure representativeness of the responses in every potential sub-category of data (e.g. by type of operator, by country, by sector, etc.), due to the large population sizes and the range of actors and geographies to be represented, as well as the lack of responses from certain stakeholder categories. However, in mitigation: All roles for economic operators (in the registration process) were represented in the survey, including only representatives, manufacturers, importers, distributors, suppliers of articles, downstream users, formulators, end users. All sectors considered were covered by respondents, with a majority of respondents from sectors manufacturing coke and refined petroleum products, basic chemicals, fertilisers and nitrogen compounds, plastics and synthetic rubber in primary forms, pesticides and other agricultural compounds, paints, varnishes, soap and detergents. Responses were received from most EU Member States (and some non-EU countries), with larger samples from Germany, Italy, Spain, France and the UK, which are the countries with the highest numbers of companies operating in the chemicals sector, as well as countries with the highest numbers of SMEs in this sector. Further information on the representativeness of cost estimates is presented in section 4.2.
The gaps in information noted below were identified: As mitigation measures, where data was missing or poor from the online survey, further insights were sought from stakeholders during follow-up interviews and two webinars. Costs of registration: Limited data was obtained from the consultation process on the cost of quantitative structure activity relationship models (QSARs) and read-across studies. How these costs have changed over time also remains as a gap. Costs of updates: most companies providing data on the average cost of updates in the online survey were large enterprises (60-70% depending on the tonnage band) and no additional insight on the specific cost of updates for SMEs was given from participants during the online workshops or interviews. SIEF and consortia: there was only anecdotal evidence on price policies in place in both SIEF and consortia and on the impacts on operators from the cost-sharing disputes and solutions found to tackle issues encountered in SIEFs and consortia. Communication obligations to downstream users: the main gap in this area is the quantification of costs of preparing the Safety Data Sheet. Ranges provided in the survey and in interviews did not allow a meaningful average cost to be calculated. Resourcing and consultants: the survey and interviews did not provide sufficient information to allow quantification of costs of external support and training costs. Information on the costs of training and the type of training sought was not identified in the literature and limited quantitative information was provided through the consultation process. Benefits: in the survey responses and from the interviews it was not possible to distinguish the benefits of the 2018 registration from benefits of REACH registration in general. Most interviewees provided their opinion on general benefits linked to the REACH registration. Effects on the chemical markets: no precise information on the number and/or percentage of product withdrawals and final product availability for consumers could be identified for any of the registration deadlines in the literature. The online survey requested information on the number of product withdrawals, however limited quantitative information was provided by respondents. Information on market share and trade was also not identified for the 2018 deadline in the literature, and information has not been obtained through the present study.

3. What was the 2018 REACH registration deadline and what was its purpose?

REACH is the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force in 2007 and its main objectives are to ensure a high level of protection for human health and the environment, the promotion of alternative test methods (i.e., hazard testing that does not involve vertebrate animals), the free circulation of substances on the internal, market and the enhancement of competitiveness and innovation.

Under the REACH registration process, manufacturers and importers of chemical substances are required to gather and submit information on the properties and uses of the substances they manufacture or import above 1 tonne per year. It operates a 'no data, no market' principle, placing the responsibility on industry (manufacturers, users) to manage the risks from chemicals and to provide safety information on the substances. The flowchart below presents key activities to register a chemical substance. Responsibilities of economic operators (chemical manufacturer or importer) are indicated in dark green.

The data requirements for registration of substances under REACH are based on volume placed on the market, with the highest requirements for substances with the highest tonnage, summarised as follows:

- **Annex X** – substances placed on the market at 1000 tonnes per year or more
- **Annex IX** - substances placed on the market at 100 to 1000 tonnes per year
- **Annex VIII** - substances placed on the market at 10 to 100 tonnes per year
- **Annex VII** - substances placed on the market at 1 to 10 tonnes per year

The information requirement comprises information on the properties of the substance including identity, classification and labelling, uses, physicochemical properties, (bio)degradation and (eco)toxicological properties.

For **substances at Annex VIII and above a chemical safety assessment (CSA) is required**. This is required to demonstrate the safe use of a chemical substance, based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure (of man and/or the environment) to that substance, taking into account implemented and recommended risk management measures and operational conditions. The CSA is documented in a chemical safety report (CSR) which forms part of the registration dossier.

For existing 'phase-in' substances[5], registration under REACH was done in a phased way, such that substances placed on the EU market in the highest volumes, along with the most hazardous substances, were registered first, with lower volumes being done later.

The **deadlines** based on tonnage and hazard were as follows:

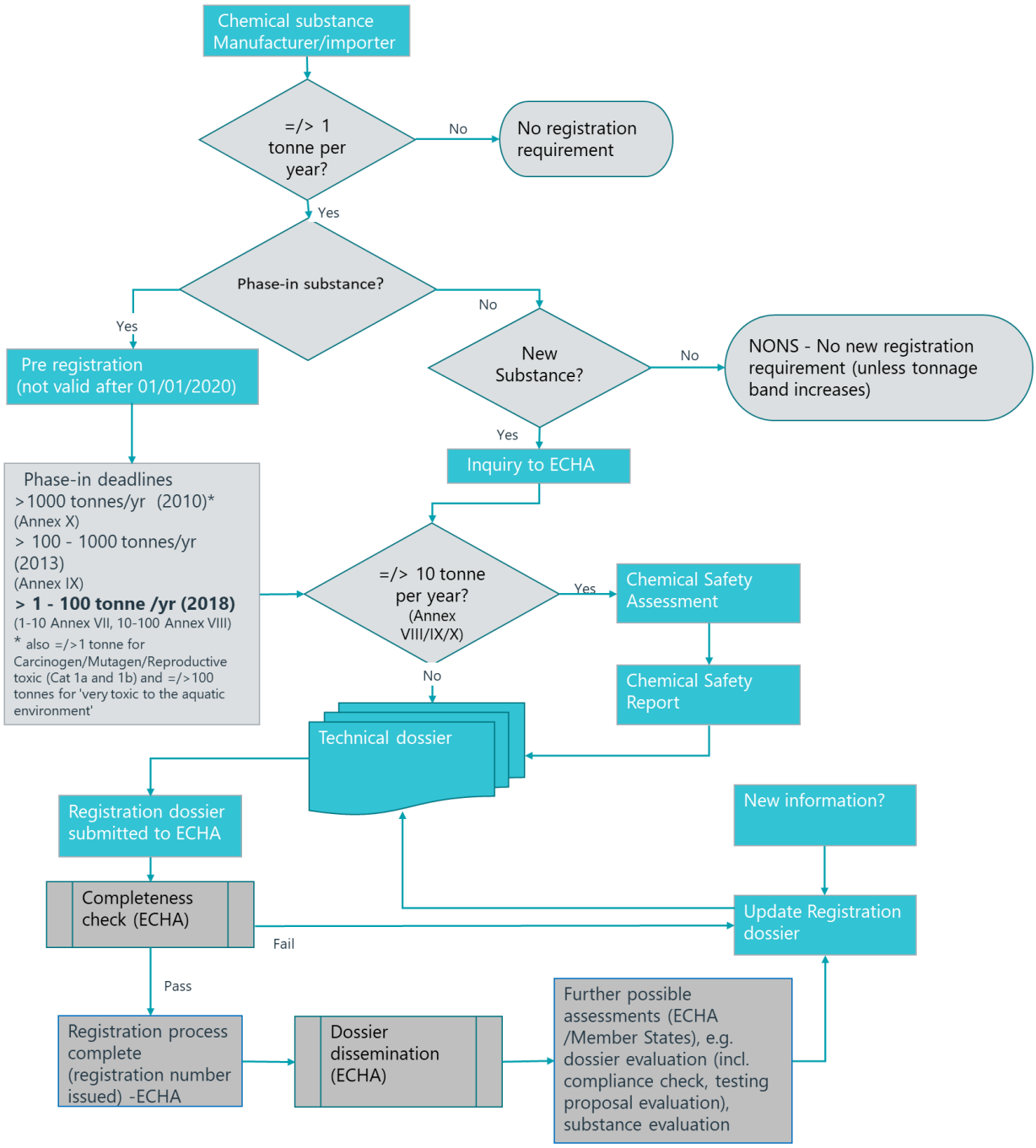
- **First phase - 30 November 2010** – Substances manufactured or imported at over 1000 tonnes per year. As well as substances classified as very toxic to aquatic organisms and may cause long-term

[5] Substances requiring registration in these 'phase-in' periods were those that met the following criteria: substances listed in the European Inventory of Existing Commercial chemical Substances (EINECS); substances that had been manufactured in the EU (including accession countries on 1 January 2007) but had not been placed on the EU market after 1 June 1992; and substances that qualified as a so-called 'no-longer polymer'. These phase-in substances could be 'pre-registered' until 31 May 2017 to benefit from the phase in deadlines – i.e. substance could be manufactured, imported and placed on the EU market without registration until the relevant phase in deadline for registration. See https://echa.europa.eu/fr/-/last-call-to-pre-register-your-low-volume-chemicals

adverse effects in the aquatic environment at or above 100 tonnes per year, and substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B at or above 1 tonne per year.

- **Second phase - 31 May 2013** – Substances manufactured or imported at over 100 tonnes per year.
- **Third phase - 31 May 2018** – Substances manufactured or imported at over 1 tonne per year.

Figure 3.1 Activities to register chemicals under REACH



Source: author's own elaboration.

The focus of this study is the third phase-in registration period (2018 deadline) and primarily on those substances registered at 1-100 tonnes per year. All of these (1-10t and 10-100t) required information according to REACH Annex VII, with those at 10-100t also requiring information according to Annex VIII.

For the 2018 phase-in deadline, by 31 May 2018, there was a total of 33,363 registrations submitted by 5,478 registrants. These were comprised of 12,233 by importers (43%), 8,126 by only representatives (29%), 6,477 by manufacturers (23%) and 1,486 by both manufacturer and importer (5%)[6]. Of the total number of registrants 17% were SMEs, which was unexpectedly a lower proportion than in 2013 (20%), but higher than in 2010 (13%). It was expected that more smaller firms would be registering in 2018 because of the lower tonnages.

Table 3.1 shows the number of companies that have registered chemicals as part of the 2018 registration deadline and a breakdown of the number by company size (micro, small or medium-sized company) as indicated by the companies. Companies' self-declarations are verified by ECHA.

Table 3.1 Registrants by company size and number of registrations in 2018

Company size	# Companies with registrations submitted	# Registrations submitted
Total	5,478	33,363
Large companies	3,964 (72%)	27,794 (83%)
SMEs (total)	1,514 (28%)	5,569 (17%)
Medium-sized companies	624 (11%)	3,059 (9%)
Small-sized companies	563 (10%)	1,878 (6%)
Micro-sized companies	327 (6%)	632 (2%)

Source: REACH registration results - ECHA (europa.eu), consulted on 8/1/2021 (based on data from 31/5/2018) Note: the table above reports the number of registrations submitted to ECHA. This number may be different from the number of registrations completed (i.e. registrations are completed when companies have received their registration numbers) as some submitted dossiers had not been checked for completeness when this information was extracted; or some were checked but still needed to provide more data to be completed; or some registrations were submitted after the compilation of this data.

The table below shows the number of registrations received from the 27 EU Member States, from the European Economic Area countries (Norway, Iceland and Liechtenstein) and from the UK.

Table 3.2 Registrations and substances by EU/EEA country for the 2018 deadline

Country	# Registrations submitted		# Substances (in completed registrations)	
Germany	8,647	25.9%	4,443	44.6%
United Kingdom	4,515	13.5%	2,020	20.3%
France	3,586	10.7%	1,789	18.0%
Italy	2,972	8.9%	1,804	18.1%
Netherlands	2,827	8.5%	1,462	14.7%
Spain	2,542	7.6%	1,558	15.7%
Belgium	2,291	6.9%	1,312	13.2%

[6] There was also one (1) downstream user taking the registrant's role.

Country	# Registrations submitted		# Substances (in completed registrations)	
Ireland	1,269	3.8%	773	7.8%
Sweden	1,159	3.5%	926	9.3%
Hungary	835	2.5%	637	6.4%
Czechia	624	1.9%	522	5.2%
Poland	378	1.1%	206	2.1%
Austria	376	1.1%	310	3.1%
Finland	324	1.0%	236	2.4%
Luxembourg	203	0.6%	125	1.3%
Denmark	160	0.5%	124	1.2%
Bulgaria	126	0.4%	51	0.5%
Greece	106	0.3%	53	0.5%
Portugal	65	0.2%	49	0.5%
Latvia	64	0.2%	55	0.6%
Slovenia	51	0.2%	50	0.5%
Romania	50	0.1%	42	0.4%
Norway	48	0.1%	25	0.3%
Slovakia	43	0.1%	34	0.3%
Liechtenstein	33	0.1%	30	0.3%
Croatia	29	0.1%	25	0.3%
Estonia	18	0.1%	7	0.1%
Lithuania	10	<0.1%	10	0.1%
Malta	7	<0.1%	5	0.1%
Cyprus	4	<0.1%	1	<0.1%
Iceland	1	<0.1%	1	<0.1%
TOTAL	**33 363**		**9 955**	

Source: REACH registration results - ECHA (europa.eu), consulted on 8/1/2021 (based on data from 31/5/2018)

4. The costs of 2018 registration

4.1 Scope of work and key messages

This chapter attempts to quantify the direct costs of the registration exercise in 2018. Costs of registration have been estimated for the relevant volume ranges (1-10 tonnes and 10-100 tonnes). The various components of registration costs have also been investigated, including: registration fees payable to ECHA; costs of dossier preparation; costs of testing; price of a letter of access; preparation of safety data sheets; costs of training, familiarisation and information; and costs of legal support.

In addition to the costs of the various component parts of the costs, estimates have been made of the range and average of the costs of registration both **per registration** and **per substance**. Based on data on the number of registrations and the number of substances registered, the **total costs** of the 2018 registration deadline have been estimated.

The estimated costs have been compared to the expected costs estimated in previous studies and impact assessments, taking into account differences in factors such as the number of registrations and the average costs per registration, compared to initial estimates.

The work draws upon literature sources (from both before and after the 2018 deadline); the survey and consultation for the current study; and information provided by ECHA.

Key findings

- For the 2018 deadline, around 22,000 registrations were submitted covering around 10,100 substances in the 1-10t range. Around 12,800 registrations were submitted in the 10-100t range, covering around 4,600 substances.
- The actual number of substances registered at 10-100t was in line with expectations before the 2018 deadline. However, the number registered at 1-10t was a just over half of the number predicted.
- The survey for the current study covered 8% of registrations and 6% of companies registering 1-10t substances. It covered 11% of registrations and 3% of companies registering 10-100t substances. The resulting estimates of costs are considered to be reasonably representative of the wider registration costs.
- Based on the survey, the estimated average costs of registering a substance per company was around €44,000 for 1-10t substances and €101,000 for 10-100t substances. Many substances were registered by multiple companies, and the estimated average costs per substance were around €95,000 and €280,000, respectively.
- The average costs of registration per substance for the 10-100t range were in reasonable agreement with those predicted (around 10% higher), but average costs per substance for the 1-10t substances were around seven times those originally predicted.
- Total registration costs are estimated as €960 million for 1-10t and €1,290 million for 10-100t, giving €2,250 million in total. This is based on estimated average costs per substance from the survey and actual numbers of registrations completed.
- This compares to costs of €2.1 billion (range €1.1 to €4.1 billion) for the 2010 registration deadline and €0.46 billion for the 2013 deadline. Across all three deadlines, total costs are

Key findings

estimated as around €4.8 billion (range €3.2 to €7.3 billion), although this is reduced to €4.3 billion if transfer payments between companies are taken into account.

- Total EU costs of registration were similar to those predicted for the 10-100t substances. However, for the 1-10t substances total EU costs are estimated to have been over three times that predicted, despite only half the number of substances being registered compared to the prediction.
- The study also investigated the costs of key components of registration. Based on the survey, costs of preparing a registration dossier were high for both the 1-10t substances (average of €18,000) and 10-100t substances (average of €39,000). This is important as the majority of companies will have incurred such costs. The costs relate to drafting, finalising a technical registration dossier and submitting it, including all administrative data, and also producing study summaries for the relevant REACH annexes.
- The costs of undertaking tests for all of the endpoints under REACH Annex VII (1-10t substances) are around €60-€70,000. However, not all of those tests will have been required, and not by all companies. Nonetheless, many companies reported incurring significant costs for physicochemical, toxicological and ecological tests for 1-10t substances. The costs of testing, where needed, for 10-100t substances was much higher, particularly for toxicological and ecotoxicological tests.
- The study highlights that testing had been particularly expensive for complex substances (e.g. UVCBs) compared to basic chemicals for which there would already be substantial testing data as well as existing literature and research. Discussions on substance identity have been particularly time-consuming.
- The majority of survey respondents that provided an informed response indicated that read-across and QSARs were used for at least some endpoints. However, a large proportion (35-41%) did not know if they were used and only a small proportion (16-19%) indicated that they were used for more than 50% of information requirements. The study also highlights issues with lack of justification in some cases for the use of read-across, and a lack of certainty as to what read-across will be accepted by ECHA. Consultation for the current study highlighted that further guidance on read-across and sameness would be beneficial for the future.
- The survey sought information on costs of changes to company systems, and of legal support. While only a small number of companies provided responses, the costs of these were clearly significant in some cases and may not have been included in some of the ex-ante assessments.
- In terms of the higher-than-expected costs for 1-10t substances, companies stated that the main cost drivers were accessing data, additional testing and external support. The costs of preparing the registration dossier were a substantial proportion of costs. The results suggest that significantly more testing was undertaken than was expected, contributing to the higher costs than those predicted.

4.2 Methodology for estimation of costs

4.2.1 Numbers of substances registered

In estimating total EU-level costs of the registration deadline, a key determinant is the **number of substances** that were registered and the **number of registrations** submitted. The latter is more than the former given that multiple companies registered many of the substances. Data on the numbers of registrations and numbers of substances registered were provided by ECHA based on the registrations actually received.

4.2.2 Costs per registration and per substance

The estimates of costs of registration per substance and per registration are based on the results of the survey of companies that registered substances in 2018.

The survey responses for are considered to be **reasonably representative** of the companies that registered substances in 2018:

- In the survey for the current study, the respondents submitted a total of 1766 registrations for the 2018 deadline at 1-10t (8% of the total of 21,986[7]of) and 1357 at 10-100t (11% of the total of 12,781).
- Of those companies that knew how many substances they had registered, 152 companies registered substances for the 2018 deadline at 1-10t, representing 6% of the 2514 companies that have registered substances in the 1-10t band.
- For the 10-100t band, responses were received from 148 companies, representing around 3% of the 5138 companies that have registered substances in this tonnage band[8].

Companies were asked to provide estimates of the costs of registration in the following ways:

- Numbers of substances registered.
- Average cost per substance registration
- Total costs of all registrations submitted by the company (for all substances registered)
- Costs of key components of registration, including:
  - Costs for preparing the registration dossier
  - Testing costs (excluding letter of access) encompassing physicochemical, toxicological and ecotoxicological tests
  - Costs of read-across and quantitative structure relationship models (QSARs)
  - Costs of chemical safety assessment and chemical safety reports
  - Costs associated with Letters of Access
  - Cost of legal support
  - Cost of training and other changes

[7] For the purposes of this analysis, intermediates are included in this figure.

[8] Total numbers of companies registering substances are based on ECHA's summary of REACH registrations by companies from 1st June 2008, and were correct as of 31/01/2021 (https://echa.europa.eu/documents/10162/23557847/registration_statistics_en.pdf/58c2d7bd-2173-4cb9-eb3b-a6bc14a6754b).

- Other costs

In estimating the total costs of registration, the **average cost per substance registration** was the primary data point used. Companies that provided such data included:

- 105 companies that provided data for substances registered at 1-10t. This covered 928 substances, or 4% of the 21,986 registrations submitted. Based on this, there is a margin of error of 3% in estimates of the costs, assuming a 95% confidence level.
- 101 companies that provided data for substances registered at 10-100t. This covered 668 substances, or 5% of the 12,781 registrations submitted. Based on this, there is a margin of error of 4% in estimates of the costs, assuming a 95% confidence level.

The above data were used in combination with the data on actual numbers of registrations (see above) to estimate the total costs of registration for the 2018 deadline.

Of the companies that provided data on costs of registration, around one third did not specify the member state that they are located in. Of the remainder, 26% were located in Germany, 19% in Italy, 14% in Spain, 8% in France and 7% in the UK. For comparison, 26% of all registrations in 2018 were from companies in Germany, with 14% from the UK, 11% from France, 9% from Italy and 8% from each of the Netherlands and Spain. There does not appear to be any particular geographical bias in the responses received.

Of those companies that provided data on costs of registration "per registration" (as used in the estimates of total costs), 51% were large enterprises, 16% medium, 21% small and 12% micro enterprises. Based on ECHA's registration statistics, of the 5314 companies that registered substances for the 2018 deadline, 75% were large companies, 10% medium, 9% small and 6% micro-sized companies. There does not appear to be any particular bias in the size of companies responding to the survey compared to those that registered substances overall.

4.2.3 Costs of key components of registration

As noted above, the costs of various key components of registration were provided by survey respondents.

Not all registrants needed to incur each of these costs, as this is dependent on the information required for a given substance and the information already available. The information provided from the survey therefore represents the total costs in each category that were incurred by respondents providing a response to a given question. This is then compared to other estimates of costs of those different cost components, such as estimates developed by ECHA.

4.3 Experience from previous registration periods

The 2018 REACH Review (COM, 2018) found the costs for the 2010 and 2013 registration deadlines to be around €2.3 to €2.6 billion. These costs are somewhat higher than initial estimates made earlier by the European Commission (ca. €1.7 billion).

A 2012 chemical market study suggested a wide range in average total costs per registration. Based on their survey, CSES (2012a) the typical value fell between €50,000 and €100,000 per substance, per registrant. For importers of chemicals, the costs tended to be towards the lower end of this cost range while for manufacturers of chemicals, average costs of above €250,000 were not uncommon. Close to 70% of firms did not experience registration costs exceeding 1% of their annual sales in 2010, though around 7% experienced costs above 5%.

4.4 Ex-ante forecasts of costs for the 2018 registration deadline

A European Commission study published in 2015 estimated that the average cost of 2018 registration per substance would be €13,000 for the 1-10 tonnage band and €253,000 for the 10-100 tonnage band[9]. The distribution of costs per substance registered was also provided in that study.

The most recent ex-ante estimate of the total EU costs of the 2018 registration was that costs for 1-10t substances is €228 million, with costs of €1,136 million for 10-100t substances (CSES, 2015). As these estimates are the main source of information used to compare the ex-post estimates derived in the present study, some further analysis of the approach adopted in the CSES (2015) study is provided in the box below.

[9] CSES (2015). This estimate included administration/liaison, preparing and submitting the dossier, testing costs, access to data, undertaking CSA/CSR and updating Safety Data Sheets, and fees to ECHA.

Summary of approach adopted in the CSES (2015) ex-ante estimate of the costs of 2018 registrations

The CSES study used a Monte Carlo simulation model to update previous estimates of the costs of the 2018 registration deadline, assuming **no changes would be made in the implementation of REACH as compared to the current practice. A related aim was to establish specific cost categories with the greatest room for achieving cost-efficiencies, as well as suggesting specific implementation measures to achieve them, while maintaining the capacity to deliver the expected health and environmental benefits.**

The model considered one substance at a time, using probabilities to generate a profile of each substance in respect of the key determinants of cost variation. The model took into account **the following factors influencing the costs:**

- whether there is already toxicological or ecotoxicological information on a substance or whether there is some or none;
- whether the substance is identified by QSARs or other evidence as meeting one or more of the criteria in Annex III and, hence, must generate the toxicological and ecotoxicological information in Annex VII (for 1-10t substances);
- the outcome of screening tests and, in particular, those for mutagenicity (where a positive result will require that further testing be undertaken);
- for chemical safety assessment (CSA), whether an exposure assessment and risk characterisation is required in addition to hazard assessments (**for 10-100t substances);**
- **the number of companies registering the substance;**
- **whether the registrants were assumed to support a joint registration or whether individual registrations would be submitted;**
- **the size of the companies registering the substance (affecting registration fees).**

The model inputs were based on data on registrations in 2010 and 2013; **statistical data on the structure of the industry; and the Commission's extended impact assessment and business impact assessments done prior to the introduction of REACH. Many of the inputs were the same as those used in the past; however some of the cost elements were updated to reflect the information available from the interviews and surveys conducted for the study. In particular, attention was paid to the costs of SIEFs and joint registration and also testing and information costs (taking into account availability of existing information, costs of individual tests and use of alternative (non-testing) methods).**

The study estimated costs in the following categories:

- 'Registration costs', including (a) administrative cost of liaising with other registrants (for joint registrations); (b) cost of preparing and submitting the dossier; and fees payable to ECHA.
- 'Information costs' including: (a) cost of obtaining information (including testing costs and purchase of data); (b) administrative cost of engaging on information with other registrants within SIEFs; (c) cost of submitting proposals for animal tests; (d) cost of producing study summaries/robust study summaries; and € costs of updating safety data sheets and producing a chemical safety assessment (for 10-100t substances).

The study assumed that substances with registration costs of in excess of €2,600 per tonne for 1-10t substances and €3,250 per tonne for 10-100t substances would not be registered and would be withdrawn. Based on their model, this accounted for 3,037 (around 15%) of the 20,000 substances at 1-10t and 504 (around 10%) of the 5,000 substances at 10-100t.

Total costs were estimated as:

- €227.8 million for 1-10t substances, comprising €77.4 million registration costs/fees plus €150.4 million information and SDS costs.
- €1,135.7 million for 10-100t substances, comprising €123.0 million registration costs/fees plus €1,012.7 million information and SDS costs.

The report also provided estimates of the costs of registration per substance, as follows:

- For 1-10t substances an average of €13,427, with a median of €7,447 and a range (minimum and maximum) of €2,982 to €95,910.
- For 10-100t substances, an average of €252,605, median of €254,818 and a range of €67,800 to €393,805.

Clearly the range of costs is very broad. It is also worth highlighting that the cost estimates for 1-10t substances had a median value much lower than the (mean) average, which is because there are two types of registration for these: those requiring only the physicochemical information in Annex VII, and those also requiring toxicological and ecotoxicological information in Annex VIII (for substances meeting the criteria in Annex III).

The 2018 REACH Review reported that registration costs may be somewhat higher for SMEs than for large companies, especially for lower tonnage bands (due to often less experience and know-how in collecting data). This suggested that costs might be high for SMEs in the 2018 registration deadline and highlighted that SMEs have generally been more affected than large companies, and have experienced more substance withdrawals (COM, 2018).

4.5 Numbers of registrations and substances registered

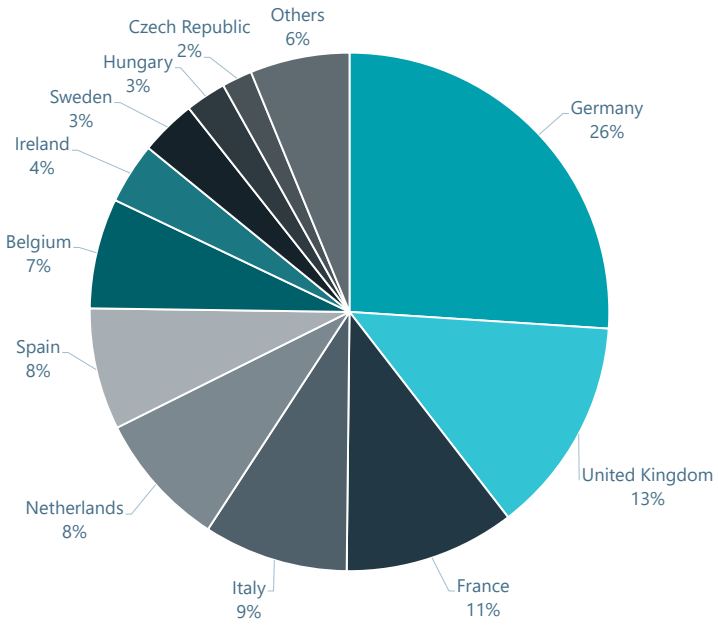
For the 2018 registration deadline, data provided by ECHA for the current study on numbers of completed registrations indicate that there were:

- 21,986 registrations for 1-10t, covering 10,088 substances (i.e. 2.2 registrations per substance on average)[10]
- 12,781 registrations for 10-100t, covering 4,617 substances (2.8 registrations per substance on average)[11]

The total number of substances registered was 11,085, which is less than the sum of the above, because some substances were registered in both tonnage bands. The total number of registrations was 34,767.

The figure below highlights the proportions of the total registrations that were submitted from different countries[12].

Figure 4.1 Share of 2018 registrations from different countries (ECHA, 2018)



[10] 1-10t includes intermediates, not all of which will actually have been at 1-10t, but are considered comparable in terms of information requirements and so are included here for the analysis made in the current study.
[11] Some substances were registered in both tonnage bands. The 10-100t figures include some substances initially registered at that level but which were subsequently moved to higher tonnage bands (100-1000t and >1000t).
[12] Based on ECHA (2018c). Note that this is based on a total of 32,515 registrations, which is less than the data provided by ECHA for this study in 2021, because not all registrations had been completed when the ECHA (2018c) data were presented (some were pending a second submission following completeness check failure, and some had an extension based on a directors' contact group solution). However, a breakdown by country is only available in the ECHA (2018c) data.

In terms of ex-ante estimates, for the 2018 deadline, it was previously expected that there would be a total of 25,000 substances eligible for registration, of which 20,000 would be registered at the 1-10t range and 5,000 at the 10-100t range (CSES, 2015). This in turn was based on the original extended impact assessment by the Commission from 2003. However, as indicated above, the costs of registration were predicted to lead to some substances being withdrawn from the market, meaning that fewer numbers were actually registered.

The ex-ante estimates are compared to the actual data from ECHA on the numbers of substances and numbers of registrations, in the table below.

Table 4.1 Predicted and actual numbers of registrations and substances registered for the 2018 deadline

Estimate	Registrations	Substances	Registrations/substance
Predicted 1-10t (CSES, 2015) [Note 1]	c. 39,000	16,963	2.3
Predicted 10-100t (CSES, 2015) [Note 1]	c. 15,000	4,496	3.4
Actual 1-10t (ECHA, 2021) [Note 2]	21,986	10,088	2.2
Actual 10-100t (ECHA, 2021) [Note 3]	12,781	4,617	2.8

Notes: 1) Number of substances registered based on 20,000 substances at 1-10t but 3,037 withdrawn due to costs of registration, and 5,000 substances at 10-100t with 504 withdrawn. Number of registrations calculated from the number of substances registered and registrations per substance in CSES (2015) (Annex D). 2) 1-10t includes intermediates, not all of which will actually have been at 1-10t, but are considered comparable in terms of information requirements. Data refer to completed registrations. 3) Some substances were registered in both bands. 10-100t include some substances initially registered at that level but which were subsequently moved to higher tonnage bands (100-1000t and >1000t).

The actual number of substances registered at 10-100t was in line with expectations, but the number at 1-10t was much lower (a bit more than half of the c. 17,000 predicted). The precise reasons for this large discrepancy are unknown, but it may be due to the much higher costs than expected for 1-10t substances, as described below.

In terms of the number of registrations per substance, the figures for 1-10t were almost exactly in line with expectations (2.2 versus 2.3) but were lower than predicted for 10-100t (2.8 versus 3.4). This tends to reduce the overall number of registrations compared to that predicted, despite the similar number of substances being registered.

4.6 Estimation of total costs of registration

4.6.1 Overview

This section provides an overview of how the data collected for the current study was used to estimate the total costs of the registration deadline. It is based on the following:

- Estimation of the average costs per registration and per substance for the two tonnage bands.
- Estimation of total costs based on the numbers of substances registered.

These are described in turn below.

4.6.2 Average costs of registration

The estimated actual costs of registration per substance and per company were collated through survey responses. In particular, the survey asked companies to provide their estimate of the average costs of registration across all of the substances that each company registered.

As noted above, since many substances were registered by more than one company, the average costs of registration across all companies responding were used to estimate registration costs per substance based on the actual numbers of registrations per substance based on data from ECHA (Table 4.1). The results are shown in the table below.

Table 4.2 Average costs per registration and per substance registered [Note 1]

Estimate	1-10t	10-100t
Average costs per registration [Note 2]	€43,699 (€31,596 - €50,979)	€100,929 (€67,678 - €123,971)
Average number of registrations per substance [Note 3]	2.18	2.77
Average costs per substance [Note 4]	€95,239 (€68,861 - €111,104)	€279,398 (€187,350 - €343,183)
Median costs per substance [Note 5]	€54,486	€124,500

Notes:
1) Figures in parentheses represent the 95% confidence intervals, representing the range of costs incurred by companies.
2) Based on the survey for the current study. The value is the mean average across all companies' reported data on their average costs per substance registered. Companies were asked to provide, on average, the overall approximate cost per substance registration to comply with the 2018 REACH registration deadline. Estimates include all costs incurred, for example administration/liaison, preparing and submitting the dossier, testing costs, access to data, undertaking the CSA/CSR and updating safety data sheets, and fees to ECHA.
3) Based on data provided by ECHA, and summarised in Table 4.1.
4) Calculated based on average costs per registration multiplied by average number of registrations per substance.
5) Calculated based on the median costs per registration (per company) multiplied by the average number of registrations per substance.

The average (mean) costs are useful in estimating the overall EU costs. The median values from the table above are lower than the average values, and are probably more representative of the costs borne by companies for a 'typical' substance registration. For both tonnage ranges, the average actual registration costs are affected by a small number of registrations that were much higher than the typical costs.

The average costs per substance have been calculated primarily to allow comparison with ex ante estimates, provided later in this chapter.

4.6.3 Total costs of registration

The total estimated costs to companies of the 2018 registration deadline were calculated by taking the average costs per substance registration and multiplying these by the number of registrations for each tonnage band. This is highlighted in the table below.

Table 4.3 Estimation of total costs to companies of the 2018 registration deadline

	1-10t	10-100t	Total
Total number of registrations [Note 1]	21,986	12,781	
Average cost per registration [Note 2]	€43,699	€100,929	
Total registration costs – best estimate [Note 3]	€961 million	€1,290 million	€2,251 million
Total registration costs – range [Note 4]	€695 to €1,121 million	€865 to €1,584 million	€1,560 to €2,705 million

Notes: 1) From ECHA, as per section 4.2.1 above. 2) From Table 4.2. 3) Calculated by multiplying total number of registrations by average cost per registration. 4) The range is based on the 95% confidence intervals for the average costs per registration (Table 4.5) multiplied by the total number of registrations.

In terms of total costs of registration for all three registration deadlines, the REACH review (COM, 2018) quotes the following estimates:

- Costs of approximately **€2.1 billion** for the 2010 deadline, with a broader range of €1.1 to €4.1 billion. This was based on an industry survey from 2011, as reported in the 2013 general review of REACH.
- Costs of **€459 million** for the 2013 deadline, as reported by CSES (2015).
- The total costs were therefore around €2.6 billion, though this was adjusted downward to account for transfer payments between companies, which were assumed to account for 11% of the registration costs, although this estimate was noted to be subject to uncertainty. This gives an estimate of just under **€2.3 billion** for the 2010 and 2013 deadlines combined.

While the current study has not included an analysis of transfer payments, taking the above figure of just under €2.3 billion for the 2010 and 2013 deadlines, and €2.25 billion for the 2018 deadline, the total cost across all three deadlines could be in the order of €4.5 billion.

As highlighted above, the estimate for the 2010 deadline included a broader range of estimates of €1.1 to €4.4 billion. Likewise, CSES (2015) note that the scope for error in the figure of €459 million is potentially large, although no quantitative estimate is given.

Assuming that the range of costs per substance registered (see Table 4.5) is indicative of the range that the total costs may lie in for the 2018 deadline, the total registration cost for 2018 could be within the range €1.6 to €2.7 billion[13].

The total cost across all three deadlines, taking into account these uncertainty ranges is therefore presented in the table below.

Table 4.4 Potential range of costs across all three registration deadlines

	Central estimate	Range
Costs of 2010 deadline [Note 1]	€2.1 billion	€1.1 to €4.1 billion
Costs of 2013 deadline [Note 2]	€0.459 billion	-
Costs of 2018 deadline [Note 3]	€2.25 billion	€1.6 to €2.7 billion
Total costs [Note 4]	€4.8 billion	€3.1 to €7.3 billion

Table notes: 1) Based on the 2013 report on the general review of REACH. 2) Based on CSES (2015). 3) Results from the current study. 4) Note that these figures do not include an assumed 11% reduction in the estimates of costs to account for transfer payments between companies, as was included in the COM (2018) REACH review (giving €2.3 billion as the central estimate for the costs of the 2010 and 2013 deadlines combined (€2.56 billion x 89% = €2.3 billion). If this 11% is applied to the total costs across the three deadlines the central estimate of costs would be €4.3 billion, with a range of €2.8 to €6.5 billion.

[13] Calculated based on the range of the 'low' and 'high' (95% C.I.) costs per substance around the mean from Table 4.6 and applied to the total estimated costs from Table 4.7). This gives registration costs in the range €695 to €1,121 million for 1-10t substances and €865 to €1,584 million for 10-100t substances, and €1,560 to €2,705 million in total.

4.7 Comparison of cost estimates with ex-ante projections

4.7.1 Comparison of average costs per registration and substance registered

CSES (2015) estimated that the costs of registration per substance would be around €13,000 for the 1-10 tonnage band and around €253,000 for the 10-100 tonnage band. Based on the numbers of manufacturers/importers per substance, this equates to, on average: €74,300 per registration per company at 10-100t and €5,800 per registration per company at 1-10t (based on registrations per substance above). This allows comparison to the data collected in the survey for this study. The table below shows the average costs per registration and per substance, and the median costs, as estimated in the present study (based on the survey results) and as included in the ex-ante estimates in CSES (2015).

Table 4.5 Average costs per registration and per substance registered

Estimate	1-10t predicted (CSES, 2015)	1-10t actual (this study)	10-100t predicted (CSES, 2015)	10-100t actual (this study)
Average costs per registration [Note 1]	€5,838	€43,699	€77,237	€100,929
Average costs per substance	€13,427	€95,239	€252,605	€279,398
Median costs per substance	€7,447	€54,486	€254,818	€124,500

Note: Data on predicted average costs per registration are based on average costs per substance and numbers of registrations per substance from Table 4.1.

The costs of registration for the 10-100t range estimated in this study are in reasonable agreement with those in the CSES (2015) study with the cost per substance being around 10% higher than predicted. However, the estimated costs for the 1-10t range are much higher than those in the CSES study, at around seven times those originally predicted (both per substance and per registration, per company). This is a key finding from the comparison, leading to the total estimated costs of registration at the 1-10t range being considerably higher than predicted (see below). It should be noted that the estimates of costs and numbers of substances expected to be registered for the 2018 deadline were considered to be one of the most uncertain parts of the cost estimates in the original impact assessment. The cost estimates for the current study are likewise subject to uncertainty but, as noted above, the number of responses received gives a reasonable degree of confidence that the results are representative of the wider pool of registrations.

The higher costs per registration may be responsible – at least in part – for the much lower number of substances registered in the 1-10t range than was previously predicted (i.e. the number of substance withdrawals may have been much higher than predicted), although there are not data available to demonstrate this conclusively. Another explanation could be that fewer substances exceeded the 1t threshold than was originally expected. Insights into the reasons for these substantially higher costs are given in analysis of the different cost components, as set out later in this chapter.

The ex-ante assessments considered the uncertainties associated with factors such as the actual numbers of registrations as well as the different components of registration costs per substance. For the current study, the actual number of registrants and substances registered is known, however there is uncertainty around how representative the results from the study survey are in terms of the average registration costs per substance.

The table below provides a summary of the estimated average registration costs per substance (based on the survey for the current study), including the associated ranges that the costs are expected to fall within (95% confidence intervals). These are compared to the average, minimum and maximum values quoted in CSES (2015).

Table 4.6 Comparison of ranges of costs per substance registered (actual vs predicted)

Estimate	1-10t predicted (CSES, 2015)	1-10t actual (this study)	10-100t predicted (CSES, 2015)	10-100t actual (this study)
Average costs per substance [Note 1]	€13,427	€95,239	€252,605	€279,398
"**Low**" **costs per substance** [Note 2]	€2,982	€68,861	€67,800	€187,350
"**High**" **costs per substance** [Note 2]	€95,910	€111,104	€393,805	€343,183
Median costs per substance [Notes 1,3]	€7,447	€54,486	€254,818	€124,500

Notes:
1) Data on average and median costs per substance are from Table 4.6 above.
2) Quoted as "min" and "max" in CSES (2015). For the current study survey results, low and high estimates represent 95% confidence intervals around the mean of the actual data on costs reported by companies, multiplied by the number of registrations per substance from Table 4.1. The values are therefore not directly comparable. The 95% confidence intervals were calculated from the average costs per registration per company (data submitted through the survey) using a modified version of the Cox method as described in Olsson (2005), which takes into account the number of data points (survey responses) and which assumes that the data are lognormally distributed.
3) The median estimated costs for the current study are lower than the range of costs around the (mean) average values represented by the 95% confidence intervals for the average. This is because the distribution of costs is skewed, with a small number of substances incurring substantially higher costs than most others. The median costs are considered more representative of the typical costs of registration per substance, while the (mean) average costs are considered most appropriate for use in estimating total costs of registration.

For the 10-100t substances, the range of costs estimated based on the survey results lies within the range predicted, albeit with a much lower median cost, due to the relatively small number of registrations with very high costs.

For the 1-10t substances, the average cost estimated based on the survey is at the very upper end of the range predicted in the CSES (2015) report. The reasons for this are investigated further in section 4.9.

4.7.2 Comparison of range and distribution of costs

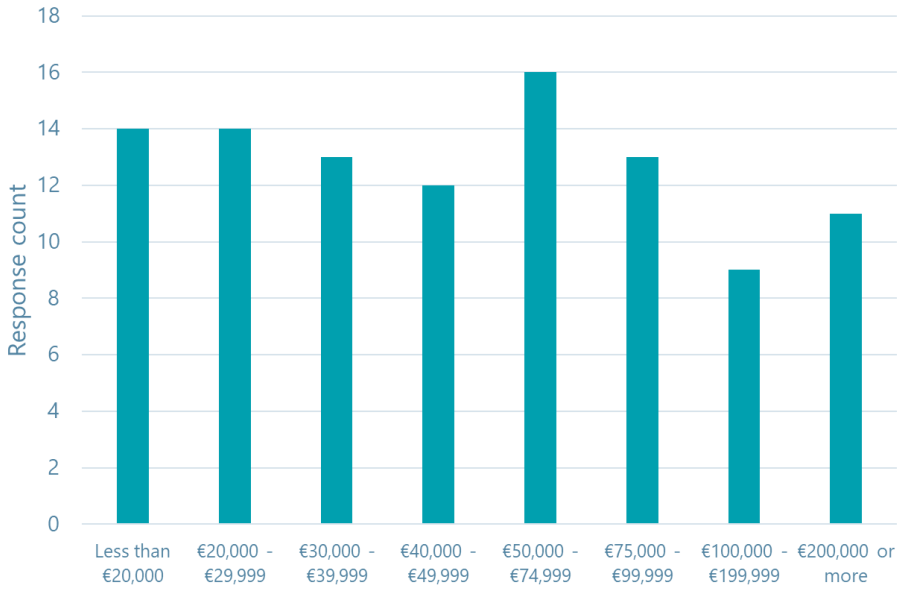
Results from the present study's online survey indicate that the direct costs per substance registration in 2018[14] ranged between €500 and €1 million for the 1-10 tonnage band and from €4,000 to €2.5 million for the 10-100 tonnage band. Figure 4.2 and Figure 4.3 present the overall approximate average cost per substance registration for each tonnage band, in ranges of costs. These costs include all costs incurred, for example administration/liaison; preparing and submitting the dossier; testing costs; access to data; developing the chemical safety assessment/report; updating SDS; and fees to ECHA. As can be seen, there is a relatively even distribution across the cost bins for both tonnage bands, indicating that there is no clear modal value of the cost.

[14] Note the question asked: "On average, what was the overall approximate cost per substance registration to comply with the 2018 REACH registration deadline?" and requested the "Approximate average costs per substance registration" for each tonnage band.

Figure 4.2 Estimated average cost per registration per company (1-10 tonnes)

Notes: N = 105.

Figure 4.3 Estimated average cost per registration per company (10-100 tonnes)

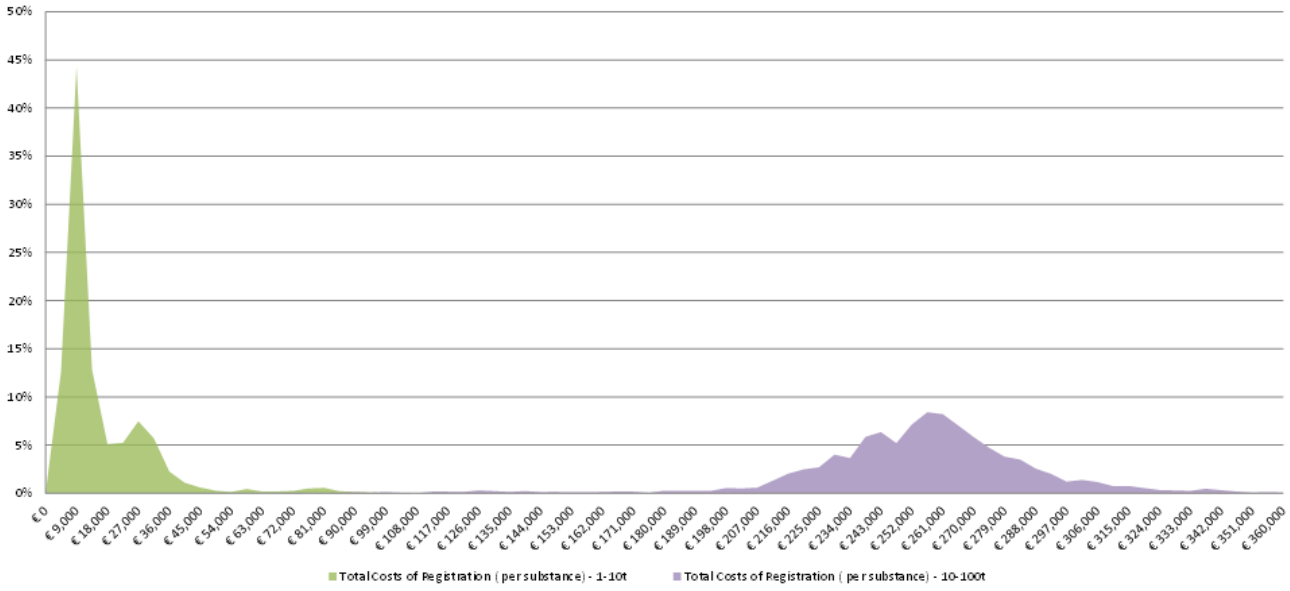


Notes: N = 102.

The distribution of costs was quite different to that previously predicted. Figure 4.4 shows the distribution of total registration costs per substance estimated in CSES (2015). The green shaded area represents the 1-10t substances, highlighting that almost all substances were predicted to have cost lower than around €45,000, with average costs of around €13,000 as above. The purple shaded area represents the 10-100t substances, illustrating that almost all substances were predicted to have a cost between around €200,000 and €320,000,

with an average cost of €253,000 as above. The distribution of costs for the two tonnage bands is also a different shape[15].

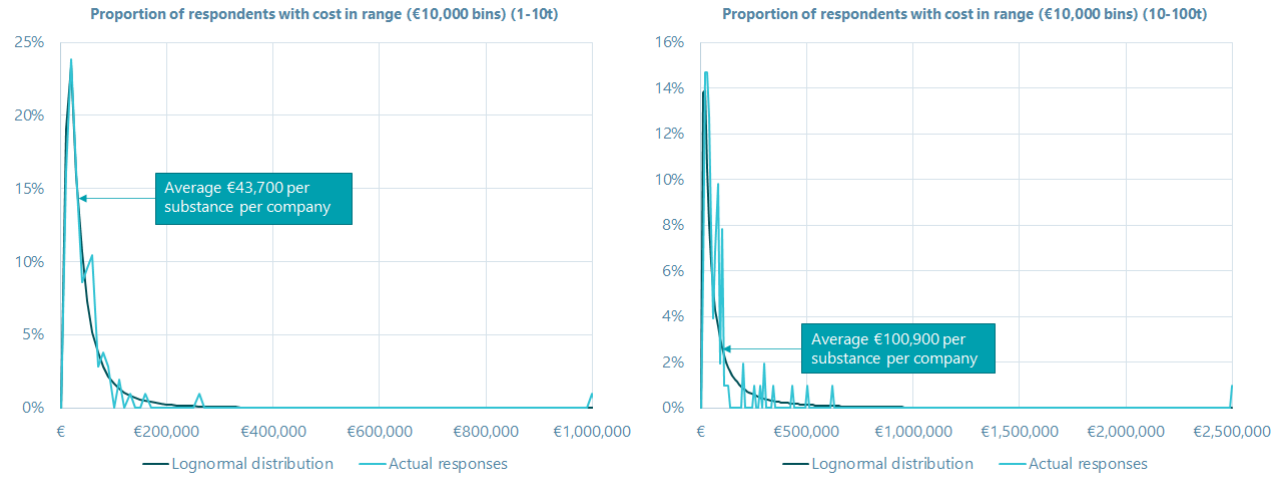
Figure 4.4 Predicted percentage frequency of total registration costs per substance (€ per substance)



Source: CSES (2015)

For the current study, information on costs was collected per substance registration *per company*. This is illustrated in Figure 4.5, in which the costs are demonstrated to broadly follow a lognormal distribution. The lighter shaded lines represent the actual responses, with the percentage of responses falling within each €10,000 range of costs ("bins"). The darker lines represent a lognormal distribution, essentially the statistical function, approximating the actual data, to allow further analysis below[16].

Figure 4.5 Actual costs of registration per substance per company and fitting to lognormal distribution



[15] For 1-10t, the data seem to suggest and approximate lognormal probability density function, while that for 10-100t appears to be approximately a normal distribution.

[16] The lines represent a probability density function based on the mean and standard deviation of the (natural) log-transformed data (responses on average costs of registration per substance, per company).

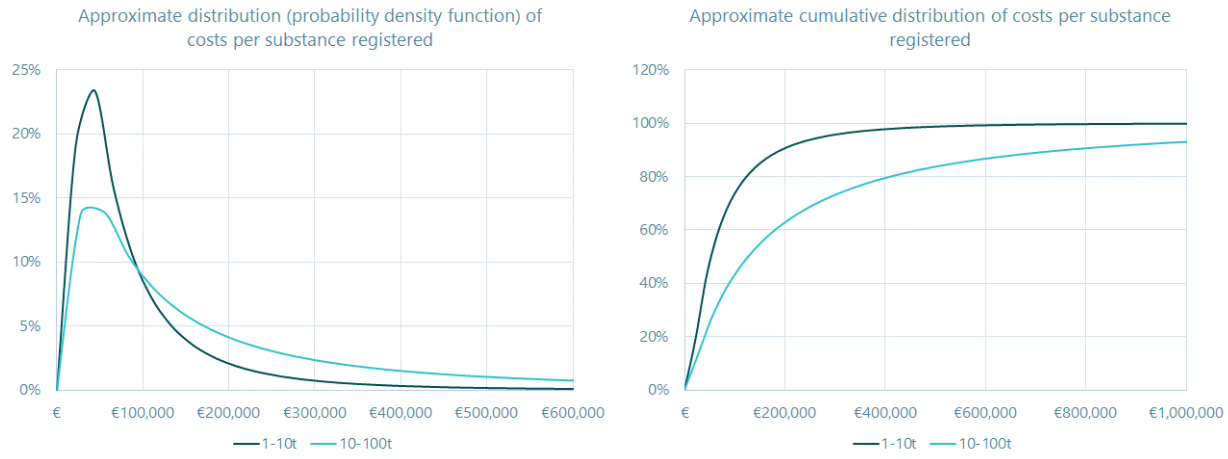
In order to compare the distribution of costs estimated based on the study survey against those in the ex-ante estimate in CSES (2015), the lognormal distributions above have been plotted below in Figure 4.6, extrapolated to the costs of registration *per substance* (i.e. the same as in Figure 4.4), based on the number of registrations per substance in Table 4.1.

The chart in Figure 4.6(a) is the distribution of costs, approximated based on the actual data on costs from survey respondents. The data are based on the smoothed lines in Figure 4.5 but presented as costs per substance, to allow comparison with the CSES (2015) data. The chart shows that:

- More of the 1-10t substances had costs at the lower end of the range than 10-100t substances. For the 10-100t, more (a greater percentage of) substances had costs that were higher.
- For both tonnage bands, the majority of companies faced relatively modest costs (median actual cost per substance of €54,500 for 1-10t and €124,500 for 10-100t), but there were a small number of substances with much higher costs, making the (mean) average cost higher (€95,000 and €279,000 respectively) than the median. The chart on in Figure 4.6(a) can be compared to the CSES (2015) chart (Figure 4.4), highlighting the difference in the distributions of actual versus predicted costs.
- There is a key difference in the distribution of costs compared to the CSES (2015) study, where there were estimated to be very few 10-100t substances with costs under €200,000 (Figure 4.4), while the current study shows that 80% of companies reported average costs less than €100,000 per registration (equating to around €280,000 per substance based on 2.77 registrations per substance).

The chart in Figure 4.6(b) illustrates that, for the 1-10t range, fewer than 10% of substances had registration costs over €100,000, while for the 10-100t range, around a third had costs over €200,000. This explains the much higher average costs for 10-100t substances, as described above.

Figure 4.6 Approximated distribution of costs of registration (a) per substance and (b) cumulative distribution



Notes: Data generated based on assumed lognormal distribution of costs per registration per company, giving mean of €43,699 for 1-10t and €100,930 for 10-100t, with standard deviation of 1.011 and 1.39, respectively. Data were then transformed to give costs per substance based on numbers of registrations per substance from Table 4.1. Note that these figures should be interpreted as approximations, rather than providing precise data, as they are based on fitting a distribution to data with only a modest sample size.

Overall, for the 10-100t substances, average registration costs estimated based on the survey results were in a similar order to those estimated in the ex-ante studies of 2018 registration costs, although the distribution of costs suggests that some companies benefited from substantially lower costs than previously estimated.

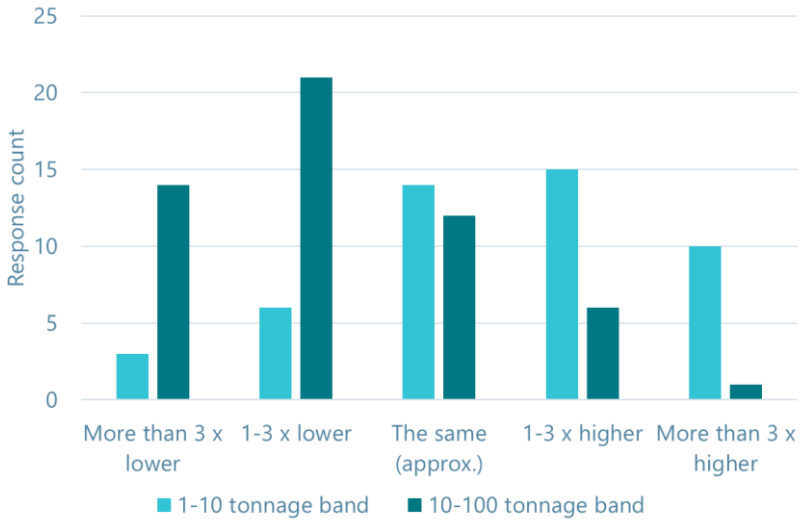
For the 1-10t substances, the estimated average cost was around 7 times that estimated in the 2015 ex-ante estimate. The possible reasons for this are investigated later in this chapter. For both groups, the (mean) average costs were affected by a small number of registrations costing a large amount, meaning that the median costs were substantially lower than the mean.

4.7.3 Survey respondents' views on actual costs compared to predicted costs

Respondents were also asked how the average costs of the 2018 REACH registration compared to the predictions made by CSES in 2015 (€13,000 for 1-10 tonnes and €253,000 for 10-100 tonnes, as above). Figure 4.7 presents the results for both the 1-10 tonne and 10-100 tonne bands.[17] Key findings include:

- For the 1-10 tonnage band, the costs of the 2018 REACH registration deadline were, overall, considered by companies to be higher than the 2015 estimate. Most respondents (31%) indicated that costs were between 1 and 3 times higher than the €13,000 estimate. However, a similar proportion of respondents (29%) reported costs to approximately be the same. Relatively few companies reported the costs to have been lower than predicted. This is in line with the actual costs that were calculated to be higher than expected.
- For the 10-100 tonnage band, the costs of the 2018 REACH registration deadline were, overall, considered by companies to be lower than the 2015 estimate. Most respondents (39%) reported costs to be between 1 and 3 times lower. Although the average costs for registration for the 10-100t band were more or less the same, the distribution of costs with 80% of companies reporting less than €100,000 per registration could explain this discrepancy.

Figure 4.7 Costs compared to the European Commission 2015 estimates



Respondents that did not/could not provide a specific cost figure for a specific tonnage band, were asked to provide cost information for the total number of substance registrations they made. These costs ranged from

[17] These figures only include responses from trade associations and companies. Responses for 'I don't know' and 'Not applicable to my organisation' are not included in these figures. Q14 asked: 'Based on your experience, how did the average costs actually incurred by your organisation – or by members, clients where applicable - compare to these predictions?' and for 'total costs, per substance, per registrant'.

€300 to €204,200 per registration[18]. This indicates a wide range of costs for a registration, per company across the tonnage bands, as supported by the information in the previous section. This range of costs falls within the 2015 estimates from the Commission. However, these results are considered to be less reliable than those for the costs per substance registration, and are not taken forward further in the analysis, because of uncertainties in estimating average costs from the total.

4.7.4 Comparison of total EU costs of registration

Two previous (ex-ante) estimates have been made of the total costs of the 2018 registration deadline. These include the Commission's Extended Impact Assessment from 2003 and the CSES study in 2015. In the most recent estimate (CSES, 2015), costs were estimated at €228 million for 1-10t substances and €1,136 million for 10-100t substances)[19].

By comparison, the current study, based on the cost estimates from the survey results (section 4.6) and on data on the actual numbers of substances/registrations from ECHA (section 4.5), total costs of registration are estimated as:

- **€1,290 million for the 10-100t range.** This is in reasonable agreement with the approximately €1,140 million quoted by CSES (2015). The number of substances registered was a little lower than predicted, and the costs per substance and per registration were a little higher than predicted.
- **€960 million for the 1-10t range.** This is over three times the estimate in the original extended impact assessment and over four times the estimate in CSES (2015).

The reason for the difference in costs in the 1-10t range is the much higher average cost per substance (and per registration) than was assumed in the earlier assessments. This is despite the much smaller number of substances registered than estimated in the ex-ante assessment. Table 4.7 summarises the different cost estimates.

Table 4.7 Comparison of estimates of total costs of registration

Estimate	1-10t	10-100t
Total registration costs (this study) [Note 1]	€961 million	€1,290 million
Total predicted registration costs in (CSES, 2015)	€228 million	€1,136 million
Total predicted registration costs (extended impact assessment) [Note 2]	€295 million	€581 million

Notes: 1) Total registration costs were estimated by multiplying the average cost per registration (Table 4.5) by the number of registrations (Table 4.1). 2) As quoted in CSES (2015).

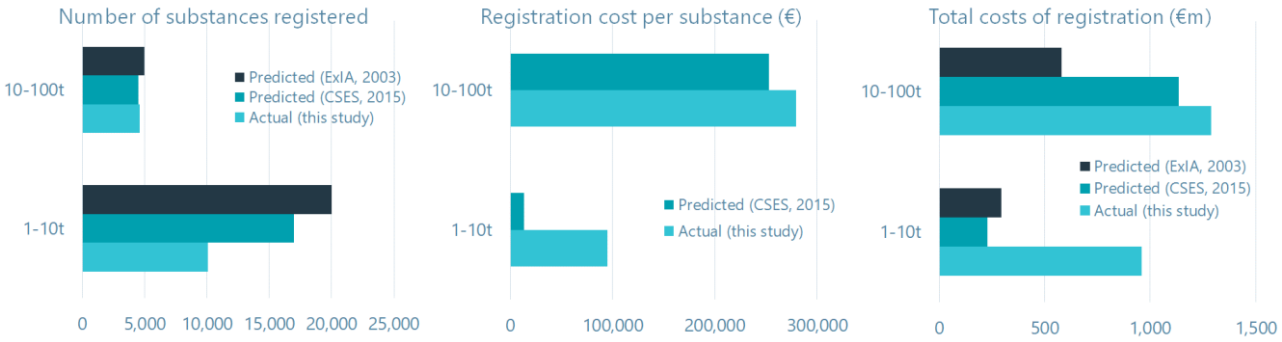
4.7.5 Summary of cost estimates compared to ex-ante estimates

The three charts below highlight some of the key conclusions from the above analysis of the costs of registration and a comparison with the previous ex-ante estimates[20] and, in particular:

[18] These costs have been calculated based on survey responses to Q11, part 3 'Number of substance registrations (where I do not know the tonnage band)' and Q13, the 'Total cost of all your 2018 REACH registrations listed in your answer to Question 11(€)'. The total cost was divided by the number of substance registrations provided by each respondent to find the cost per substance registration.
[19] The estimate for 1-10t was similar to the extended impact assessment estimate of €295 million, while the estimate for 10-100t was much higher (than €581 million estimated in 2003, partly because of an assumption that validation and acceptance of negative and positive QSAR and read-across would not occur to the same extent as previously envisaged.
[20] Note that these only include the central estimates, not the estimated ranges discussed earlier in this chapter.

- The good agreement between predicted and actual values in terms of numbers of substances registered at 10-100t, as well as the costs of registration per substance and the total EU costs of registration.
- The significantly lower number of substances actually registered compared to what was predicted for the 1-10t substances. The significantly higher costs of registration per substance than were predicted may have been a direct contributor to the lower number of registrations[21], though this is by no-means clear (and the ex-ante estimates for the 1-10t substances were subject to significant uncertainty).
- Despite the lower number of substances registered at 1-10t, the total EU costs of registration are concluded to be much higher than were predicted because of the greater costs per-substance.

Figure 4.8 Summary of key data on registration costs



4.8 Costs of key components of registration

4.8.1 Summary of key cost components from study survey

Based on analysis of the survey responses, the table below provides a breakdown of estimated average costs for different cost components (which are per company registration, not per substance).

Table 4.8 Summary of average costs per registration per company, and costs of key components

Cost component	1-10t	10-100t	N (1-10t)	N (10-100t)
1. Average costs per substance registration	€43,699	€100,929	105	101
2. Cost for preparing the Registration Dossier [Note 1]	€18,225	€39,484	116	115
3. Physicochemical requirement study costs [Note 2]	€10,463	€13,125	81	80
4. Toxicological requirement study costs [Note 2]	€14,197	€104,911	56	56
5. Ecotoxicological requirement study costs [Note 2]	€11,760	€26,293	54	58
6. Costs of read-across and QSARs	€3,577	€6,019	11	13
7. Costs for a chemical safety assessment / report	-	€14,801	-	41

[21] Indeed, the ex-ante assessments assumed that the extent of withdrawal of substances from the market would be directly related to the registration costs.

Cost component	1-10t	10-100t	N (1-10t)	N (10-100t)
8. Costs of letter of access [Note 2]	€16,986	€30,626	107	108
9. Cost of legal support	€12,559	€12,590	26	23
10. Costs of training or changes to company systems	€3,314	€3,998	21	23

Notes:
1) See section 4.8.4 for details of the different elements included in this component.
2) For cost components 3, 4, 5 and 8, respondents provided data in the survey in ranges of costs. In these cases, the average costs were taken by assuming that on average, costs were in the midpoint of the range, and a weighted average cost was calculated accordingly (i.e. by summing the numbers of companies responding in each range by the cost for that range, and then dividing the total by the total number of responses. For all other cost components, the cost is the mean average of all responses provided.
3) The number of responses used in calculation of each cost component is provided in the final two columns.

The different components in the table above cannot simply be added to give the total average costs per substance registration (top line), because not all substances/registrations would have required all cost components (e.g. toxicological testing). These costs, other than the 'average costs per substance registration' are therefore not used directly in estimating the total costs of registration.

The different cost elements (items 2 to 10 in the table above) do not include information on fees payable to ECHA, which are explored in the following sub-section, followed by a discussion of the other cost elements.

It is also important to note that only some companies will have incurred costs related to (eco)toxicological testing study results, for example, while other companies will have incurred costs associated with a letter of access to those same study results. Thus, it is expected that lead registrants will typically have reported costs associated with cost components 3-7 while members may have report the LoA cost (component 8), which would cover the same tests.

Likewise, companies that incurred costs associated with testing/information in items 3 to 6 in the table above will not have necessarily incurred costs associated with all costs of each type (for example, they may have already had or waived the need for some toxicological tests but not others). In the subsequent subsections, some comparisons are made against an ECHA (2018b) study on 2018 REACH deadline registration costs. That ECHA study includes the costs of all relevant tests under each category, so the two estimates are not necessarily equivalent.

The costs of training and of legal support, as well as the cost of physicochemical study results, do not vary substantially between the two tonnage bands, which is likely to contribute, in part, to the higher-than-expected registration costs for 1-10t substances.

4.8.2 ECHA fees

Fees payable to ECHA vary with the volume of the substance (the higher the volume, the higher the fee) as well as the size of the company (SMEs have lower registration fees). For every registration, the company needs to pay a fee to ECHA.

In the 2013 General Report on REACH (COM, 2013), fees were included in the assessment of the main drivers of registration costs. In the past, ECHA fees have often represented 50% or more of the total costs of registration for the previous periods, especially in the case of simpler substances and for smaller firms. For 60% of companies, registration fees accounted for less than 25% of the total registration costs (COM, 2013). Here, the average total costs were typically within the range of €50,000 to €100,000. However, a 2015 study of the 2013 REACH deadline (COM, 2016a) found registration fees, on average, to account for only 14% of total registration costs of the companies surveyed.

The literature indicated that the main cost elements for more complicated dossiers related to data collection and costs related to SIEF and consortia. The main cost is that of compiling and generating the required data to fulfil the information requirements of REACH registration (COM, 2018).

While information was not specifically collected from the current study survey on costs associated with fees payable to ECHA for registration, information is available in the Fees regulation on the fees payable by different sizes of companies according to tonnage band.

Table 4.9 Fees payable to ECHA for registration (1-100t substances)

	1-10t (individual / joint)	10-100t (individual / joint)
Standard fee	€1,739 / €1,304	€4,674 / €3,506
Medium enterprise	€1,131 / €848	€3,038 / €2,279
Small enterprise	€609 / €457	€1,636 / €1,227
Micro enterprise	€87 / €65	€234 / €175

Source: Commission Regulation (EC) No 340/2008 of 16 April 2008

ECHA has published information on the fees received in 2018, which equate to €81.6 million for REACH fees[22]. Approximately 14% of the income from REACH/CLP fees and charges was for registration of 1-10t substances, with 30% for registration of 10-100t substances. Substances registered at >100t accounted for around 35%[23]. It should be noted, however, that some substances initially registered in one tonnage band in 2018 (e.g. 10-100t) were subsequently updated to a higher registration tonnage, leading to payment of higher fees.

In any case, assuming the total fees received of €81.6 million, this is approximately 3.5% of the total registration costs of €2,251 million (€961 million for 1-10t and €1,290 million for 10-100t, as above, which included fees payable to ECHA). Clearly the fees for some companies will have been a greater proportion of the total.

4.8.3 Survey respondents' views on key cost drivers

Costs depend on the complexity of the dossier, e.g., based on the intrinsic properties of the substance, the volume placed on the market and the range of uses of the substance, the level of data sharing between registrants, the complexity of the SIEF (where relevant), and the availability of information (e.g. already existing information or new tests to be performed) (COM, 2018).

Respondents were asked to list key factors behind the costs per substance of the 2018 REACH registration, in their company (or based on their experience of the deadline) and for each tonnage band. Companies were asked to list up to 3 issues, ordered by importance from 1 (most important) to 3.

Table 4.10 and Table 4.11 present results to three questions.

[22] ECHA (2019a), General Report 2018, European Chemicals Agency (https://echa.europa.eu/documents/10162/21877836/general_report_18_en.pdf/4b442bd7-5b03-e2ce-ed3d-3ac1b785861c).
[23] ECHA (2019b), Financial accounts – financial year 2018, European Chemicals Agency, https://echa.europa.eu/documents/10162/13611/echa_annual_accounts_2018_en.pdf/9d97d89f-7c5b-7b83-9179-0e8d788bc5ba).

Table 4.10 What were the key factors behind the costs of the 2018 REACH registration, per substance, in your company (or based on your experience of the deadline) (1-10 tonnes) (top 3 factors)

Selection	1 (most)	2 (second)	3 (third)
The costs of accessing existing data	71	14	13
The costs of additional testing and/or generating new data	34	22	17
The costs of other external support, via consultants	12	45	35

Notes: Respondents were asked to list their top 3 factors behind the costs. Results include all stakeholders responding to this question. Only the top 3 responses, by number of respondents, are included.

Table 4.11 What were the key factors behind the costs of the 2018 REACH registration, per substance, in your company (or based on your experience of the deadline) (10-100 tonnes) (top 3 factors)

Selection	1 (most)	2 (second)	3 (third)
The costs of accessing existing data	64	18	13
The costs of additional testing and/or generating new data	30	28	18
The costs of other external support, via consultants	17	30	37

Notes: Respondents were asked to list their top 3 factors behind the costs. Results include all stakeholders responding to this question. Only the top 3 responses, by number of respondents, are included.

Key findings from the above include:

- Results were similar for both tonnage bands. The costs of accessing existing data were reported as the number one key cost factor for 2018 REACH registration for both tonnage bands. Note that the costs of accessing existing data is directly linked to the costs of testing, where that testing has already been carried out by another organisation.
- The next number one key cost factor reported was the costs of additional testing and/or generating new data.
- The costs of other external support, via consultants, was also reported to be a key factor behind costs, but this was not considered the number one key cost factor by most, instead generally scoring a two or three in terms of importance. The low number of registrants to share costs was also selected as a key factor cost but by a smaller number of respondents.
- For both tonnage bands, issues which few selected in their top three key cost factors included the data being of poor quality and requiring additional work; not being able to rely on read-across for the dossier; and the complexity of a substance.

4.8.4 Costs of producing a registration dossier

As set out in earlier sections, both the ex-ante assessments as well as this study consider the costs of registration *per substance*, as well as the costs *per company* to register that substance. For the 2018 deadline, between 2.2 and 2.8 companies, on average, registered each substance. Each company incurred costs in producing a registration dossier.

CSES (2015) estimated (ex ante) the cost of producing a registration dossier as:

- For individual registrations: €1,500-€3200 at 1-10t and €7,000-€10,000 at 10-100t
- For joint registrations: €2,000-€3800 at 1-10t and €9,000-15,000 at 10-100t

The survey for this study asked respondents for information on the costs, per substance registered, of producing a registration dossier, including the costs of drafting, finalising a technical registration dossier and submitting it, including all administrative data and producing study summaries for the relevant Annexes (VII to XI). This does not include chemical safety assessment (CSA) / chemical safety reports (CSR).

The study results suggest an average cost of around €18,000 at 1-10t and €39,000 at 10-100t (as highlighted in Table 4.8). This is one of the main reasons behind the significantly higher costs per registration per company. As highlighted in section 4.8.2, the costs of accessing data, generating data and external support were key drivers behind the high costs.

In terms of costs for preparing the registration dossier, the approximate average cost per registration per company for a 1-10 tonnage substance varied between SMEs and larger enterprises. Figure 4.9 presents these results. Overall, most reported costs to be below €20,000, for both tonnage bands. However, the average cost was above this for 10-100t (around €39,000 as highlighted above) due to a number of companies with significantly higher costs.

For the 1-10t substances, the distribution of costs for large enterprises and SMEs was similar, although, a slightly higher percentage of SMEs than large enterprises reported costs of above €40,000. A similar percentage of large enterprises and SMEs reported costs below €5,000. However, looking more closely at the distribution, more SMEs experienced costs between €2,500 and €4,999 than large enterprises, and more large enterprises experienced costs of below €2,500 than SMEs. The reasons for this are unknown, but could include for example larger companies having efficiencies related to economies of scale in knowledge and familiarity with dossier development (with larger companies more likely to register multiple chemicals). Smaller companies were also more likely to outsource work to consultants, likely meaning that costs would not fall at the lower end of the range.

For the 10-100 tonnage band, overall, costs were higher than for the 1-10 tonnage band. Most respondents reported costs below €25,000, regardless of tonnage band. However, large enterprises appear to have faced higher costs than SMEs, with a larger percentage of large enterprises than SMEs reporting costs of above €50,000. Also, 17% of large enterprises experienced costs of more than €100,000 compared to only 9% of SMEs. Figure 4.10 presents these results. This is reflected in the higher average cost for 10-100t substances than for 1-10t substance.

Figure 4.9 Cost for preparing the Registration Dossier (1-10 tonnes)

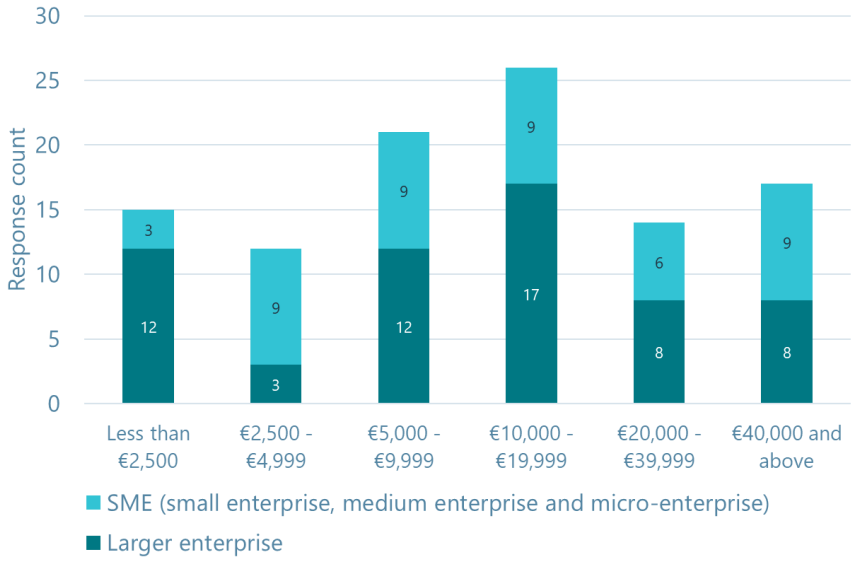
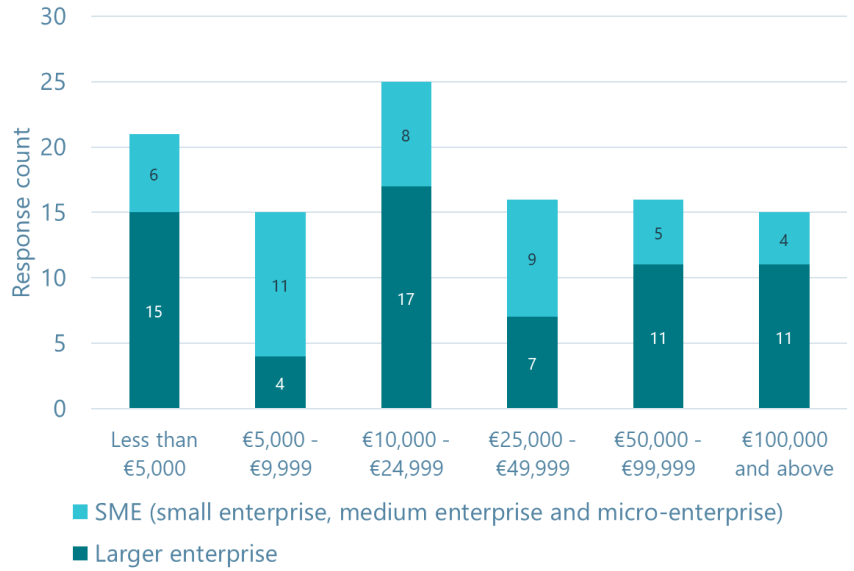


Figure 4.10 Cost for preparing the registration dossier (10-100 tonnes)



Conclusions on costs of registration dossiers

The average costs of producing a registration dossier are estimated to have been higher than those predicted in ex-ante assessments for both tonnage bands. For 10-100t substances the costs seem to have been around 3-5 times higher than expected, while for 1-10t substances the costs were around 5-12 times higher. Since the cost of the registration dossier is incurred by all registrants, this is thought to be a major contributor to the overall higher-than-expected costs.

It is important to recall that the range of costs varies significantly, with many companies incurring much lower costs than the average.

4.8.5 Costs of testing

Ex-ante estimate

CSES (2015) estimated that around one third of the €228 million cost for 1-10t substances would be associated with the information requirements of registration. Assuming exactly a third, this equates to €76 million, or around €4,500 on average for each of the c. 17,000 substances expected to be registered. In turn this equates to around €1,950 per registration, based on 2.3 manufacturers/importers per substance, as assumed by CSES (2015). This implies that, on average, relatively few additional tests would have been required[24].

ECHA study on 2018 REACH deadline registration costs

ECHA (2018b) estimated the costs associated with fulfilling Annex VII and Annex VIII information requirements in the 2018 REACH registration deadline, applying to 1-10t and 10-100t substances respectively as described in section 3. For 1-10t substances, the average cost of the studies for registration was €66,933 and for the 10-100 tonnage band it was €348,369 with costs, on average, split between 3 to 4 companies per registration[25]. It is important to note that these costs relate to the costs of studies for all endpoints required under each Annex, whereas in reality registrants will not have required tests for all endpoints, because they used adaptations foreseen by REACH, such as waiving of tests, use of existing data, or other adaptations outlined in REACH Annex XI.

For Annex VII, the range of costs was between €15,988 and €226,938 and for Annex VII + VIII, €84,909 to €744,674 (ECHA, 2018b). No correlation was seen between substance type and study prices (ECHA, 2018b).

ECHA (2018b) compared the above costs with results of CSES (2015) and concluded that, in Europe, the costs of individual studies were higher than expected. It was suggested that a contributing factor may have been contracts taken out late and at a time of market saturation with limited availability of laboratories.

The table below summarises the estimated **average** costs of all cost elements for Annex VII and VIII, along with the ranges of costs identified in the ECHA (2018b) report.

Table 4.12 Estimates of total average costs of tests for different REACH annexes (ECHA, 2018b)

	Annex VII (1-10t)	Annex VIII (10-100t)	Total
Physicochemical properties	€24,873 (range €4,929 to €80,738)	-	€24,873 (range €4,929 to €80,738)
Toxicological data	€23,263 (range €6,489 to €71,746)	€248,207	€271,470 (range €65,846 to €492,960)
Ecotoxicological data	€18,797 (range €4,570 to €74,454)	€33,229	€52,026 (range €14,134 to €170,976)
Total	**€66,933** (range €15,988 to €226,938)	**€281,436**	**€348,369** (range €84,909 to €744,674)

Note: Ranges were not provided for Annex VIII costs alone.

[24] The exact assumptions are not known from the report.
[25] It was assumed that studies needed to be performed for all information requirements.

In terms of key contributors to the above costs:

- The most expensive study overall is the screening for reproductive/developmental toxicity (repeated dose toxicity) study (OECD 421 or 422) representing 55% of the cost of all toxicological studies (with an average price of €148,328).
- The most expensive physicochemical study was water solubility (maximum price of €11,134 and average of €4,641) and octanol/water partition coefficient (maximum €21,236 and average €3,993).
- The most expensive ecotoxicological study was hydrolysis as a function of pH (OECD 111) with a maximum value of €32,880 and an average cost of €13,240).

Table 4.8 earlier in this section highlights the average costs of different types of testing and read-across/QSAR requirements based on responses to the survey for the current study.

The figures from ECHA (2018b) are greater than those collated for the current study, but this is expected as the ECHA report assumes that studies needed to be performed for all endpoints. The data presented in Table 4.8 are lower (€39,997 for 1-10t (Annex VII) and €160,047 for 10-100t (Annex VII and VIII)) as they represent the average costs of each cost component, *in cases where those costs were borne by respondents*, and noting that most respondents would only have needed some tests, not all, within each category. Costs will also have been shared amongst registrants, meaning that e.g. some of the costs for each test will have been borne by companies other than those initially paying for them, such as through letters of access.

Tests and studies required for study survey respondents

Most companies needed laboratory tests for at least some information requirements, and results were overall similar for each tonnage band. Around a fifth to a quarter of respondents reported that laboratory tests/studies were required for *all* information requirements. Table 4.13 presents the responses on the proportion of information requirements that laboratory tests and studies were required for, for each of the tonnages for the 2018 REACH registration deadline. The use of read-across is presented in the next section.

Table 4.13 Laboratory test/studies required for information requirements

1-10 tonne substances			**10-100 tonne substances**		
Number of respondents (Total: 129)	% of total respondents	% of information requirements laboratory tests/studies were needed for	Number of respondents (Total: 127)	% of total respondents	% of information requirements laboratory tests/studies were needed for
10	8%	For no information requirements	9	7%	For no information requirements
18	14%	For less than 25% of information requirements	16	13%	For less than 25% of information requirements
16	12%	For 25% - 50% of information requirements	11	9%	For 25% - 50% of information requirements
13	10%	For 50% - 75% of information requirements	19	15%	For 50% - 75% of information requirements
19	15%	For over 75% of information requirements	16	13%	For over 75% of information requirements

1-10 tonne substances			10-100 tonne substances		
26	20%	For all information requirements	31	24%	For all information requirements
27	21%	Don't know	25	20%	Don't know

Comparison of testing costs from literature with survey responses

One key question is the reason for the significant difference between registration costs for 1-10t substances identified in the present study compared to previous estimates. Based on Table 4.8, these were around €10,000 for physicochemical properties, €14,000 for toxicological study costs, €12,000 for ecotoxicological study costs and €3,500 for read-across/QSARs. These should not be viewed as the average costs across all registrations, as some substances will have required little or no additional testing data, while others may have required the majority of information set out in Annexes VII and VIII of REACH as highlighted in table 4.10 above. However, relatively large numbers of companies reported costs for physicochemical properties (81), and for toxicological (56) and ecotoxicological (54) tests.

The specific reasons for divergences between the actual situation and that assumed in the previous assessments are not known. However, the following considerations seem relevant:

- The costs of undertaking tests for all of the endpoints required under Annex VII are estimated (based on the authors' internal confidential data) to be around €60,000 per substance. ECHA (2018b) also estimated the costs of around €67,000.
- As per Article 12 and Annex III of REACH, information on physicochemical properties is required for all 1-10t substances, and this could cost up to around €40,000 if, hypothetically, no data existed. The ECHA (2018b) report also provides an estimate, albeit somewhat lower at €24,873.
- Other data, on toxicological and ecotoxicological properties may also be required, if a substance is either (a) predicted to be carcinogenic, mutagenic or a reproductive toxin based on modelled data; or (b) has (i) dispersive/diffuse use in consumer mixtures or articles and (ii) is predicted to have any health or environmental hazard classifications, or for certain nanoforms. For Annex VII these may cost between around €20,000 per substance (based on the authors' experience from other studies) to around €42,100 (ECHA, 2018b).

Given that the costs may be substantial if testing is required for all endpoints, one of the contributing factors to the much higher overall registration costs per substance than predicted could therefore be that more substances required data on physicochemical properties than was predicted, and/or that fewer substances were exempted from (eco)toxicological test data based on the criteria in Annex III. However, there is insufficient information in the survey results or interviews to confirm this.

4.8.6 Costs of read-across and quantitative structure relationship models (QSARs)

Quantitative structure activity relationship models (QSAR) are mathematical models used to predict physicochemical, biological and environmental fate properties of compounds from knowledge of the compound's chemical structure[26]. QSARs are a method used to avoid unnecessary testing on animals, but a QSAR needs to provide reliable information that is both comparable and sufficient to fulfil information requirements under REACH.

Read-across is a technique for predicting endpoint information for one substance, by using data for the same endpoint from (an)other substance(s). It is often used as an alternative to testing chemicals on animals under

[26] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/qsar-models

the REACH regulation and fills data gaps in registrations submitted. Both QSARs and read-across avoid the need for testing, which may involve animal testing, and are also typically expected to be (but are not always) less expensive than testing.

Few existing literature sources discuss costs associated with read-across and QSARs, and their role in the overall costs of REACH registration for companies. The table below presents results from the online survey on the information requirements read-across was used for. Table 4.8 indicated that the average costs of read-across and QSARs was around €3,500 for 1-10t substances and around €6,000 for 10-100t substances, for those companies that incurred (and reported on) such costs.

Table 4.14 Read across used to predict the properties of one substance from the properties of another substance, 1-10 and 10-100 tonnage substances

1-10 tonne substances			**10-100 tonne substances**		
Number of respondents (Total: 104)	% of total respondents	% of information requirements read across was needed for	Number of respondents (Total: 106)	% of total respondents	% of information requirements read across was needed for
10	10%	For no information requirements	8	8%	For no information requirements
23	22%	For less than 25% of information requirements	18	17%	For less than 25% of information requirements
12	12%	For 25% - 50% of information requirements	24	23%	For 25% - 50% of information requirements
6	6%	For 50% - 75% of information requirements	6	6%	For 50% - 75% of information requirements
6	6%	For over 75% of information requirements	7	7%	For over 75% of information requirements
4	4%	For all information requirements	6	6%	For all information requirements
43	41%	Don't know	37	35%	Don't know

Read-across was broadly used for the same percentage of information requirements for each tonnage band. Although, double the number of respondents in the 10-100 tonnage band reported using read-across for 25%-50% of information requirements than in the 1-10 tonnage band. Slightly more respondents in the 1-10 tonnage band reported using read-across for less than 25% of information requirements than those in the 10-100 tonnage band.

Looking more closely at the results by company size (and excluding 'don't know' responses), for the 1-10 tonnage band, SMEs appear to have used read-across for more information requirements than large companies: 89% (24 of 27) of SMEs reported they had used read-across for at least 25% of the information requirements, with 59% having used read-across for over 50% of the information requirements. In comparison, only 6% (2 of 35) of large companies used read-across for over 50% of the information requirements. Large companies still used read-across, but most reported only using it for less than 25% of information requirements or for no information requirements. Based on the above, it seems that SMEs tended to use read-across for more information requirements than larger companies, regardless of tonnage band.

For the 10-100 tonnage band, results are similar: 77% (20 of 26) SMEs used read across for more than 25% of information requirements, with 46% having used read-across for more than 50% of information requirements. In comparison, 45% (20 of 44) of large enterprises reported having used read-across for less than 25% of information requirements or for no information requirements. No large enterprises reported using read-across for all information requirements, compared to 23% of SMEs reporting to have done so; possible reasons for this might include larger enterprises being more aware of the criteria needed for robust read-across and hence use it with more caution, or alternatively reflecting that larger companies are more likely to have access to existing data.

There was limited quantitative data provided by respondents to the online survey on the costs of read-across and quantitative structure relationship models (QSARs). Only 12 respondents indicated that they knew the cost of QSARs for the 1-10 tonnage band, with 11 providing quantitative detail. For the 10-100 tonnage band. 15 respondents knew these costs and 13 reported quantitative detail.

- For the 1-10 tonnage band, the average costs for QSARs/read across studies per substance ranged between €1,000 and €10,000 with an average (mean) of around €3,600 and a median of €3,100.
- For the 10-100 tonnage band, the average costs for QSARs/read across studies per substance ranged from €0 to €20,000 with an average (mean) of around €6,000 and a median of €5,000[27].

Application of QSARs often involves only a modest amount of time input, and also may not be itemised per substance and endpoint (several are often run at once), which may explain why relatively few companies knew the associated costs. Interviewees consistently reported that the costs of testing were a major driver of registration costs, though grouping of substances in order to carry out read-across was raised as a substantial source of costs, as this is not always a straightforward process. Several interviewees also indicated that, often, read-across was not accepted by ECHA, which in turn, raised the overall costs of testing. In their view, there was a need for more acceptance of read-across and other alternative testing methods.

Case study box: use of read-across in dossier preparation

Read-across is a technique for predicting endpoint information for one substance, by using data for the same endpoint from (an)other substance(s). It is often used as an alternative to testing chemicals on animals under the REACH regulation and fills data gaps in registrations submitted. The Read-Across Assessment Framework (RAAF)[28] demonstrates how ECHA assesses read-across in registration dossiers. Grouping substances in order to carry out read-across has been raised as a substantial source of costs, and is therefore explored further in this case study.

During the consultation activities carried out for this study (survey, interviews and webinars), industry stakeholders (companies, consortium managers and trade associations) made the following points on challenges encountered, some impacts and best practices.

<u>Challenges encountered when using read-across within the registration process</u>

- There is uncertainty as to what is acceptable read-across. Stakeholders reported that often ECHA does not accept read-across and requires further testing to be undertaken. One industry interviewee noted that the more stringent rules (under the Read-Across Assessment Framework (RAAF)) introduced in 2017 partly led to additional testing requirements.
- A multi-national company noted that ECHA had not previously easily accepted read-across for the previous deadlines and so they did not use read-across for the 2018 deadline. ECHA highlighted that reasons for why they do not accept read-across in some instances, is that limited justification is provided for why a substance should have read-across applied or for why extrapolation can be used.
- There needs to be sufficient data to provide confidence to ECHA that the substance is safe. ECHA has also only received 50% of the studies it expected for the 2010-2018 deadlines. ECHA indicate that companies have used read-across more widely than was foreseen and, during compliance checks, in many cases it has become apparent that companies have

[27] The zero value may reflect a response where a company just spent a very small amount of time on this aspect.
[28] https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a

Case study box: use of read-across in dossier preparation

extrapolated data without providing solid justification. Data is now having to be generated which should have been generated back in 2009.

- One trade association noted that a high level of granularity is required under the Commission Implementing Regulation (2016/9) and it can be difficult to determine the exact cost for each substance when read-across is used. The uncertainty that read-across may not be accepted by ECHA also makes it difficult to justify financial costs to registrants and customers (this was also highlighted by another interviewee).
- A company noted that future costs can be incurred as data access through read-across can be limited and there can be issues with data-sharing and data-ownership.
- For some substances, registrants would like to use read-across but there is not enough information available to do so.
- A company noted that the RAAF only applied to organic substances, with guidance and read-across applicability for inorganic substance (e.g., metals) being limited.

Impacts of using read-across on registration costs

Cost-components in the assessment of read-across data:

- One survey respondent noted cost components from read-across include both administrative and project costs (e.g., consultant costs, costs of buying samples for testing and project management, amongst others).

Positive:

- A range of stakeholders reported that, in some instances, read-across can be used to lower registration costs as read-across can be less expensive than testing.

Negative:

- Several industry representatives reported that read-across was not accepted by ECHA, which in turn, raised the overall costs of testing as further testing was requested. ECHA's requirement for validation and further tests meant that in some instances, testing would have been less costly than read-across.
- A consortium manager reported that read-across is not necessarily less expensive compared to other alternative methods to meet information requirements (i.e., testing), and it can depend on how many studies are needed for the read-across and the cost of (access to) these studies.
- Purchasing samples for testing for some substances can be significant (understood to be to demonstrate sameness/similarity of substances).
- A consortium manager reported that ECHA's expectations of read-across changed after 2018. Where registrants were using studies containing older data, these studies have already been paid for (so come at no/minimal cost). The interviewee thought the costs per registrant could increase as ECHA considers (in their view) older studies to be unreliable.

Best practice to effectively use read-across and decrease potential registration costs

- ECHA's Read-Across Assessment Framework (RAAF) was used by several interviewees to support their use of read-across. Other studies and documents were discussed in interviews, such as the OECD Adverse Outcome Pathway (AOP).

Conclusions and Recommendations

Based on the above, it is clear that some companies have not been able to use read-across to the extent that they had expected. This will have had the implication of tests being undertaken where they were not expected, involving cost to industry (and in some cases use of experimental animals, including vertebrates).

Several recommendations were made by interviewees. These include:

- More acceptance of read-across as an alternative method to testing is required. One interviewee noted that the objective of reducing animal testing was not being met, as ECHA asks for further animal test studies to satisfy the read-across.
- Further guidance on what is acceptable read-across, with better support on read-across and sameness provided, such as through webinars or the development of an acceptance framework. A simplification of the sameness procedure is also favoured.
- Merging the RAAF with the weight of evidence approach, to simplify the documenting of activities was suggested.
- An explanation why read-across/extrapolation can occur. If companies were to generate as much data for the lower tier Annex VII and VIII, they could then extrapolate data for the more expensive studies (Annex IX and X), where there is sufficient underlying data.

Case study box: use of read-across in dossier preparation

Other conclusions include:

- Authorities seem not to be required to provide the same level of completeness when proposing categories and grouping. In their view, registrants must provide more proof than this for read-across, and this appears unfair.

Interviewees also indicated that testing had been particularly expensive for complex substances compared to basic chemicals for which there would already be substantial testing data as well as existing literature and research available. In such cases, discussions between registrants and with ECHA (before testing) regarding the identity of substances have reportedly been particularly time-consuming, compared to other substances for which the composition was already known.

Case study box: complexity of dealing with UVCBs in dossier preparation

Substances of unknown or variable composition, complex reaction products or biological materials are collectively known as **UVCBs** under REACH. UVCBs have many different constituents, of which some may be unknown, some may have composition that is variable or difficult to predict.[29] A UVCB cannot be sufficiently identified by its chemical composition.

Examples of UVCB substances include – among many others – linear, branched or cyclic alkane-based compounds with varying chain length.

Differences in steps and activities in order to register basic chemicals versus complex substances such as UVCBs

- Interviewees indicated that testing had been particularly expensive for complex substances, e.g. UVCBs, compared to basic chemicals for which there would already be substantial testing data as well as existing literature and research. In such cases, discussions (before testing) regarding the identity of substances have been particularly time-consuming, compared to other substances for which the composition was already known.
- In the metals industry, it was reportedly difficult to demonstrate robustness of read-across for some complex substances (metals), with testing not able to replace read-across in some instances.
- A consortium manager reported that it can be difficult to provide ECHA with the analytics required, where complex substances have a lot of constituents. A company also reported that in some cases, ECHA request analytical elements for UVCBs which are impossible to provide.
- One company reported they had found it difficult to find available laboratories which could analyse complex substances.

Complex substances, UVCBs and their registration costs

- The interviews highlighted that greater complexity does not necessarily mean a higher cost for testing or that testing is more complex. One consultant noted that it can be the rarity of a substance that impacts the cost. Another consultant reported the volatility of a substance that can make complex substances more expensive to test.
- Companies and a consortium manager reported the costs of registering UVCBs was high, with specific cost elements including testing and methods for substance characterisation and identity (as above, costs for other, basic chemicals for which identity and composition is already well known would be much lower) . One interviewee noted that the detailed requirements for CSR and exposure scenarios can make the costs of testing complex substances high. The methods for characterising substances were also reported by an interviewee to be expensive.
- One interviewee noted that they expected that updates to UVCB registrations will be expensive.

Best practice to register complex substances

- To reduce registration costs, one consultant reported that a common approach to testing was a phased approach to end-point testing. A first batch of tests is done and then, on the basis of these tests, further tests may or may not be undertaken. The first batch of tests would include, for example, solubility and partition co-efficient and skin corrosion tests. Depending on these test results, testing may need to be revised at the next stage. This process can take a bit longer.
- A consortium manager takes the approach of creating families in of substances and registering in categories, where possible, in their consortia.
- When registering complex substances, read-across can be used (where possible) to reduce costs and testing.

[29] https://echa.europa.eu/support/substance-identification/what-is-a-substance

Case study box: complexity of dealing with UVCBs in dossier preparation

ECHA has provided information to support companies on how to gather information to register a multi-constituent or a UVCB substance e.g. for *toxicological information*.

4.8.7 Costs of chemical safety assessment and chemical safety report

Chapter 3 provides an overview of the role of **Chemical Safety Assessments (CSA)** and **Chemical Safety Reports (CSR).** The chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process for substances registered at 10t or more; it is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios. It also forms a basis for other REACH processes including substance evaluation, authorisation and restriction[30].

The online survey results indicate that the average costs of a CSA/CSR per company, per substance, for the 10-100t substances ranged from €1 to €150,000, with an average (mean) of around €14,800. This is based on 41 respondents that provided quantitative information on the costs of CSA and CSR.

This compares to estimates in CSES (2015) of around €6,800 to €11,000 per substance, comprising: €3,000 to €6,000 for physicochemical and health/environmental hazard assessment, €750 for PBT/vPvB screening, €4,000-7,000 for exposure assessment and risk characterisation where required (40% of cases) and further testing for PBT/vPvB assessment where required (7%) of cases. The result from the survey is somewhat above the upper end of this range, but is in the same order of magnitude.

4.8.8 Costs of letter of access

The Letter of Access (LoA) is used to describe the agreement on the sharing of data and right to that data between a registrant and the owner of the data required for the REACH registration. As described previously, the costs of one registrant purchasing a letter of access is essentially a redistribution of the costs incurred by the organisation that owns and/or paid for the original test results.

ECHA (2018a) report the range of costs of a letter of access (LoA) for the 2018 REACH deadline as €500 to €239,351, with a modal value (most common response) in the interval of over €20,000 (36% of companies); of these responses, more than half (55.6%) were for registrations in the 1-10t range. No clear trend was observed between company size or registration tonnage band and the distribution of costs. It was thought this could be due to differences in the size of the joint submission or the availability of existing data for the higher tonnage bands (ECHA, 2018a). For SMEs, LoA costs were up to €15,000 and the most reported shared costs of joint registration were between €1,000 to €4,999. Most large companies reported costs above €20,000.

The higher costs for 1-10t substances, whilst initially surprising given the lower information/test requirements compared to higher tonnage substances, may be explained by the availability of existing data for higher tonnage substances and conversely the need for more new studies amongst lower tonnage substances (ECHA, 2018a). The report also found that, on average, LoA costs, were higher for larger companies. SMEs experienced higher costs for higher tonnages.

Table 4.15 presents a summary of ECHAs (2018a) findings on LoA costs for the 2018 REACH registration deadline.

[30] https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report

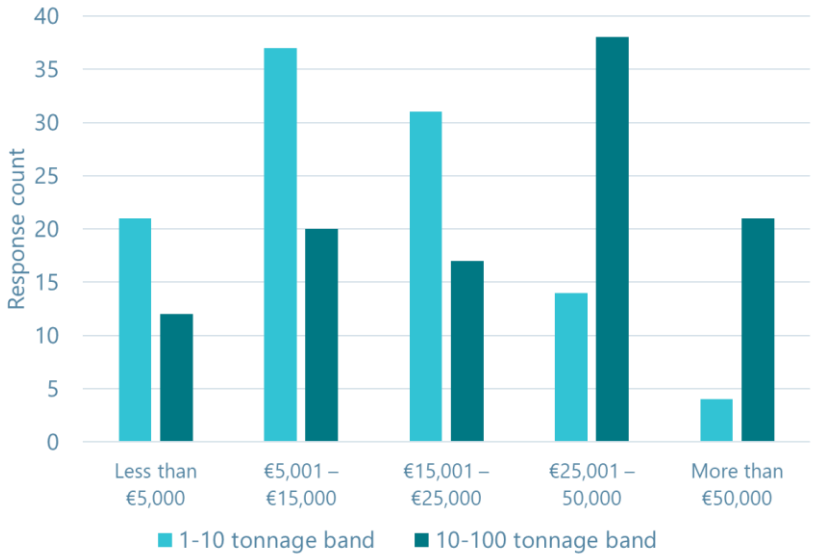
Table 4.15 Summary of Letter of Access costs found in the ECHA (2018a) report.[31]

% of respondents	Cost interval
2%	€500 - €999
24%	€1,000 - €4,999
14%	€5,000 - €9,999
14%	€10,000 - €14,999
10%	€15,000 - €19,999
36%	More than €20,000

The figure below presents the findings of the present study. For both tonnage bands, costs were well distributed across the cost ranges provided. Overall, costs for LoA were higher for those registering in the 10-100 tonnage band than for the 1-10 tonnage band: the modal costs were in the €5,000-€15,000 range for 1-10t and in the €25,000-€50,000 range for 10-100t. The average value was €17,000 for 1-10t substances and €31,000 for 10-100t substances. Again, it should be noted that not all companies will have needed a letter of access (though even where a LoA is not required, companies in joint registrations would have incurred costs in building the joint data package).

Overall, the costs of a letter of access can clearly be substantial in many cases. The results of the current study are in reasonable alignment with those in the ECHA (2018a) study.

Figure 4.11 Summary of key data on registration costs: Costs associated with Letters of Access



Notes: N = 134 for 1-10t and N = 132 for 10-100t.

For the 1-10 tonnage band, most respondents reported LoA costs to be between €5,001 and €15,000. For the 10-100 tonnage band, the most reported range was between €25,001 and €50,000. Figure 4.12 and Figure 4.13 present the costs associated with Letters of Access by company size and for each tonnage band.

Figure 4.12 Costs associated with Letters of Access by company size, 1-10 tonnage band

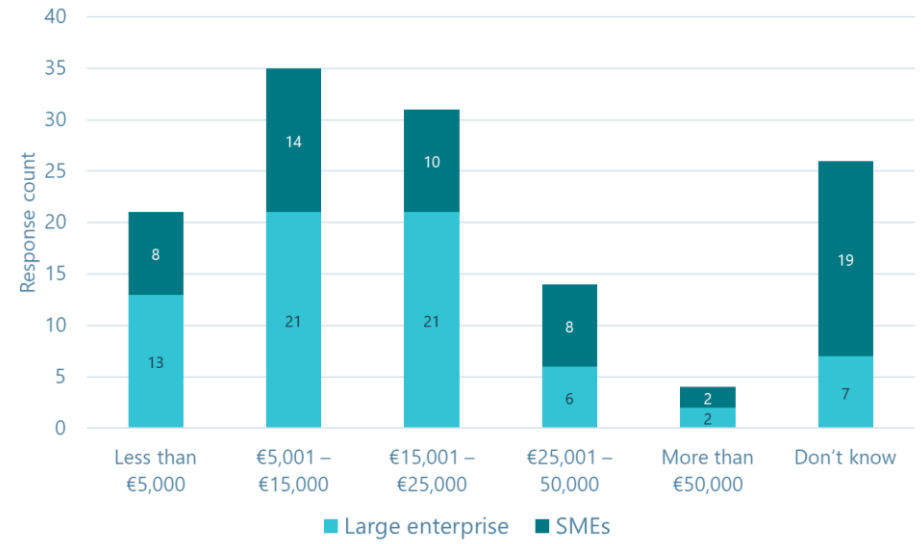
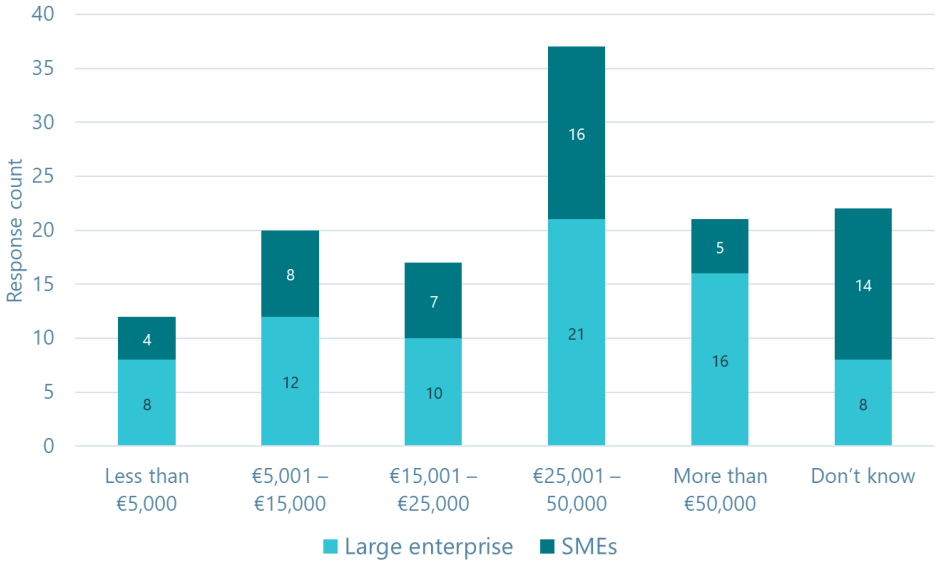


Figure 4.13 Costs associated with Letters of Access by company size, 10-100 tonnage band



One interviewee reported that industry runs strategic cost-benefit assessment around LoA. For example, a company produces substance A, that is sufficiently close to substance B so that read across could be made if testing data from substance B was available. This company could be willing to be part of a SIEF/consortium covering substance B but, if the LoA is too expensive, the company will prefer undertaking new testing, rather than obtaining testing data for substance B to carry out read-across to avoid the high cost of LoA, despite this leading to further animal testing.

Results from interviews showed that the costs of LoA were a major cost driving the overall cost of registration. In particular, interviewees expressed that a large part of the cost is associated with project management, validation with consortia members, and meeting time to discuss strategies to build a dossier. Several interviewees noted that, in some cases, the LoA has been as expensive as carrying out testing. While the costs of the LoA should in principle be considered as a redistribution of (e.g. testing) costs (as in some of the ex-ante impact assessments). However, the practical implementation has clearly required a lot of time and other resource inputs that have contributed to the costs associated with sharing of data being more than simply the costs of generating that data in the first place.

4.8.9 Costs of training, changes to company systems and legal support

There is little existing information in the literature on the costs of training and the types of training sought for REACH registration activities, or for information relating to the costs of legal support. Costs associated with the use of external help, including consultants, is covered in the section on resources and consultants.

The online survey requested quantitative information on the costs of training or of changes to company systems[32], per tonnage band, for the 2018 deadline. Limited quantitative detail was obtained, with 24 respondents indicating they knew the costs of training or of changes to company systems for the 1-10 tonnage band and 25 for the 10-100 tonnage band with costs ranging from very modest levels to quite substantial costs per company:

- For the 1-10 tonnage band, the costs of training or of changes to company systems for registration, per substance, ranged from €100 to €16,000 with an average (mean) of around €3,500.
- For the 10-100 tonnage band, the costs of training or of changes to company systems for registration, per substance, ranged from €100 to €26,000 with an average (mean) of around €4,000.

The online survey also requested quantitative information on the costs of legal support for each tonnage band.

- For the 1-10 tonnage band, the costs of legal support for registration, per substance ranged from €100 to €100,000 with an average of around €12,600.
- For the 10-100 tonnage band, the costs of legal support for registration, per substance ranged from around €60 to €100,000, also with an average of €12,600.

As can be seen from the above, there was very little difference reported in the costs of training and legal support between the two tonnage bands. While only a small number of companies provided responses to these questions, it is clear that, at least in some cases, such costs were significant, and may not have been included in some of the ex-ante assessments. While only some companies will have incurred such costs, these will have contributed to the (higher-than-expected) average costs of registration.

4.8.10 Other costs

The interviews highlighted several 2018 REACH registration deadline cost elements which are not quantifiable. These include:

- Clear and reliable translations of documents on the ECHA website were not always available. For some companies, it was also difficult to find consultants to accurately translate the specific technical terms used in the Regulation, the implementing measures, and all registration documents, such as Safety Data Sheets. This may be particularly important for SMEs.
- Exchanging with ECHA in languages other than English would have facilitated the process. One organisation recommended that ECHA sets up an application that could translate technical documents that need to be submitted for the registration process.
- The difference in requirements to register 1-10 tonnes and 10-100 tonnes was significant, in particular for SMEs. Interviewees recommended that the increased level of requirements should be more progressive.
- Establishing a 'market testing phase' was suggested, that would be in place for the first one or two years of a chemical being placed on the market, for which only a certain share of the

[32] This might include, for example, changes to company IT, information management and communication systems.

testing (and related costs) would be incurred by the company. This would allow the company to test their market, before filling in a complete dossier.

- In some sectors, e.g. dyes, where companies are likely to have portfolios with a high number of low-tonnage substances, it has been a challenge to proceed with so many registrations at the same time.

A common point of feedback from interviewees was that there was a general understanding, for both large and smaller companies, that most of the activities under the registration process would be finalised with the 2018 deadline. They noted that organisations could have better assessed their needs in terms of human resources if it had been clearer in communications from ECHA that the registration process would not be completed in 2018. Organisations indicated that they now expected to be similarly busy after the deadline, to address updates and testing proposals, in addition to the registration of new substances. This point was also made in the webinars.

The online survey also requested qualitative information on any other costs incurred. Responses included costs associated with consortia, consultancies and updates which are further explored in later sections of this report. Other costs reported included IT costs associated with IUCLID[33], the costs of monitoring import volumes as well as the costs associated with substance characterisation and substance identification. Travel costs were also reported.

The online survey also asked for information on actions taken by companies to lower costs spent on REACH registrations. Many respondents reported actions which included hiring consultants, cost-sharing and joint registration, and increasing prices of substances and ceasing of production of some substances. Some respondents indicated that not hiring consultants was taken as an action to reduce costs. The use of QSARs and read-across was also reported to be used to reduce costs, as well as participation in consortia.

In the interviews, companies and the consortium manager frequently reported that the changes to the IUCLID software had caused issues, with submitting dossiers made more time consuming or leading to resources having to be outsourced. Updates to IUCLID also had implications for training within companies, with one company reporting they then stopped internal training and outsourced the work to prepare dossiers and register these through the IUCLID platform. The training provided by ECHA was reported to be useful, but one interview reported that documents are not easy to find on the ECHA website.

4.9 Reasons for higher than predicted costs for 1-10t substances

Reflecting on the significantly higher costs identified in this study particularly for 1-10t substances, the data in the previous sections help to provide an understanding of the main contributors to registration costs.

Firstly, all companies would have been required to prepare a registration dossier at around €18,000 per company on average. This already takes the costs per substance and per registration significantly above those in the extended impact assessment and CSES (2015).

A large proportion of companies would also have been required to purchase a letter of access. It could be assumed that the average cost of around €17,000 would have been borne by up to 54% of companies[34] i.e. around €9,200 per company on average.

[33] IUCLID is software used to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. ECHA co-develops the software with the OECD.

[34] There were on average 2.18 registrants per substance, In simplistic terms, it could be assumed that one member of each joint submission, on average, would not bear LoA costs because they generated/provided the test results themselves. Therefore on average 1.18 out of 2.18 registrations (54%) could have required an LoA. This is a highly simplistic approach and is subject to much uncertainty, but it does highlight the potential for LoA to be a significant contributor to the registration costs.

Together, these cost elements give around €27,000 per registration. Taking into account the fact that some companies would also have paid for testing, read-across and QSARs according to Annex VII (and noting that these are incorporated into the costs of LoA purchased by other companies), as well as legal support, training, etc. it is understandable that the costs are substantially higher (€44,000 per registration) than that estimated in the CSES (2015) study (which equate to around €6,000 per registration). Further information on the costs of testing is set out in later sections.

To better understand the key drivers for costs in those cases where costs were higher than expected, the table below highlights responses from those companies that faced costs of over €15,000 per registration. It includes details of the most important cost drivers and top 3 most important cost drivers for those companies. This highlights that the main cost drivers were accessing data, additional testing and external support. *Note that these data are a subset of the data provided in section 4.8.3 above, with more detail provided here in order to focus on those companies experiencing the highest costs in the 1-10t range.*

Table 4.16 Key drivers of costs for companies that experienced the greatest registration costs at 1-10t

Key driver of costs	% with this as the most important cost driver	% with this as one of the top-3 cost drivers
The costs of additional testing and/or generating new data	34%	64%
The costs of accessing existing data	30%	60%
The low number of registrants to share costs	17%	47%
The costs of other external support, via consultants	13%	64%
The data was of poor quality and required additional work	0%	6%
We could not rely on read-across for our dossier	0%	6%
Complexity of the substance	0%	21%
I don't know	2%	2%
Other	0%	4%

Notes: The table displays information for companies responding that costs of registration at 1-10t were over €15,000 (51 out of 115 companies that provided a numerical response to Q14). Companies were asked "What were the key factors behind the costs of the 2018 REACH registration, per substance, in your company (or based on your experience of the deadline) Please list up to 3 issues and order by importance, 1 being the most important."

5. Costs of updates

5.1 Scope of work and key findings

This chapter sets out the results of work to quantify the costs for firms updating registrations as well as updating extended Safety Data Sheets. The main drivers behind the costs and the different cost components of updates are identified, as well as key hurdles and challenges with updates.

Key findings

- Costs to update were lower for 1-10t substances compared with 10t-100t.
- The costs of updates do not appear to be related to the size of a company and the costs to update were, overall, affordable for SMEs.
- Companies tend to wait for ECHA to request an update to a registration rather than submit them proactively.
- Frequent changes to IUCLID software and information requirements caused issues for companies to update dossiers, as well as changes being made to the guidelines which then change the requirements for companies.
- Problems were encountered relating to data-sharing, cost sharing or communication.
- Limited capacity or delays by laboratories have impacted updates (and may be due to COVID-19).
- Deadlines specified under REACH to cover updates (depending on the type of decisions, e.g. testing proposals in article 40, requests for further information in article 46, etc.) were considered to not be aligned with the required work for companies. Capacity constraints among consultants and laboratories were also highlighted.

5.2 Updates and related costs

A registration dossier must reflect the most up-to-date knowledge on how a substance can be safely used. The registration dossier therefore needs to be reviewed on a regular basis and updated as new information becomes available. Keeping a registration up-to-date is a legal obligation for all registrants[35].

The update of registration dossiers by companies has been identified as a weak point with regular reviews of REACH data only conducted by 25% of dossier owners, and 50% of dossier updates being done following a request from ECHA (COM, 2018). It was concluded by ECHA, in 2016, that stronger incentives may be required for companies to undertake updates of their registration dossiers, and in particular updating information on use, exposure and tonnage (COM, 2018).

The Implementing Regulation (EU) 2020/1435 on the duties placed on registrants to update their registrations[36] of 9 October 2020 was not in place for the REACH 2018 Registration deadline but was introduced during the course of this study. Further information was not obtained in this study on the impacts of the Implementing Regulation on updates.

[35] https://echa.europa.eu/reach-2018/keep-your-registration-up-to-date
[36] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1435&from=EN

ECHA (2018a) evaluated the issue of awareness of the update process in its survey concerning the 2018 REACH registration deadline. It was found that 81% of respondents (of 243 registrants across 22 European countries) were familiar with the updating process. Of these, 51% had already undertaken discussions on the procedures to navigate future updates (ECHA, 2018a). However, that study considered that these results may be impacted by the survey being conducted at a time when the most intensive dossier preparations were taking place. Therefore, the focus of registrants will have been on submitting 2018 deadline submissions, with perhaps a reduced discussion on future updates taking place at this time (ECHA, 2018a).

Table 5.1 presents the extent of REACH registration dossier updates, as reported by respondents to the online survey. In total, 37% (102) of companies did not update their registrations. Of these 102, 29% were large enterprises; 26% were small enterprises; 23% were medium-sized; and 20% were micro-enterprises. Company size therefore does not appear to have had an impact on companies not updating their dossiers.

Table 5.1 Responses to the question: Has your company updated any of your existing registrations?

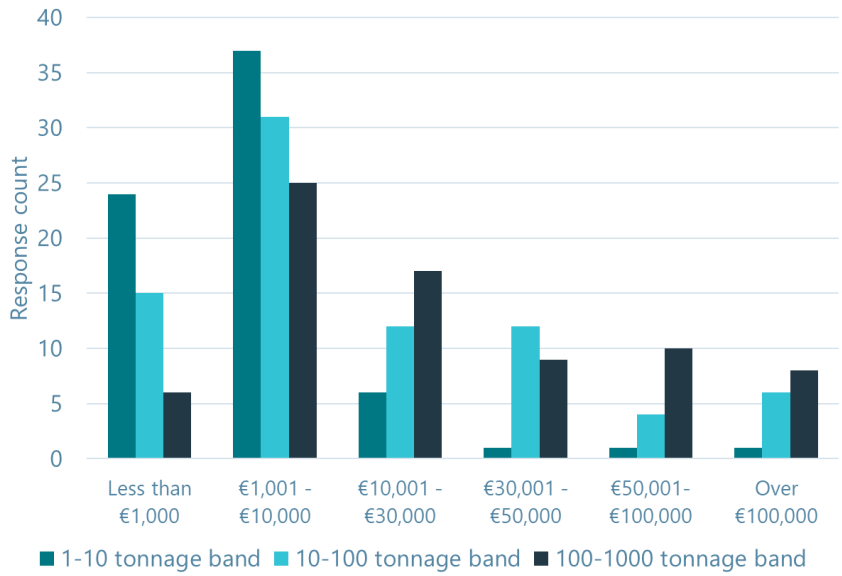
Response	Response count	Response %
Yes, updates to registrations from the 2018 deadline	41	15%
Yes, updates to registrations from the 2010 and/or the 2013 deadline	56	20%
Yes, updates to new registrations	5	2%
No	73	26%
No, but we intend to in the future	29	11%
I don't know	25	9%
	Total: 276	

Regarding the number of updates made, of those that reported they had made an update to registrations from any deadline or to new registrations, most respondents reported having made one update (28%: 41 of 146) or two updates (21%). The number of updates reported by respondents ranged from 1 to around 540, with a median of 3.

The main reasons why companies did not update registrations was because it was not perceived as required or because there was no new information available. The online survey did not specify whether companies had been asked to update their dossiers due to an evaluation decision or whether it was a spontaneous update. Although, feedback from the interviews with companies indicated that they often wait for ECHA to request an update to be made, such as through compliance checks, evaluations or dossiers being considered incomplete. This can then result in testing. One consultant also reported that updates may be spontaneous but thought that most registrants updated because of decisions from ECHA.

Information on the average approximate cost of an update, per substance was also requested through the online survey. Figure 5.1 presents the results for the different tonnage bands.

Figure 5.1 Average approximate cost of update for EU and non-EU stakeholders



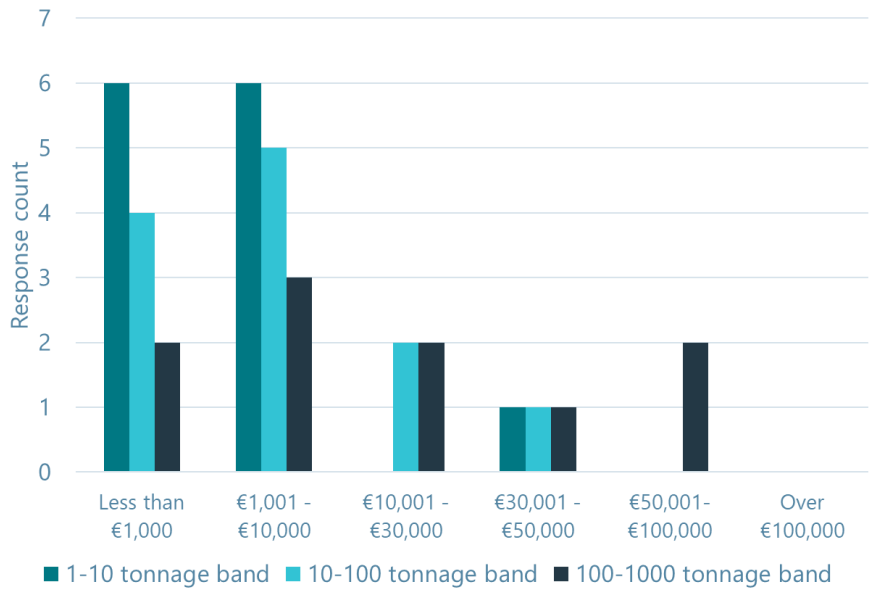
Notes: N=285

The results show that overall most updates incurred costs between €1,001 and €10,000 for all three tonnage bands. Costs were lower for the 1-10 tonnage band compared to the 10-100 and 100-1000 tonnage bands, which are associated with higher costs. For companies and trade associations only, key results include:

- For the 1-10 tonnage band, 35% (8) SMEs reported costs to update to be less than €1,000 compared to 24% (12) of large enterprises, and 26% (6) SMEs reported costs between €1,001 and €10,000 compared to 49% (25) of large enterprises. It appears that more SMEs (17%) than large enterprises (4%) experienced costs between €10,001 and €30,000, although respondent numbers were very small.
- For the 10-100 tonnage band, the most frequent response for both large enterprises (30%: 18) and SMEs (38%: 8) was that costs were between €1,001 and €10,000. No SMEs reported costs of between €50,001 and €100,000, compared to 7% of large enterprises.

The costs of updates do not appear to be related to the size of a company, for either the 1-10 or 10-100 tonnage band. Results are similar when looking at the costs for updates for stakeholders outside the EU. Figure 5.2 presents the results for non-EU stakeholders only.

Figure 5.2 Average approximate cost of update for non-EU stakeholders only



Notes: N=41

Looking closer at the results for companies and trade associations outside the EU only, the following are key results regarding costs of updates:[37]

- For the 1-10 tonnage band, the majority (86%: 12) experienced costs of less than €1,000 or between €1,001 and €10,000 (as in Figure 5.2). No respondents indicated costs of over €50,001.
- For the 10-100 tonnage band, results appear to be slightly higher than the 1-10 tonnage band. 29% (4) reported costs less than €1,000 and 36% costs between €1,001 and €10,000. In comparison to the 1-10 tonnage band, two respondents reported costs of between €10,001 and €30,000. However, no respondents indicated costs of over €50,001 (the same as the 1-10 tonnage band).
- For the 100-1000 tonnage band, costs were more spread across the cost ranges. However, no respondent indicated costs above €100,000.

5.3 Cost drivers

The online survey investigated the cost drivers by requesting information on the most expensive part of the registration dossiers to update. Table 5.2presents the results for each tonnage band.

Table 5.2 Most expensive parts of dossiers to update, by tonnage band.

Response	1-10 tonnage band (% responses)	10-100 tonnage band (% responses)	100-1000 tonnage band (% responses)
Testing costs	33%	38%	42%
QSARs / read across studies	1%	0%	3%

[37] Note that most companies and trade associations outside the EU responding to the survey were large enterprises.

Response	1-10 tonnage band (% responses)	10-100 tonnage band (% responses)	100-1000 tonnage band (% responses)
Costs for a chemical safety assessment (CSA) and producing chemical safety reports (CSR)	0%	15%	9%
Safety Data Sheet (SDS)	1%	0%	0%
Letter of Access	26%	19%	17%
I don't know	27%	22%	22%
Other	12%	5%	7%
Total responses	***78***	***91***	***92***

Note: figures include companies only.

For all three tonnage bands, testing costs were reported as the most expensive part of the dossier to update. The higher the tonnage band, the more likely it was that testing costs were the most expensive part. This is expected, as lower tonnages have less onerous and less costly testing requirements.

The Letter of Access was also reported by a large proportion of respondents to be the most expensive part of the dossier to update, across the three tonnage bands by a large number of companies. The lower the tonnage band, the more often it was reported that the Letter of Access was the most expensive part to update.

Note that additional testing and LoA costs during updates may be more likely when updates are made following a request from the authorities, rather than updates made on the registrants' own initiative.

Results were, overall, very similar when looking at non-EU companies. Across the three tonnage bands, testing costs were reported to be most expensive part of the dossier to update, followed by the Letter of Access.

5.4 Issues with updates

Affordability

Interviews and questionnaire results from the ECHA (2017a) study of the 2010 and 2013 deadlines, reported strong concerns among companies regarding the fact that financial costs of updating REACH dossiers were much higher than the benefits potentially provided from the updated information. Many of the SMEs felt that, for their businesses, REACH represents only a regulatory burden with no benefits at all; there was a general lack of understanding as to why dossiers needed to be updated if registration was already in place (ECHA, 2017a).

The study identified that, according to businesses, there needs to be a business case made for why a given company would spend additional funds and resources to update their dossier when they perceive that they are already compliant. This also reflects the fact that registrants do not always realise that Article 22 requires mandatory updates when new data is available (ECHA, 2017a).

The online survey for the present study found that 62% of respondents (92) agreed with the statement that updating dossiers was a complex process. The survey found that 51% of respondents (76 of 147) agreed that updating dossiers was affordable for their business, with 40% disagreeing and 8% reporting 'don't know/no opinion'. Looking at the results for companies and trade associations only, by company size, 52% (27 of 52) of SMEs agreed that updating dossiers was affordable, and 52% (41 of 79) of large enterprises reported the same. Similar results were seen for those that disagreed that updating dossiers was affordable, with 40% of

SMEs and 43% of large enterprises reporting this. This suggests that the perceived affordability of updating dossiers is not impacted by a company's size.

Software, guidelines and technical issues

The literature review pointed out many issues with updates for the 2010 and 2013 deadlines. For instance, ECHA (2017a) highlighted that the majority of respondents did not have a system to help them monitor whether new data was available to assist with a REACH dossier update.

Companies reported facing technical problems with updating dossiers – the software used to update dossiers was described as unpractical and created additional work for companies, even when minor changes had to be made to the dossiers. Many companies in the ECHA (2017a) study found it difficult to identify exactly what needs to be updated in the dossiers, finding that guidelines provided by ECHA were often vague (in their view). This represented a further burden on the companies that had to invest further time in finding out which information had to be updated.

The online survey for the current study requested qualitative information on issues associated with updating registrations. IUCLID version upgrades and changes by ECHA were frequently reported by a substantial number of respondents to have been an issue for them updating dossiers, as well as changes being made to the guidelines which then change the requirements for companies. This was also confirmed in interviews with companies, with IT updates entailing additional costs to update internal systems and staff training. A consortium manager also noted that changes in reporting standards between IUCLID 5 and 6 has made people wary of changes to IUCLID. The online survey also found that 69% (102 of 148) agreed that registration updates were expensive because of new data, study requirements or other technical issues. 18% (26 of 148) disagreed and 20 respondents reported 'Don't know/no opinion'.

Data-sharing, cost-sharing and communication

The ECHA (2017a) study found a clear definition of who is responsible for updates to be a crucial point in reducing costs of updates, to clarify the roles of lead registrant and co-registrant in the update process.

The online survey for the current study found that 49% (71 of 146) agreed with the statement that they encountered problems relating to data-sharing, cost sharing or communication. 34% disagreed with the statement and the remaining responses were 'don't know/no opinion'. This was further reported in several interviews, which showed that industry would find it difficult to address the update requirements following the 2018 registrations in a short amount of time. The deadlines specified under REACH to cover these updates (depending on the type of decisions, e.g. testing proposals in article 40, requests for further information in article 46, etc.) was considered to not be aligned with the required work for companies as well as capacity constraints among consultants and laboratories. Companies have faced difficulties to comply with the registration deadline given the limited capacity of laboratories, which were reportedly overwhelmed with requests for analysis as the 2018 deadline approached. A similar situation is expected to arise regarding future requests for update, for some companies. In addition, it was mentioned that the workload of companies was likely to increase, in order to address new regulatory obligations resulting from Brexit.

Interviewees recommended prioritising dossiers based on urgency, e.g. where the CLP classification is expected to change as a result of new information, with exposure of concern or a direct substantial impact on environment/health. One trade association has developed criteria to prioritise dossiers for which update is essential, under a tracker of opportunity for improvement (OFI), that helps prioritise the update work on a yearly basis.

Several interviewees indicated that changes to the information requirements were detrimental to the whole registration process and predictability was key in preparing dossier updates. Various industry programmes have been put in place by trade associations to provide support in updates as well as to improve the quality of registration dossiers, e.g. the CEFIC-ECHA Action Plan. MISA is another example of a voluntary programme

that is endorsed by metals and inorganics consortia that signed a framework for cooperation on dossier update. The agreement included a rolling action plan for 2018-2020, which aimed to identify, by the end of 2020, any outstanding REACH and CLP standard information endpoints, as well as further information, supply chain communication or risk management needs, where relevant.

COVID-19 impact on updates

The interviews investigated whether the COVID-19 situation[38] had affected updates. Responses varied, with two trade associations reporting there to be delays or the postponement of work by laboratories and one trade association reporting the postponement of work by consultants. However, one of the two trade associations noted that it was difficult to know if this was a result of COVID-19 or for other reasons. Another trade association reported that it had not received any feedback from members relating to COVID-19 having impacted updates; however this did not mean that members had not been affected.

Responses also varied amongst companies, with one company reporting that COVID-19 had not impacted its costs of updates due to their final testing programme having been adopted after a lockdown. Another company reported no impact on the progress of tests. However, another company reported that illness amongst its external researchers has led to delays, which the company struggled to recover from. Another company also reported that ECHA had not been flexible during the COVID-19 period, as companies attempt to postpone costs to later years.

[38] This study was developed during a period affected by the global Coronavirus (Covid-19) pandemic.

6. SIEF and registration consortia

6.1 Scope of work and key findings

The aim of this chapter is to set out the results of work to describe the pricing policies of the substance information exchange fora (SIEF) and consortia, as well as to establish their affordability, with a focus on transparency, fairness and communication practices. The impact from the Implementing Regulation 2016/9 on joint submission of data and data-sharing is also investigated[39].

Key findings

- Costs associated with joint registration for survey respondents in the 1-10 tonnage band varied between less than €1,000 and more than €20,000. A substantial share of survey respondents experienced costs between €1,000 and €10,000. A significant share of respondents also reported costs of above €20,000 for the 10-100 tonnage band.
- There are mixed views on whether the Implementing Regulation on joint submission of data has been successful or not.
- More problems with SIEFs than with consortia were reported for the REACH 2018 deadline, except in the case of affordability (where more problems were reported for consortia). However, almost half of survey respondents reported they had not faced any problems with SIEFs, and over half of respondents reporting having faced no problems with consortia.
- Many registrants faced issues regarding disputes with pricing policies, cost sharing, prices of data or unexpected costs for SIEFs. It was often difficult to provide information to registrants (and difficult for registrants to obtain information) on the split of the Letter of Access costs between members of a SIEF and/or consortium.

6.2 SIEF and registration consortia overview

A Substance Information Exchange Forum (SIEF) is formed once stakeholders agree that they have pre-registered the 'same substance' within the REACH-IT system. The main purpose of the SIEF is to share information (thereby avoiding the duplication of studies, including vertebrate animal testing) and to work together to compile, and submit, a joint registration dossier for the registration of the substance. This is mandatory under REACH under the principle of 'one substance, one registration'.

A consortium on the other hand is a voluntary form of co-operation for potential registrants of a substance, or group of substances, to fulfil the REACH requirements in time, with the consortium agreement providing a legal framework for safeguarding the essential business interests of the participating companies. What makes it different to SIEF is that it is voluntary, involves pooling of resources, provides a contractual agreement on liabilities and cost-sharing mechanism, and protects common business interests.

For the 2018 registration deadline, over half (58%) of the business operators responding to the survey participated in SIEFs and 43% participated in consortia. Many respondents therefore have experience with data-sharing, and costs associated with both SIEF and consortia, which are further explored in this chapter.

[39] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0009

6.3 Costs associated with Joint Registration

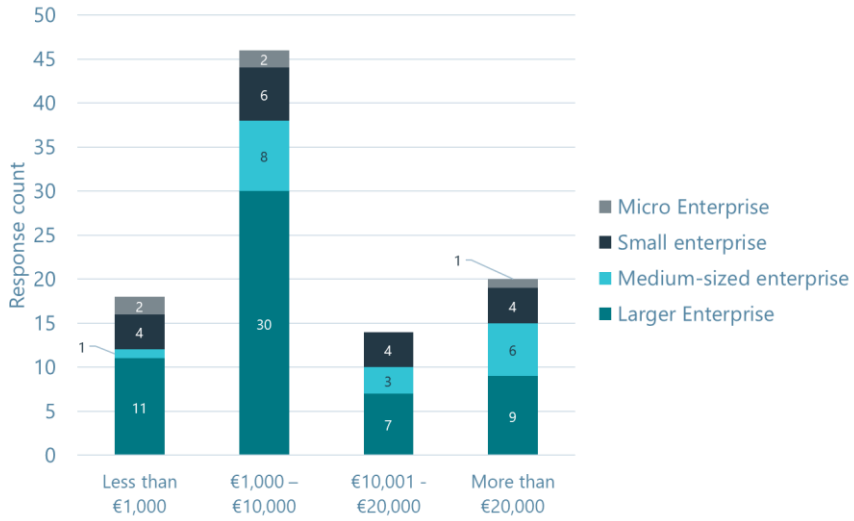
The literature had already identified, for the 2010 and 2013 registration deadlines, that a significant number of firms considered cost-sharing, related to joint registration, to be a problem (CSES, 2015). For larger firms with substances requiring more complicated studies, costs relating to SIEFs and registration consortia were reported to often exceed €100,000 per company and SIEF/consortia costs were often the main cost element in registration (CSES, 2012a). Costs were reportedly often incurred at this level (exceeding €100,000) even when costs of testing were excluded.

For SMEs, given that they typically produce (or import) lower volumes, unit costs can be higher in comparison to larger companies: for SMEs with many substances to be registered, costs can substantially increase and competitiveness of SMEs can become an issue (CEPS, 2013b). For manufacturers and importers, a study by the European Commission (COM, 2017a) found the costs of engaging with other registrants on shared information (as part of the SIEF) for each registrant to be €1,000 and the cost of engaging in dossier preparation to be €750 per joint registrant. Further, the cost savings from SIEFs were reported by CSES (2012a) to be smaller than firms expected, with problems identified to relate to communication and co-ordination. The study found that 75% of companies suggest significant costs were driven by engaging in SIEFs to exchange and share information (CSES, 2012a).

Results for the 2018 REACH registration deadline from the online survey show costs associated with joint registration remain quite high, at least for some companies. Costs of joint registration for the previous deadlines were found to often exceed €100,000 (CSES, 2012a) but this may not be directly comparable with the figures for the current study[40].

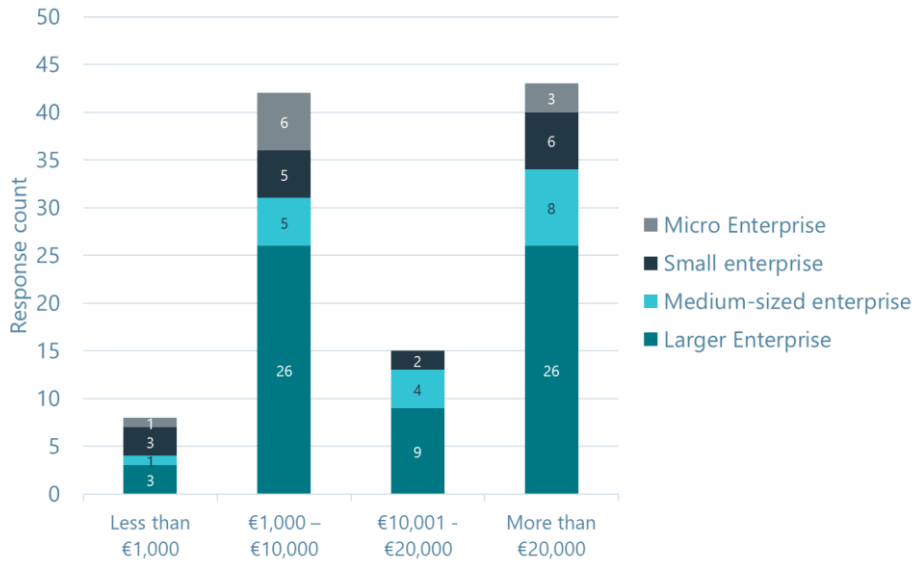
The approximate costs associated with joint registration for the 1-10 tonnage band vary between less than €1,000 to more than €20,000, with a substantial share of respondents having had costs between €1,000 and €10,000. For the tonnage band 10-100 tonnage band, a significant share of respondent also reported costs of above €20,000. Figures 6.1 and 6.2 show the results from the online survey on cost associated with the joint registration for the 2018 REACH registration deadline. This includes joint registration and SIEF administrative costs, the costs of liaising with other parties and other costs involved with the SIEF per company; however, it excludes Letter of Access costs.

Figure 6.1 Costs associated with Joint Registration for 1-10 tonnage band



[40] The figures in the CSES (2012a) study of €100,000 are understood to include costs of additional tests in some cases but not in others (page 43).

Figure 6.2 Costs associated with Joint Registration for 10-100 tonnage band

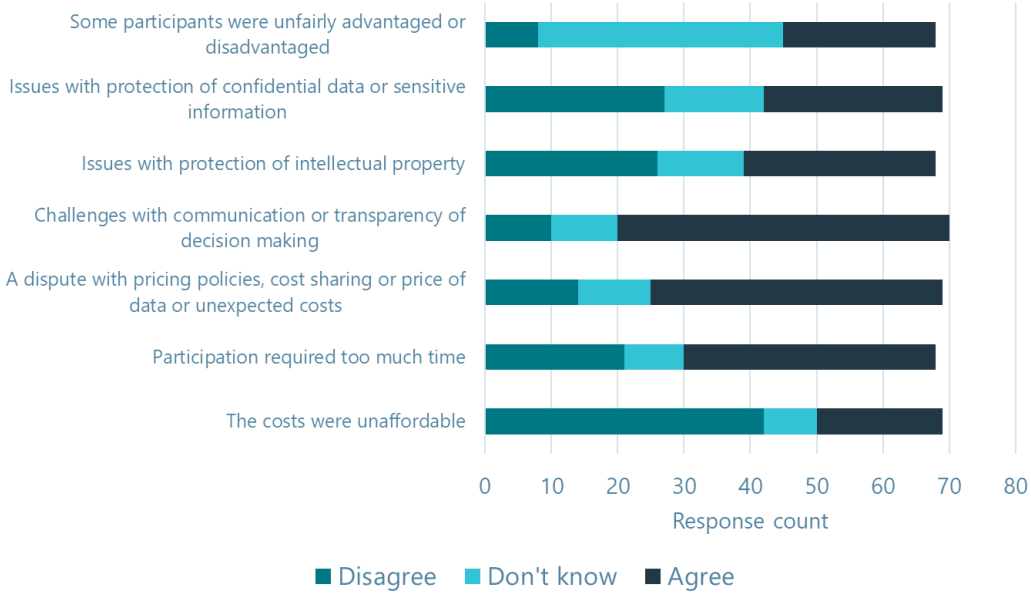


6.4 Issues faced with SIEF and consortia

Figures 6.3 and 6.4 present the types of issues faced with SIEFs and consortia. These include issues associated with affordability, costs and disputes, amongst others.

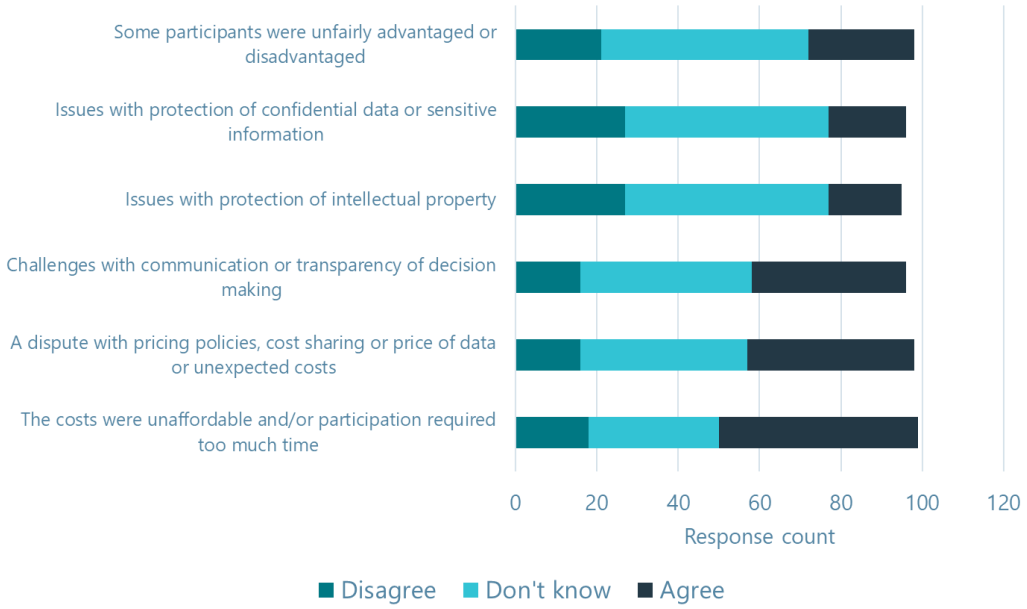
The literature review highlighted several issues faced by economic operators with SIEF and consortia. A lack of clarity on substance identity and the resulting scope of SIEFs was identified as a problem with the 2010 deadline (CSES, 2012a). Indeed, it was recommended by COM (2013) that ECHA provides greater guidance relating to transparency, non-discrimination and fair cost sharing within the SIEF framework. A report by the European Parliament (2013) also highlighted this, with SMEs expecting to have no knowledge of the costs after the SIEF has been established.

Figure 6.3 Views on different issues faced for the 2018 REACH registration deadline, **for SIEFs**



Notes: N=68-70 per statement, 418 in total

Figure 6.4 Views on different issues faced for the 2018 REACH registration deadline, **for consortia**



Note: N=95-99 per statement and 582 in total.

Generally, issues raised in the survey seem to report more problems with SIEFs than consortia, except for affordability. However, 47% (114) reported that they had not faced any problems with SIEFs, and 54% (115) of respondents reporting having faced no problems with consortia. Similar results were seen for companies and trade associations outside the EU, with 53% (17) reporting they did not face any significant problems or challenges in relation to the operation of SIEFs and 63% (19) reported they did not face any significant problems or challenges in relation to the operation of consortia.

For those that had experienced problems in relation to the operation of SIEFs, 22% (45) had these problems resolved and 11% (26) faced problems which were not solved. Similar results were seen for companies and trade associations outside the EU.

For those that had experienced problems in relation to the operation of consortia, 14% (31) faced significant problems or challenges, which were, however resolved and 4% (9) faced problems which were not solved. For companies and trade associations outside the EU, 20% (6) reported they did not know, and 17% (5) reported that they did face problems or challenges, but that these were resolved.

Pricing policies

A pricing policy is how SIEF or consortia set the prices for paying for activities undertaken by the group, administrative costs and access to data. A range of pricing policies can be used by SIEF and consortia. Examples of pricing policies include:

- Costs are split by cost type. For example, consortium administration and management, general studies and local exposure assessment costs, etc.
- There are examples where both fixed levy fees and tonnage-based levy fees are charged, as well as fees related to specific projects undertaken by the consortium.
- Where new members pay the pro-rata fees when joining, monies received are typically refunded to other, already existing, consortia members.

- In some examples, study owners are required to rate their studies based on a ranking provided by a specific source (e.g. Klimisch score). The lead registrant selects a key study, and only the costs of key studies are shared. All members who require a specific key study for their information requirements will contribute to the study's costs. The cost of a key study is the sum of a standard price per study defined for each endpoint, plus study administration costs.
- Administrative costs being shared equally across all registrants, irrespective of the substance registered, and for technical aspects, a "points system" was created, depending on the tonnage band (1-10t, 10-100t) as well as the substance. This points system was used to determine the cost related to technical aspects for each registrant.

Feedback from the workshop and interviews highlighted that splitting the cost based on company size and production quantities made the costs to participate in a consortium both proportionate (i.e. the higher the production of the substance, the higher the cost to participate in the consortium) and affordable (i.e. smaller sized companies would incur a lower cost than larger companies involved in the consortium). This approach is considered a good practice compared to an equal split of the costs, and it relies on objective criteria (i.e. size of company and production).

A lack of clarity with regards to setting prices for LoAs was also found to be an issue by COM (2012), with high costs a concern for smaller firms and problems associated with the functioning of SIEFs also reported by the European Parliament (2013). With regards to LoA, the CSES (2012a) survey found that the LoA costs were considered to be high and that it was not clear how these prices were decided, with the possible explanation that (in their view) larger firms aim to push smaller competitors out of the market. For SMEs, the letters of access approach is often taken where an SME does not have the resources or is unwilling to participate in creating and sharing of data associated with SIEFs (CSES, 2012a). A report by CSES (2015), found SMEs to have limited willingness to have an active role in registration, expecting that this could lead to a situation in 2018 with no companies being active in new SIEFs and registrations facing significant issues due to the process being started too late. The evidence gathered through the interviews of this study did not confirm this assumption.

This study found costs of be more unaffordable for consortia than for SIEFs for the 2018 REACH registration deadline, with 28% (19 of 69) agreeing that SIEF registration costs were unaffordable and 50% (49 of 99) agreeing that the costs of consortia were unaffordable and participation required too much time. This conclusion is surprising, given that participation in consortia is voluntary, while participation in SIEFs was mandatory.

Overall, the study found there to be more problems with SIEFs compared to consortia for the 2018 REACH registration deadline. For example, regarding challenges with communication or transparency, it can be observed that many more respondents agreed with the fact that there were more challenges with communication or transparency of decision making for SIEFs compared to consortia: 72% (50) and 40% (38) respectively. As above, reasons for this may include that participation in consortia is voluntary.

In 2016, the European Commission introduced Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing. This aimed to address issues identified in 2015 concerning transparency, communication and cost sharing within SIEFs. The Implementing Regulation on joint submission of data is intended to ensure that costs relating to sharing and jointly submitting information should be determined in a fair, transparent and non-discriminatory manner[41]. The experience from 2010 and 2013 deadlines was that provisions on data-sharing and joint submission were not used to their full potential, with small and medium sized enterprises experiencing prejudice. The present study investigated the impact of the Implementing Regulation on joint submission of data and data-sharing on the costs for the 2018 REACH registration deadline.

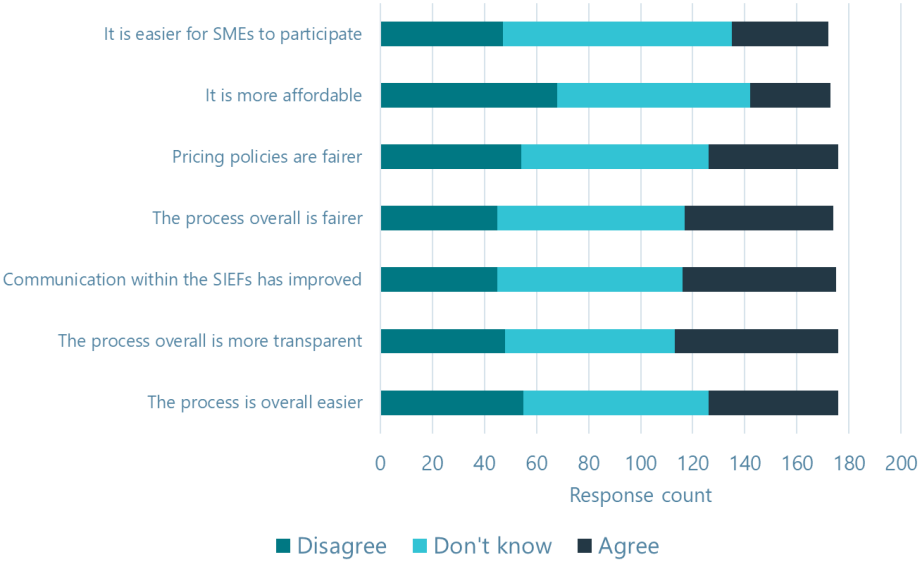
[41] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0009&qid=1453380621080&from=EN

Figure 6.5 outlines respondents' views about how the SIEF process changed since 2016, when the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing was put in place. This demonstrates that, whilst some survey respondents agree that the Implementing Regulation on joint submission of data has been successful in its aims, a similar proportion disagree.

These diverse views were also demonstrated in interviews. Most interviewees across the stakeholder groups thought that the Implementing Regulation on joint submission of data brought some improvements related to the transparency and fairness of costs, with organisations feeling more comfortable inquiring about costs and raising questions about the split of costs. Trade association and company interviewees reported that, on several occasions, the Implementing Regulation balanced the power between lead registrants (i.e. data owners) and co-registrants and, thanks to the regulation, several legal actions have been avoided. However, it should be noted that such an impact of the Implementing Regulation EU) 2016/9 on joint submission of data and data-sharing may be common, but that balancing the power between data owners and co-registrants is not a necessity.

However, other companies reported that these improvements were not significant and that issues related to data sharing and joint registration raised for the previous registration deadlines (as mentioned in the 2018 REACH review) remained. The Implementing Regulation on joint submission of data was reported to be too broad and not fully understood by industry, especially by small companies. They reported that it requires a substantial amount of work to implement and adopt procedures. This evidence suggests that, whilst the Implementing Regulation on joint submission of data has delivered some benefits in terms of the fairness and transparency of costs, there is still work to do to achieve the fair, transparent and non-discriminatory submission of data in SIEFs.

Figure 6.5 Views on different statements for the 2018 REACH registration deadline, **for SIEF**



Note: N=172 – 176 per statement and 1222 in total.

Cost sharing

Members of a SIEF need to agree on how they share costs for both existing and new studies. Registrants in the SIEF only need to pay for the information they require to complete their dossier and fulfil their own tonnage band registration requirements. How the costs are shared costs must be determined in a fair, transparent and non-discriminatory way.

45% (32 of 70) of respondents from the online survey agreed that they faced issues regarding disputes with pricing policies, cost sharing or price of data or unexpected costs for SIEFs, and 42% (29 of 70) reported this for SIEFs.

This was supported by most interviewees from companies and trade associations who indicated that it was difficult to split the cost of the LoA among consortia members, as there are several transversal tasks (e.g. administration, meetings) that cannot be easily allocated to specific substances or consortia members. Furthermore, interviewees mentioned that it is a challenge to achieve the level of granularity required in the Implementing Regulation on joint submission of data for consortia covering a high number of substances, where read-across is widely used. Industry faced difficulties to list the various cost components per substance. In some cases, companies had to pay for the development of data for more uses than was necessary to them; the additional uses registered required more testing which generated unnecessary data for them. In addition, even in cases of good cooperation with the consortium, companies may be pushed to resort to an external lawyer to validate communications from the Lead Registrant, e.g. on the content of the Letter of Access, order confirmations and invoices.

During the webinars it was further mentioned that large companies usually have the necessary expertise for registration, which small companies benefit from by being part of the same SIEF or consortium. This expertise from larger companies is, however, not necessarily covered by the costs of a letter of access. Several economic operators noted that it was difficult for them to obtain detailed information on the split of the letter of access costs between members of a SIEF and/or consortium, confirming the survey results: this was particularly the case for administrative costs, which some participants thought to be higher than testing costs. One operator stated that, in their experience, the process of cost sharing had generally been fair to companies involved, although disputes can arise.

Finally, a member of a trade association indicated that cost sharing was applied in several ways, depending on the specific consortium, which makes it difficult to provide general views on the process of sharing costs among members and on possible issues encountered. The participant further stated that the perception from consortia members on cost sharing depended on their level of involvement in the preparation of the registration dossier.

Dominant position and disputes

With regards to updating dossiers, a study carried out by ECHA (2017a) on the 2013 registration deadline found intervention or enforcement was ineffective where SIEF disputes arose with lead registrants, suggesting the potential problem of a dominant position by large groups or lead registrants. Disputes regarding cost-sharing were also considered to potentially result in delaying updates. Cost-sharing disputes appear to be associated with updating dossiers (ECHA, 2017a).

Survey results suggest that some participants of SIEF and consortia were unfairly advantaged and disadvantaged. This is supported by several interviewees who indicated that consortia have led to the creation of a dominant position, by larger groups or lead registrants. In some cases, this led to threats of legal action and intimidation against smaller parties, in order to discourage potential reactions from smaller parties. This, in turn, led to reputational damage and hassle costs (e.g. to settle through a competent authority or ECHA). Other interviewees reported that their competitors took the lead of a consortium and implicitly blocked other companies from their sectors, by imposing a high cost to join the consortium, and hence the registration process. Finally, it was raised that some companies were not reimbursed once more registrants joined a consortium (which should normally decrease the price per consortium member as it is shared among all). In principle, the cost of a letter of access should simply be a transfer payment, to apportion the costs (e.g. of tests) among the registrants that use the information. However, this comment suggests that in some cases the equitable distribution of costs may not always have occurred as intended.

With regards to disputes, the survey found that 64% (44 of 69, covering all stakeholder types) agreed that a dispute involving pricing policies, cost sharing or price of data or unexpected costs in SIEFs had occurred. For

consortia, 42% (41 of 98) agreed with the statement. The lower number for consortia may reflect their voluntary nature. Looking at companies only, 68% (19 of 28) of SMEs agreed with the statement for SIEFs on 'a dispute with pricing policies, cost sharing or price of data or unexpected costs' and 57% (16 of 28) of large companies agreed with the statement. This suggests companies of all sizes agree that disputes occurred within SIEFs. It was reported in one interview that SMEs can be vulnerable to some of the larger companies. It can be difficult for small companies to challenge in SIEF and consortia, with regards to issues with cost-sharing. Some large companies and consortia can also make it difficult for companies to access the market, by asking them to pay for data they do not need. For example, one interviewee's view was that, in relation to a substance evaluation decision, a lower tonnage registrant should not have to pay for a higher tier study (e.g. 2-generation study) which they do not need for their registration purposes. Under the Implementing Regulation, 'fair' now means a registrant is required to only pay for the share of costs that it requires for its own registration. ECHA provides guidance on the rules for sharing data and costs during substance evaluation[42].

Decisions from the Board of Appeal have assisted SMEs by clarifying that cost and data sharing mechanisms must be transparent, fair and non-discriminatory. Where ECHA previously assessed disputes on cost and data-sharing by assessing the behaviour of parties involved, this has more recently progressed to focusing on fairness, transparency and non-discrimination. With regards to the process of disputes, where there is a lack of transparency, appeals are lost. For example, there have been Board of Appeal cases where price discounts for cost-sharing for only some members are potentially unfair and/or discriminatory. Where transparency is deemed to be present, the Board of Appeal/ECHA then assess for fairness and non-discrimination. It was reported in one interview that the Implementing Regulation on joint submission of data has made the approach to cost-sharing issues more objective, than was previously the case. The interview also highlighted that the post-reconciliation of costs has significantly improved since 2010, in relation to data-sharing.

Rules under REACH on how SIEFs should organise their work were considered insufficient by some interviewees, e.g. on how industry, including competitors within a sector, should cooperate in implementing their REACH obligations. For example, provisions related to the reimbursement of the letter of access are not sufficiently elaborated under the implementing regulation. Discussions in the webinars showed that despite being particularly complex to manage, SIEF cannot be further regulated as they fall under the principle of 'freedom of contract', i.e. organisations can form contracts without government restrictions. Two participants noted that this lack of regulation and enforcement in SIEF decreases their effectiveness.

It was recommended by some interviewees from trade associations that the Commission and ECHA further address the issue of transparency in joint submissions, especially related to SMEs; support from public authorities to companies should not only take the format of technical guidance or reduced fees, but could also include control of letter of access costs within SIEF by an independent third party.

Other issues identified

Confidential information concerns as well as the costs associated with the letters of access were reported in a study by CSES (2012a) as contributing to pushing smaller firms out of the market. Issues associated with information sharing in the SIEFs and consortia are reported to arise, and in particular, relate to conflicts concerning intellectual property and confidential business information (CSES, 2012b). SIEFs may be run by larger, dominant firms or suppliers and were able to have access to participant confidential information with SMEs not being in a strong enough position to complain (CSES, 2012b; European Parliament, 2013). In a review undertaken by the Commission (COM, 2013), specific problems were identified in relation to the Lead Registrant's power and the potential for this power to result in disproportionate amounts for SIEF registration being charged, as well as a flat fee for letter of access. Another misuse of SIEF participation was also

[42] ECHA. (2020). *Registrant's guide – How to act in substance evaluation.* ECHA: Helsinki. Available at: https://echa.europa.eu/documents/10162/13628/how_to_+act_in_substance_evaluation_en.pdf/29e1197a-4d02-840b-03ed-6d02632c12ed

identified, with some companies using their participation to obtain market information on other firms (CSES, 2012a). Over 40% of SMEs agreed that "participation in SIEFs allowed some firms to abuse their dominant position". The rules of competition law were not considered to be helpful by SMEs, as resources associated with pursuing infringements were high (CEPS, 2013b). For SMEs, SIEFs were considered to present a challenge due to SMEs having few resources and thus being more vulnerable to unfair treatment as well as language barriers (COM, 2012). Several interviews with registrants in the 2018 registration deadline indicated that several of these issues were still taking place.

In addition, one economic operator indicated that SIEFs work well when led by a third-party organisation although this increases the costs.

Case study box: addressing the issue of 'free-riders'

Free riders, in the context of REACH, relates to companies that take advantage of the registration process under REACH, without paying for it. This includes companies that do not register their substances (purposely) or companies that register their chemicals while benefiting from data generated or collected in consortia, without paying consortia fees.

In 2015, ECHA reported on inspection and enforcement of compliance with registration obligations by manufacturers, importers and only representatives in close cooperation with customs (ECHA, 2015) and noted that, although there was no indication of a systematic break with the legislation for the previous registration deadlines, a small number of free riders was identified that did not register their substances at all. From the 1,169 companies inspected, ECHA identified 2% as free riders, who had not registered any of their substances (this figure does not include inspected companies with some missing registrations, which could be considered as genuine mistakes). The report further notes that the worst case investigated covered a company with seven non-compliant substances out of seven substances inspected and the highest number of non-compliant substances identified within one company was 13 (where non-compliance relates to registration and not ECHA's evaluation process). For most cases, non-compliance occurred because companies had not submitted the registration for their substances. In addition, the 2018 REACH Review (COM, 2018) highlighted free riding in registration or the maintenance of dossiers as an unintended effect but noted that the extent of such bad practices is expected to be limited.

While the above paragraph covers occurrences from the previous REACH registration deadlines, several interviewees noted that there were still free-riding issues taking place for the 2018 registration deadline. The following examples were provided:

- One company, while in a data-sharing dispute taking place just before the 2018 registration deadline, was granted access to the dossiers and effectively benefited from a registration between 2018 and 2020, despite not paying for the information.
- One national competent authority suspected that a number of companies were stealing registration numbers from safety data sheets available online. However, no evidence for this was identified from other sources in the present study.
- Several companies and trade associations indicated that free riders typically use the same data for multiple and different substances within one registration dossier, which should each have their own specific registration number.
- In another example, two companies outside of the EU, part of a consortium, only provided old data, which led to difficulties for both the consortium and ECHA to classify the substance.

ECHA indicated that it does not publish information on those so-called free riders for confidentiality reasons. However, one interviewee suspected that free riders are mostly coming from outside the EU and using Only Representatives.

Potential avenues to address free riding

One recommendation is that ECHA would have to carry out checks in much greater depth before giving out a registration number if such free riding is to be addressed. The interviewed NGO added that registration numbers should be revoked if the underlying registration data is proven to not be accurate, which would, in turn, provide an incentive for companies to submit accurate and adequate data for the registration. This is also supported by the newly launched Chemical Strategy for Sustainability, which calls on the Commission to strengthen the principles of 'no data, no market' under REACH, by requiring compliance of all registration dossiers, and where necessary, by revoking the registration numbers where non-compliance can be demonstrated. The Forum for Exchange of Information on Enforcement could also focus part of ongoing enforcement efforts within the Member States on identifying issues such as the points made above regarding falsification of registration numbers.

7. Communication obligations for downstream users

7.1 Study scope and key findings

This chapter sets out the results of work to establish and assess the major effects and cost drivers for downstream users with regard to communication obligations under REACH (Title IV, safety data sheets, substances in articles, etc.). The intention is to identify if communication has improved across supply chains and conclude on the major concerns in relation to the implementation of REACH to facilitate targeted policy responses.

Key findings

- REACH has led to an increase in costs of managing information exchange along the supply chain. However, this increase is perceived differently by companies – communication obligations, and in particular the costs of preparing eSDS, are a more significant burden for smaller companies.
- Some companies find communication in the supply chain to be a complex and time-consuming process (complex data requirements, low awareness of some small downstream users, or non-EU manufacturers, etc.) which requires significant staff involvement. This involvement does not necessarily decrease over time because of the need to update eSDS.
- eSDS (and in particular exposure scenarios) are often considered lengthy, complex and too technical for the audience they are addressed to (users, workers). Streamlining eSDS and simplifying exposure scenarios were therefore among companies' suggestions to improve communication in the supply chain.

7.2 Overview of communication obligations

Communication obligations between downstream users and suppliers ensure that relevant information is passed through the supply chain. As per Article 31 of REACH, manufacturers and importers of substances must provide their customers with a Safety data Sheet (SDS), when they supply substances or mixtures that are: (i) classified as hazardous according to the CLP Regulation, (ii) persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); and (iii) substances included in the Candidate List of substances of very high concern (SVHC).

If a hazardous substance is registered in a quantity above 10 tonnes per year, the SDS should be complemented with an exposure scenario and is referred to as Extended Safety Data Sheet (eSDS). SDSs include information on the properties and hazards of the substance or mixture; instructions for handling, disposal and transport of the substance; and exposure control measures. The annexed exposure scenario provides information on how to control exposure of workers, consumers and the environment. According to Article 31(5) of REACH, the SDS must be supplied in an official language of the Member State where the substance or mixture is placed on the market, unless the Member State concerned provides otherwise. The SDS must therefore be translated, requiring appropriate language skills.

Downstream users also have responsibilities with regards to communication in the supply chain. When receiving a safety data sheet, downstream users should apply adequate measures to control the risks linked to the substance, and check whether the exposure scenario covers their use of the substance. If not, they may

make their use known to their supplier and request an updated exposure scenario. Downstream users must also provide information on safe use to their customers, when necessary.

7.3 Communication from downstream users to suppliers

To prepare the safety data sheet and the exposure scenario, suppliers need to gather information on the uses of the substance from downstream users. Information on uses is typically collected by downstream user organisations and communicated to suppliers through sector-specific use maps. A report on the operation of REACH (COM, 2012) found that downstream users have encountered difficulties communicating their uses up the supply chain to registrants. In addition, a Commission study from 2012 identified among the factors hampering supply chain communication at the time the general lack of knowledge of companies on how and what to communicate on uses, which is demonstrated by the extensive lists of use descriptors being exchanged between EU entities such as ECHA and companies, and the difficulties in specific identifications of uses (COM, 2012). The 2018 REACH Review (COM, 2018) also identified communication within the supply chain as a central theme and found that information flows do not always work well. It reported a significant number of cases where the information provided was too lengthy and technical or does not provide enough practical information to implement appropriate risk management measures.

In interviews carried out for the present study, manufacturers confirmed that some of the issues identified in 2012 (see above) in relation to the collection of information on uses from downstream user organisations were still present, in particular the lack of knowledge on what information should be communicated. Three interviewees commented that they struggled in gathering information on uses from their customers; one of them suggested that it was not because those uses were confidential but because their customers were small companies not fully aware of REACH processes. One interviewed company suggested that when use maps are submitted by sectoral organisations to ECHA, suppliers do not receive enough information. According to the interviewee, information on uses should be better shared with the registrants, particularly the lead registrant. One company interviewed also indicated that since REACH does not currently have a legal obligation for downstream users to report on their use, upstream suppliers were not fully aware of how their substances may be used by their customers.

7.4 Communication from suppliers to downstream users

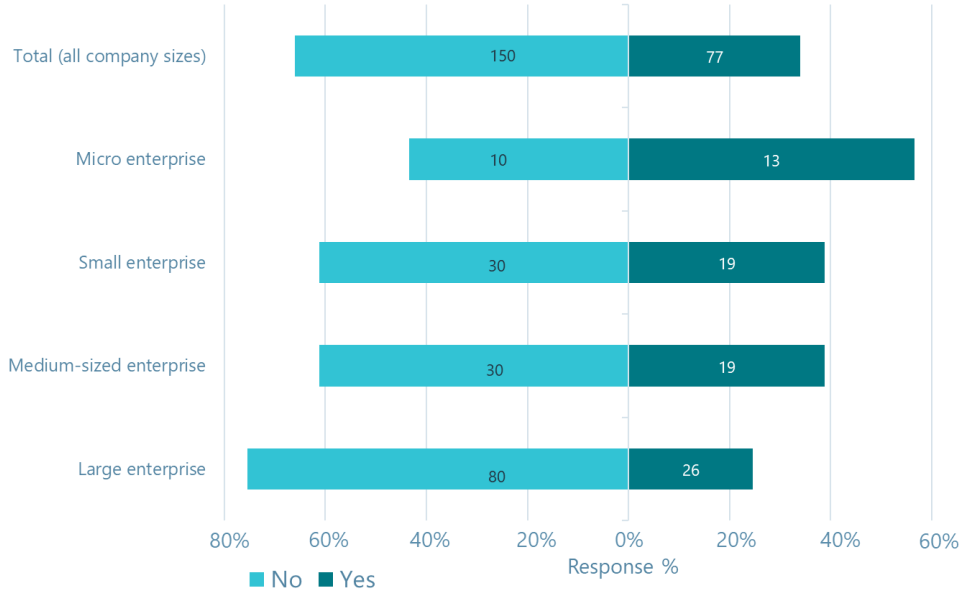
7.4.1 Cost of preparing eSDS and exposure scenarios

Literature has shown that, since the early years of REACH, communication obligations through the supply chain have increased costs of information exchange incurred by companies compared to the period before the entry into force of REACH. For instance, in a survey carried out in the 2012 interim evaluation on the functioning of the European chemical market after the introduction of REACH, it was found that for most of the respondents (close to 70%) REACH appeared to have led to an increase of the costs of managing information exchange along the supply chain (CSES, 2012a). This increase has been found to be more of a burden for SMEs. According to a Commission study from 2013, SMEs face greater difficulties and higher relative costs compared to larger companies because of the supply chain communication. In relative terms, the costs of compliance with the REACH Regulation tend to have a greater impact on the profitability of SMEs, even though this also depends on the sector and the substance involved (COM, 2013). In the 2018 REACH Review (COM, 2018), costs associated with the obligation to transmit information in the supply chain (which includes management of extended SDS and their translation) was also raised as problematic, the main reason being that most of the transmission was done manually (i.e. on paper).

The survey carried out for this study however found that most companies that responded to the survey (66%, 155 out of 235) did not consider costs associated with communication obligations as part of the 2018 REACH registration to be significant for their business. However, larger companies (75%, 80 out of 106) shared this

view more often than SMEs: around 60% of medium companies (30 out of 49) and 44% of small companies (10 out of 23), confirming findings from earlier registration deadlines that communication obligations are at least slightly more burdensome for smaller companies. This is presented in Figure 7.1. Companies and trade associations indicated during interviews that producing quality information in SDS was an important challenge for small companies as the costs to produce SDS and CSRs can be very high. These points were also made in the second webinar organised as part of this study.

Figure 7.1 Did you consider that costs associated with communication obligations as part of the 2018 REACH registration were a significant cost for your business?



Cost drivers

The main cost drivers for companies communicating information in the supply chain as reported for the first registration deadline were: the staff costs for the preparation and/or handling of eSDS, the investment in IT systems, and the time-consuming nature of communication in the supply chain, often due to a low level of awareness of this aspect of REACH among many companies, mainly with regard to small downstream users and those exporters using ORs (CSES, 2012a and CSES, 2012b). IT systems are often purchased by firms to support the handling of SDSs with costs ranging from a few thousand euros to more than a million depending on the size of the firm and the extent to which they are integrated in the firms' resources management systems (COM, 2012). An important part of these costs – investment in IT or initial development of SDSs – should be considered as one-off costs but there are still aspects that will incur on-going costs, as companies will have to keep updating SDSs and ensuring communication to downstream users for years to come. In addition, the extent of translations to be done can also influence the cost, as the typical costs for the preparation of an SDS is around €200 and over €500 for an extended version but can reach up to €2,500 in the case of translation into all European languages (CSES, 2012a).

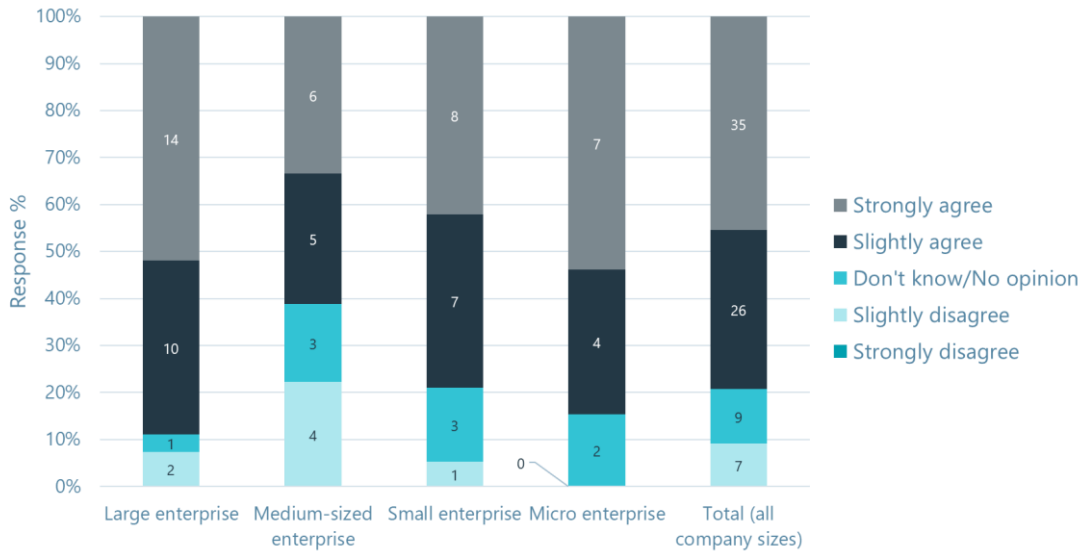
In the survey, companies that considered the costs associated with communication obligations to be significant for their businesses highlighted the complexity of communication obligations and data requirements as the main cost drivers. Respondents to the survey were asked if the following costs were significant. Costs have been ranked according to the share of respondents considering them as significant:

- Complicated data requirements associated with communication requirements (79% of respondents agreed strongly or slightly). A break-down of these responses by company size is presented in Figure 7.2, showing that the largest shares of strongly agreeing companies were

among larger and micro companies. There were no major differences in the responses of EU and non-EU companies.

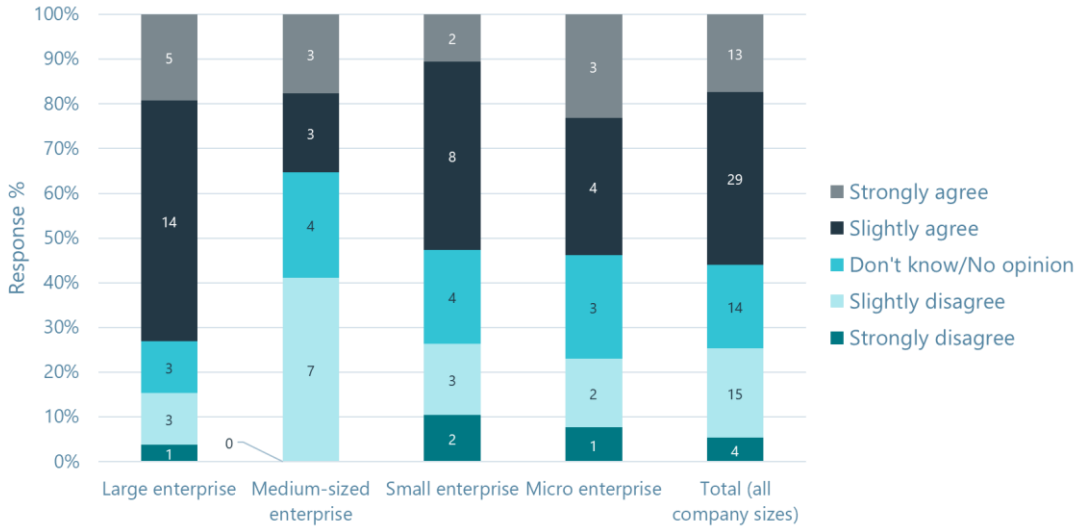
- Understanding the communication obligations (73% of respondents). While only 26% (7 out of 27) of large companies strongly agreed that this was a major cost, the share was higher the smaller the company was, with micro companies representing the largest share (46%, 6 out of 13). There were no major differences in the responses of EU and non-EU companies (i.e., roughly the same proportion of EU and non-EU companies slightly or strongly agreed with the statement).
- Poor communication from others in the supply chain (61% of respondents). A slightly higher share of small and micro companies slightly or strongly agreed that this was a major cost, although the largest share of companies strongly agreeing was among larger enterprises (37%, 10 out of 27). Among non-EU companies eight out of the ten non-EU companies that responded slightly or strongly agreed it was a major cost.
- New ways of working with their supply chain (i.e. communicating up and down the supply chain to meet the requirements of REACH) (56% of respondents). A break-down of these responses by company size is presented in Figure 7.3. showing that larger companies found it a significant cost more frequently than SMEs. There were no major differences in the responses of EU and non-EU companies.
- Time the communication obligations consumed for staff (51% of respondents). The share of companies slightly or strongly agreeing with this statement was higher among larger companies. There were no major differences in the responses of EU and non-EU companies (i.e., roughly the same proportion of EU and non-EU companies slightly or strongly agreed with the statement), although a larger share of non-EU companies strongly agreed that it was a major cost.
- Lack of single standard format for safety data sheets (52% of respondents). Smaller companies tended to see this as a more significant cost driver. Six out of nine non-EU companies that responded slightly or strongly agreed it was a major cost).

Figure 7.2 To what extent do you agree or disagree that **complicated data requirements** were a major cost of the communication obligations for the 2018 REACH registration deadline?



Note that no companies selected 'strongly disagree'

Figure 7.3 To what extent do you agree or disagree with the following statements about your communication obligations for the 2018 REACH registration deadline? **New ways of working with our supply chain was a major cost for our business**.



In the second webinar organised for this study, the complexity of the substance – e.g. whether the substance contains several components – was also mentioned as a cost driver.

Another cost driver mentioned by one interviewed consultant was the lack of knowledge of non-EU manufacturers of the EU market. The consultant explained that, when non-EU manufacturers prepare an SDS (or ask a consultant to prepare it), they do not know what uses their downstream users have in the EU and therefore, decide to have all exposure scenarios prepared, which can be very costly. As mentioned in Section 7.3, several interviewed EU companies have also reported difficulties in collecting information on uses from downstream users. Increased efforts on passing information on uses up the supply chain might help focus eSDS on customers' uses and reduce costs of preparing them.

Evidence gathered through literature and consultation tend to show that the complex and time-consuming nature of communication in the supply chain (complex data requirements, low awareness of some small downstream users, or non-EU manufacturers etc.) is a major cost driver leading to significant staff involvement, which does not necessarily decrease over the years because of the need to update eSDS. Investment in IT systems was also raised as a significant (one-off) cost that not all companies can afford.

Quantification of communication costs

As the result of the many factors that can influence the costs of communicating in the supply chain, very varied ranges of costs of preparing an SDS have been provided in the literature and in the survey. As previously mentioned, CSES, 2012a provided a cost range of €200-500, which can go up to €2,500. Another Commission study from 2012 did not provide a cost range but found that the ongoing cost of communication obligations in a company represent approximately the cost of one full time equivalent (FTE) member of staff, plus the cost of IT system installation and maintenance (per business unit) (COM, 2012). In the survey carried out for this study, respondents indicated that costs of preparing SDS ranged between €200 to €50,000. Several companies mentioned during the second webinar that the low cost of €200 was likely the cost to prepare a single SDS, and higher costs represented the cost to prepare SDS for a portfolio of substances, as it was reported that the time and cost to prepare an SDS highly depended on the number of products in a portfolio. This is broadly consistent with the 2012 study mentioned above, which cited a requirement for around 1 FTE for a typical company.

One interviewed consultant mentioned that the low cost – €200 – could be the cost of an automated SDS. Another consultant indicated that, in their experience, an SDS costs around £350 (€390) and for the translation, £100-250 (€110-280) per language. Few cost data have been found on IT systems for handling eSDS but one estimation of the cost of such IT systems is between a few thousand to over one million Euros, depending on the size of the firm and the extent to which they are integrated in the firms' resources management systems. There were no estimates regarding the costs of new/updated IT systems that would have occurred irrespective of the introduction of REACH (COM, 2012). Very few data could be collected through interviews on those costs; only one interviewed consultant indicated that the user licence for a software automating the process would be around £60,000 (circa. €67,000), which is rather on the lower end of the range indicated by the 2012 study.

7.4.2 Complexity of eSDS and exposure scenarios

In 2012, literature on the implementation of REACH already reported challenges linked to communication in the supply chain and in particular concerning eSDS. The interim evaluation on the functioning of the European chemical market after the introduction of REACH found that exchange of information along the supply chain was seen as a complicated process by companies. The main problem faced by companies in relation to handling of eSDSs was that there was no single standardised format and that eSDSs could be very long, making information extraction from downstream users time consuming (CSES, 2012a). Those challenges persisted as the ECHA report on the operation of REACH and CLP from 2016 noted that effective communication through the supply chain of information on substances and how to use them safely needed further attention (ECHA, 2016).

Interviews carried out for this study highlighted similar challenges related to communication across the supply chain. In particular, communication related to the exposure scenarios (e.g. their review, update or potential clarifications on those), remained difficult across the supply chain. Interviewees (mostly companies) frequently reported that the information contained in the registration dossier was often inadequate to develop a useful Safety Data Sheet, as it was perceived as too long and too complex. As a result, eSDS are often considered as extremely complicated or confusing, even for technical staff. Several interviewed companies highlighted that eSDS can sometimes be up to hundreds of pages of detailed information, while the key aspects for safe use of chemicals could fit on one page. Some companies (during interviews and the second webinar) considered that long eSDS are even counter-productive because they are not read. During the second webinar, participants also pointed out that SDSs received from suppliers from outside the EU sometimes miss relevant information.

However, as shown in section 9 on benefits, the increased amount and quality of information on safe use through the supply chain is considered as one of the main benefits of REACH registration, in spite of the issues highlighted above. As a result, improving communication in the supply chain may also lead to increased benefits.

Case study: Suggestions for improved communication through the supply chain through SDS

During the consultation activities carried out for this study (survey, interviews and webinars), industry stakeholders (companies and trade associations) made the following suggestions to improve communication through the supply chain through SDS:

Streamline and standardise the content of the SDS

SDS are perceived by companies as lengthy and complex, which can sometimes be counter-productive given that their main purpose is to provide users with practical information on safe use. An example of how to provide more straightforward instructions on safe use to workers was proposed in the second webinar organised for this study: in the Netherlands, workplace 'instruction cards' are made available to workers which summarise the main hazards and the safety instructions in a very practical way for a specific activity or task. In addition, the lack of standardisation of SDS was brought up by several interviewees as a factor increasing the complexity of SDS. They stressed the need for a standard template to produce SDSs.

Case study: Suggestions for improved communication through the supply chain through SDS

Re-assessing the need for exposure scenarios, or at least simplifying them.

Several participants in the second webinar explained that simplified exposure scenarios should be considered to avoid complexity and make documents more readable because internal staff also found it difficult to understand exposure scenarios. Participants noted that, in addition to general guidance, a standard template could be developed by ECHA. They also suggested that other working groups could help prepare the templates for exposure scenarios.

Making standard SDS available in all languages. Automated translation of SDS for substances with harmonised classification.

Several stakeholders brought up the issue of the translation of the eSDS in the survey, interviews and webinars. Translation was generally perceived as costly, time consuming and/or difficult, in particular for SMEs. A trade association, which has many SMEs as members, explained that most companies do not have access to an automatic tool to translate the eSDS. Suggestions made by stakeholders were generally that the producer of the eSDS should make it available in all (EU official) languages. This goes beyond the obligation under REACH to produce the eSDS in the language of the member state in which the substance or mixture is supplied (unless the Member State(s) concerned provide otherwise). It was not always clear whether the suggestions were that the supplier should be responsible for this automated translation; and it was assumed that the suggestions covered substances with harmonised classification because these are the most hazardous.

Providing XML files of all SDS in addition to pdf. A company made this suggestion with a view to increase the ease of use of the information provided in the SDS and the ability for companies to use it, as REACH already states that the SDS must be provided for free of charge on paper or electronically.

ECHA or the lead registrant providing the SDS based on the information received through registration.

The suggestion that ECHA would provide a model SDS per substance might not be feasible as information on the uses of the substance included in the registration dossier might not provide sufficient details to prepare eSDS in all cases. Participants in the second webinar highlighted that eSDS are specific to companies' uses and it is not always possible to resort a single SDS for a substance for all customers. Setting up a legal obligation of the lead registrant to provide the CSR and eSDS to joint registrants, inclusive in the price of Letter of Access (LoA).

Several participants in the second webinar disagreed with the suggestion (from the survey) that the SDS should be provided by the lead registrant within the LoA. They explained that the lead registrant might not have all the necessary information to do so because SDS and eSDS were specific to companies' uses and substances, and therefore, there would be a risk that products are placed on the market without verifying the applicability of the SDS beforehand, leading, in turn, to liability issues. This view was supported by other participants noting that, in some sectors, companies use different mixtures involving a given substance, and therefore, it would not be possible to resort to a single SDS made for all uses by the lead registrant. Participants suggested that trade associations or consortia could provide guidelines, templates and support on how to draft eSDS, while the companies themselves would actually draft them, thereby increasing the consistency and harmonisation of eSDS; one interviewed trade association stated that they were already providing such guidance on SDS and exposure scenarios to their members.

8. Resources and consultants

8.1 Scope of work and key findings

This chapter explores how registrants have adapted to REACH in the last registration deadline, whether they had adequately qualified staff in-house to deal with REACH or contracted consultants. It investigates the extent to which registration activities were outsourced and reasons for doing so, along with the type of activities outsourced. It further considers the availability and quality of consultants and progress made over time in dealing with activities to adapt to REACH.

Key findings

- For the 2018 registration deadline (and compared to the previous deadlines), companies were less likely to have a dedicated REACH unit/manager within their organisations and more likely to outsource some or all of the registration activities to consultants. This may be explained by the fact that a larger share of registrations was submitted by SMEs, which may lack sufficient staff to divert some of their activities to REACH.
- Overall, smaller companies were more likely to outsource registration activities to consultants and laboratory facilities than larger companies.
- Key reasons to outsource registration activities include the limited internal human resources as well as the lack of both technical and regulatory expertise in-house, in particular for those companies registering chemicals for the first time.
- The main tasks outsourced cover the overall preparation of the dossiers and encoding in IUCLID, SIEF/consortia management and technical support (e.g. monitoring technical studies).
- While consultants providing services of management and coordination related to SIEFs and consortia are available, there were insufficient consultants/laboratories with in-depth technical and scientific knowledge specific to certain (groups of) substances being registered, especially complex substances.
- Overall, the quality of consultants was satisfactory but the costs of services provided by external consultants were considered high by a majority of respondents, although these costs depended on the type of consultancy.
- Several suggestions for technical training and support were made by surveyed entities. These included the simplification of IUCLID, as well as step-by-step instructions to access and input information; tutorials (including videos) on steps to register; webinars on read-across; and clarity on future compliance requirements.

8.2 Reasons to outsource registration activities

The main reasons for outsourcing tasks to external consultants is the limited internal human resources and technical expertise in many companies – in particular, SMEs – to prepare registration dossiers and handle the registration process. For the first registration deadline, CSES (2012a) found that 35% of small and micro firms created a dedicated REACH unit, in contrast to 63% of surveyed large firms. In the case of multinational firms, REACH centres have often been created with the intention of increasing efficiency through the centralised coordination of REACH related work. In most of the cases (55% of the total respondents of the business

survey) REACH units occupied between 1 and 5 full time equivalent (FTE) while among smaller firms 0.5-1 FTE were typically occupied in REACH related activities (CSES, 2012a).

Similarly, a study published by ECHA in 2017 found that many companies had limited human resources, many of whom were working to meet the 2018 phase-in registration deadline. A great number of these companies interviewed as part of the ECHA study noted that the REACH 2018 registration deadline, when combined with data requests for REACH substance evaluations (i.e. both the 2018 REACH registration and ongoing substance evaluation taking place at the same time) and the need to update dossiers placed significant burdens on them. The same study found that SMEs had very limited resources and often little regulatory expertise in REACH – and as such were even more burdened by the direct costs of registration (ECHA, 2017a).

The survey results for this study confirmed the above earlier findings that SMEs have in general less in-house staff allocated to REACH activities, increasing the reliance on external support. 73% of companies that replied to the survey mentioned that they have only allocated one or less than one FTE for the REACH 2018 registration activities, with a higher proportion among SMEs[43]. 24% (28 out of 116) of large enterprises have allocated between 2 and 5 FTEs and only 1% of companies (3 out of 258), all large companies, have allocated more than 15 FTE for the REACH 2018 registration activities.

In addition to the lack of staff, the lack of technical expertise was mentioned by interviewed companies as a reason to outsource registration tasks to consultants. For companies producing/importing a small number of substances, it was not considered efficient to build capacity to deal with REACH within the company. Similarly, most SMEs lacked the understanding of the regulations and needed quick advice regarding compliance and ways to address public authorities. Regulatory advice from consultants was particularly useful in the 2018 registration deadline for companies with no previous experience with REACH registration. In addition, the absence of in-house technical knowledge and expertise to cover testing etc., which were outsourced to laboratories, especially for SMEs that do not generally hold testing facilities.

In relation to consortia, another reason mentioned by some companies was having a third-party organisation, that could act on behalf of the consortium, in an independent and fair way (including cost sharing among members of the consortium). This was particularly relevant for larger consortia that include several competitors.

Overall, findings from this study confirmed that companies registering chemicals still outsourced some or all of their activities to external resources, such as consultants or laboratories, as was the case for the previous registration deadlines. Findings show that the reasons to outsource some of the registration activities were similar for the 2018 registration deadline to the reasons for previous deadlines, including:

- Limited human resources within the company, especially for SMEs with fewer staff that can be diverted to REACH activities. Only a minority of large companies were able to allocate a large number of staff to such activities. Given the high number of SMEs involved in this registration phase (as shown in section 3), this can be expected to be a key factor limiting the ability of registrants to carry out all registration activities in-house.
- Lack of technical expertise within the company, for example for testing, which was outsourced to laboratories. This is mainly the case for SMEs which generally do not hold testing facilities in-house.
- Lack of regulatory expertise within the company, in particular for those registering chemicals for the first time.

[43] 61% (71 out of 116) of large, 84% (45 out of 54) of medium-sized, 80% (49 out of 61) of small and 86% (23 out of 27) of micro-sized enterprises.

8.3 Extent to which registration is outsourced

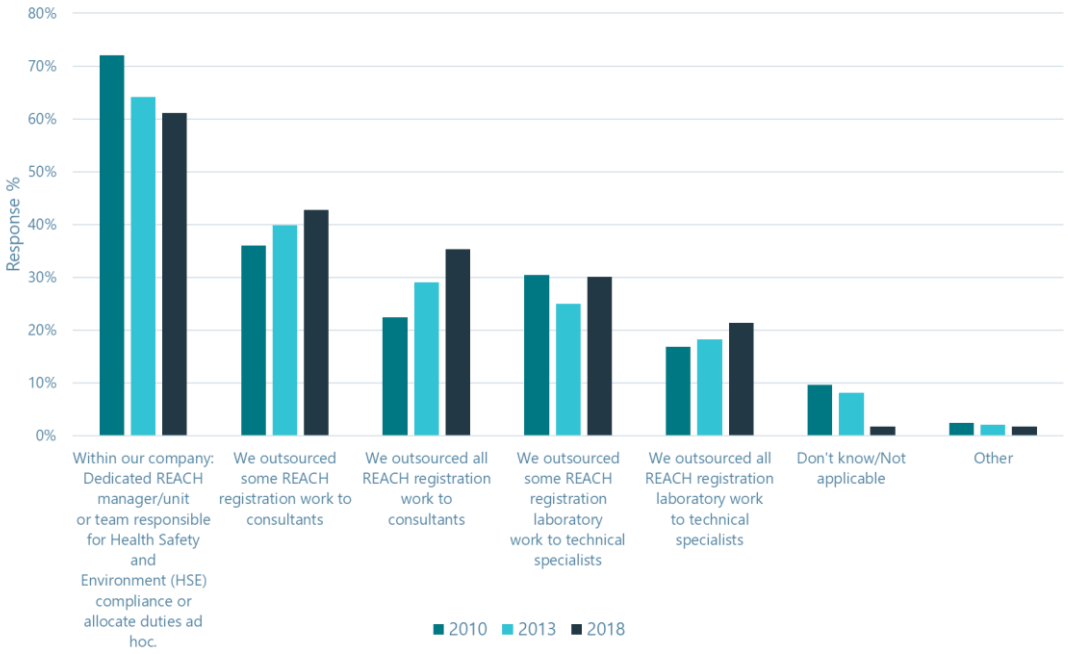
The literature on the implementation of REACH shows that consultants have been hired by companies for each registration deadline. For the first registration deadline, external consultants were used to a significant extent by companies instead of or in addition to in-house staff with small companies often outsourcing most of their REACH-related activities (CSES, 2012a). The extensive reliance of SMEs on consultants, due to limitations in in-house staff, was confirmed by a report from CEPS (CEPS, 2013b).

Findings from this study confirm those from previous registration deadlines in that, for the 2018 deadline, most companies outsourced some or all of the registration work to either consultants and/or laboratory facilities, as illustrated in the figures below. It was possible for respondents to select more than one response, and hence some companies had a unit/staff covering REACH while also outsourcing parts of the activities. Findings show the following trends which can be observed in the two figures below:

- **Companies resourced their REACH registration activities differently through time (figure 9.1):**
  - For the 2018 deadline, companies were less likely to have a dedicated REACH unit/manager within their organisation than for previous registration deadlines (about 60% in 2018, versus over 70% in 2010). This may be explained by the fact that a larger share of registrations was submitted by SMEs, which sometimes lack sufficient staff to divert some activities to REACH.
  - Companies were more likely to outsource some or all of the registration activities to consultants in 2018 compared to the previous deadlines. This increase is more pronounced for companies outsourcing all registration activities to consultants (about 35% in 2018, versus a little over 20% in 2010).
  - The evolution (between 2010 and 2018) of outsourcing some or all activities to laboratory facilities did not show any particular trend.
- **For the 2018 registration deadline, (in figure 9.2) smaller companies were more likely to outsource registration activities to consultants and laboratory facilities:**
  - While over 80% of large and 70% of medium-sized companies had a dedicated REACH unit/manager, only 30% of small and micro companies were able to have one. This is mirrored by the findings that both medium, small and micro-sized companies were found to outsource some registration activities to consultants[44] and, in fact, 50% of small and micro-sized companies outsourced all activities to consultants, versus about 20% of larger companies.
  - While larger companies only needed to outsource some of the work to laboratory facilities, medium and small sized companies were more likely to outsource all of the laboratory work.
- For countries with the greatest number of respondents (i.e. France, Germany, Italy, Spain, UK, which were also countries with the highest number of registrations), over a third of companies taking the survey had a dedicated REACH unit for France, Italy and Spain, and up to about two thirds for the UK and Germany. In a similar trend, registrants from the UK and Germany were less likely to outsource all registration activities to consultants. The number of responses for other countries was not sufficient to draw out meaningful conclusions at this level of granularity.

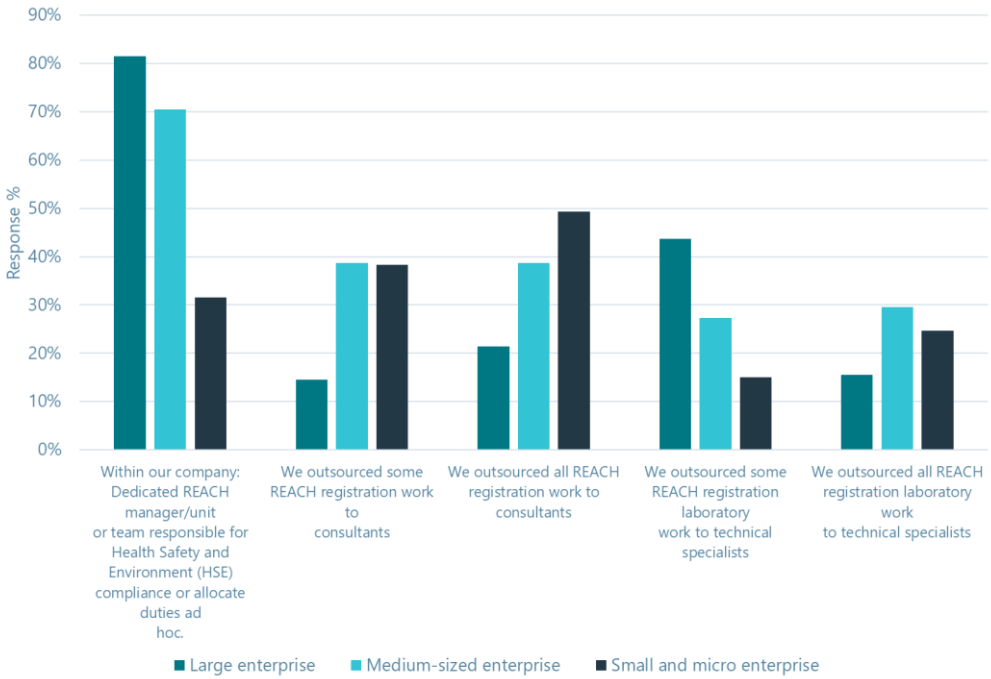
[44] 77% (17 out of 22) of medium, 88% (21 out of 24) of small and 86% (6 out of 7) of micro companies in 1 to 10 tonne band; and 76% (16 out of 21) of medium, 93% (27 out of 29 of small, and 92% (12 out of 13) of micro companies in 10 to 100 tonne band.

Figure 8.1 Ways to resource REACH registration activities **across registration deadlines** (2010, 2013, 2018)



Total responses = 274; for 2018 = 229; for 2013 = 148; and for 2010 = 125.

Figure 8.2 Ways to resource REACH registration activities in the 2018 registration deadline, **across company sizes**



Total responses = 220; Large companies = 103; medium-sized companies = 44; small and micro-enterprises = 73 (merged for confidentiality reasons).

8.4 Type of activities outsourced

During the first registration deadline in 2010, small firms often outsourced most REACH related activities including the preparation of registration dossiers, the communication within SIEFs and the exchange of information with suppliers and customers limiting the internal resources dedicated. Large and small firms also used consultants for legal or technical support or for training in relation to specific aspects of REACH. Regarding testing, 89% (88% for large firms and 93% for SMEs) of respondents (38% of which were SMEs) used external laboratories, of which 52% "sometimes", and 37% "always" (CSES, 2012a).

Findings from this study are consistent with the above, revealing that the tasks carried out by consultants for the 2018 registration deadline were similar to what was found in 2012 and were mostly:

- The overall preparation of dossiers and the encoding of the dossier in IUCLID[45]. Staff from several companies interviewed had initially undertaken self-training but preferred to outsource these activities, given the complexity of IUCLID and the regular changes to the platform. Encoding the dossier in IUCLID was considered particularly time-consuming for SMEs.
- SIEF/consortia management: coordinating a consortium, representation of companies in the SIEF and/or consortium, financial management, cost sharing, invoicing, etc.
- Technical support: monitoring technical studies (e.g., exposure assessments) where in-house staff do not have sufficient expertise, interacting with the laboratories, data gaps, assessment of complex substances, read-across justifications, communication with authorities and legal advice.

8.5 Capacity and quality of consultants

Interviews with companies showed that there is a reasonable number of consultants that can cover the management and coordination activities for SIEF/consortia. One trade association indicated that the availability of qualified consultants had improved for the 2018 deadline, since 2010.

However, there is a lack of consultants/laboratories with in-depth technical and scientific knowledge that is specific to certain (groups of) substances being registered. In particular for complex substances, the number of laboratories able to carry out the appropriate testing was limited.

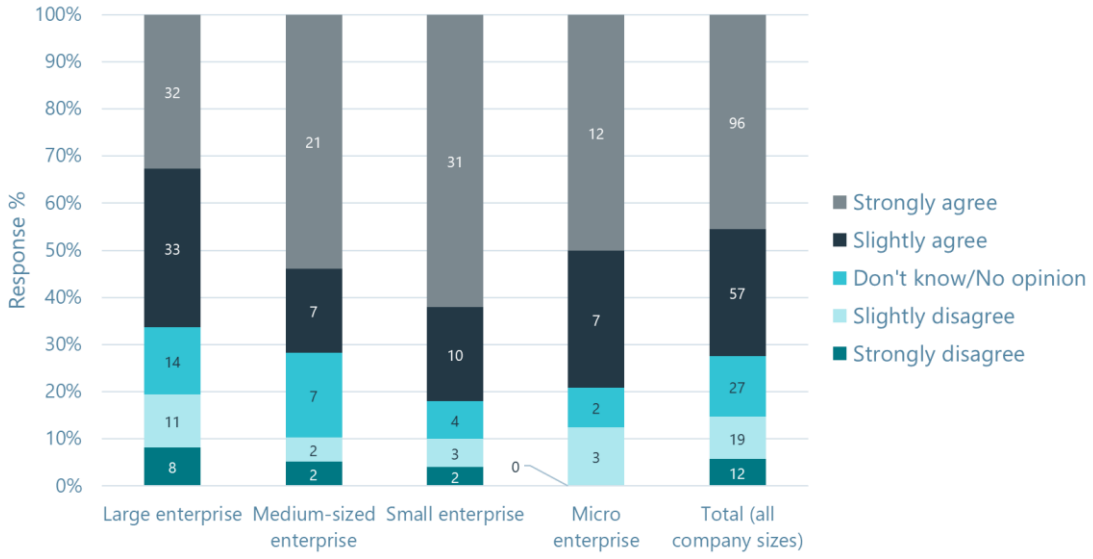
As a result, laboratories and testing facilities have reportedly been overwhelmed with requests for analysis before the 2018 deadline: in particular, tests to comply with the 2018 registration deadline took place at the same time as testing proposals following up from the previous deadlines, which led to overwhelmed laboratories, and delays in carrying out all studies commissioned, which was reported by several companies as an issue to comply with the deadline in 2018. Some companies were able to submit an incomplete dossier on IUCLID, while waiting for the analysis results to arrive, rather than miss the deadline. When the results came in, they were able to submit a full dossier and were informed by ECHA that the registration was accepted. To address this particular issue, ECHA reported that solutions were put in place in 2018 (similarly to 2010 and 2013) by the Directors' Contact Group[46], to enable registrants that find themselves in exceptional circumstances to still be compliant with the registration obligations. The most used solution was the Directors' Contact Group's solution 10.3 (638 applications for this solution out of 672 applications for DCG solutions, of which 562 were granted). This solution allows registrants to be compliant with REACH

[45] IUCLID is a free software package, co-developed by ECHA and the OECD, to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances. REACH registration dossiers submitted to ECHA must be in IUCLID format.
[46] The Directors' Contact Group (DCG) is a platform for the informal exchange of views and information between ECHA, the European Commission, and participating Industry Associations, with the objective to provide support and orientation to duty-holders under the REACH 2018 registration deadline, in particular small and medium-sized companies.

obligations even when the data required in Annexes VII and VIII was not yet available by the deadline, by submitting evidence that laboratory studies had been ordered in a timely manner (including information such as detailed estimates, quotations, purchase orders and contracts with those laboratories that perform studies on the relevant information requirements). As a consequence, companies were given a reasonable amount of time to complete their dossiers. Several companies interviewed expected a similar issue to take place with the numerous requests for updates in the future. One recommendation made was that such requests be better timed in the future (e.g. updates, testing proposals) to ensure that industry, as well as consultants and laboratories, can better plan resourcing and prioritise.

Results showed that most companies were satisfied with the services provided by hired consultants: 73%, (153 out of 211) and respondents across all company sizes, considered that the services provided by consultants were of good quality while 15% (31 out of 211) did not consider the services were of good quality and 13% (27 out of 211) did not have an opinion, as reported in the figure below. Companies which indicated that the services of consultants were not of high quality were mainly located in the US, Spain and Italy, although the survey did not investigate the origin of the consultancies. In addition, 19 out of the 31 respondents making this statement were large, 4 medium, 5 small and 3 micro. Companies interviewed added that consultants had built knowledge with industry over time, since 2010, as well as gained in both understanding and efficiency in the registration process.

Figure 8.3 Do you agree or disagree that the services provided by external consultants were of good quality?



8.6 Costs of outsourcing to consultants

Although the above sections pointed to the necessity of outsourcing some or all registration activities for smaller companies, hiring consultants represents a non-negligible cost for SMEs. The available literature does not provide figures on consultants' fees for any of the registration deadlines, except one study which provides an indication of the magnitude of these costs, by looking at the share of consultation fees out of the overall registration costs. They found that, for the first registration deadline, the costs of consultants corresponded to some 10% of registration costs, at times toward 10%-25% (European Parliament, 2013). Although the present study did not seek to confirm those figures, results from the survey show that most respondents (71%, 151 out of 214) considered that the cost of services provided by external consultants were high while 17% (35 out of 214) did not consider those costs high and 13% (28 out of 214) did not have an

opinion. A similar proportion of large and small/medium-sized companies thought that the cost of services provided by consultants was high. No geographical pattern could be observed.

This general trend was not systematically confirmed in interviews as opinions from companies interviewed on the on the cost of consultants diverged. Companies consulted agreed that the costs would depend on the type of consultancy (firms, freelancers, etc.) and based on individuals. In addition, it is often difficult to accurately assess the amount that will be spent on consultants, as companies cannot anticipate the future requirements from ECHA, such as testing proposals, updates, etc., for which consultants' inputs will be necessary. Increased competition among consultants (to address the shortage for some technical aspects) would improve value for money and availability. Several companies, especially SMEs, estimated, however, that it was less expensive to hire a consultant than to establish a REACH department in-house. For such cases, in 2016, ECHA drafted a 'practical guide for SME managers and REACH coordinators'[47], supporting SMEs to fulfil their information requirements at tonnages 1-10 and 10-100 tonnes per year and to help them understand what they needed (and did not need) to provide to / require from consultants.

8.7 Training

In-house training often took the form of self-training, the cost of which interviewees reported as very difficult to quantify. Less than 10% of survey respondents were able to provide estimates for the cost of training: on average, costs of training were about €3,500 (range of €100 to €16,000) for the 1-10t substances and €4,000 (range of €100 to €26,000) for the 10-100t substances. Such training covered compliance with the general REACH registration procedures and obligations, as well as on Safety Data Sheets and IT tools. The fact that continuous training was necessary to keep up to date (versus one-off starter training) was perceived as a challenge in terms of planning and resources.

Companies interviewed frequently reported that training organised and provided by industry associations, from helpdesks and/or ECHA were perceived as very useful and important in improving the registration process. Free training provided by ECHA, as well as guidance documents on its website have considerably limited the financial impacts of training costs for organisations. Companies however mentioned that the information can be sometimes difficult to find on the ECHA website, given the large number of available resources (e.g. webpages, documents, etc.).

While overall, surveyed entities had positive feedback on the training and support provided by ECHA and national helpdesks, several suggestions were made:

- Support registrants on definitions and concepts: several respondents indicated that there was a need for more precise definitions, along with a guide to ensure a common understanding and interpretations of key concepts, as well as a clear interpretation of legal texts. However, respondents did not elaborate on which definitions and concepts they thought were ambiguous.
- Increase direct and informal contacts with ECHA: several respondents thought it would be helpful to have direct, faster and sometimes informal contact with ECHA, especially regarding complex issues, including on cost-sharing within SIEFs. However, while recognising the benefits from such contact, it was clearly not practicable for ECHA to have individual contact with many/all registrants, given their high number.
- Further technical training and support on:

[47] Available at https://echa.europa.eu/documents/10162/13655/pg_sme_managers_reach_coordinators_en.pdf/1253d9f9-d1f0-4ca8-9e7a-c81e337e3a7d

- Simplification of IUCLID, as well as step-by-step instructions to access and input information.
- Tutorials (including videos) on steps to register: One respondent noted that such a tutorial was provided by ECHA but too close to the deadline. There were several requests for hands-on examples through videos, to avoid further guides and documentation to read.
- On the preparation of exposure scenarios and CSRs.
- Webinars on read-across.

- Provide clarity on future compliance requirements, e.g. on polymer registration.

9. Benefits to companies

9.1 Study scope and key findings

This chapter aims to assess whether gathering information for the purpose of registration has led to positive impacts for businesses, e.g. better physicochemical and (eco)toxicological information on substances at company level, advantages from increased product awareness, improved knowledge on the use of substances and exposure levels, or improved risk management measures, etc.

Key findings

- Companies generally struggled to identify direct benefits to companies from REACH registration. Those who did highlighted that REACH registration can be considered as a competitive advantage and that it increased the transparency of the market.
- Benefits that have already materialised, following the three registration deadlines, are the availability of information on substances and the dissemination of information on safe use through the supply chain is considered as a significant benefit from REACH registration, as it has had a positive effect on risk management practices and occupational safety in companies.
- Increased information on substances seems to encourage companies to reduce the use of hazardous chemicals, although results are less clear cut on this issue.

9.2 Overview of expected benefits

Benefits of REACH can refer to **direct benefits to companies**, in terms of competition, market transparency, knowledge, innovation, risk management, etc. and to **wider benefits to workers, consumers, society and the environment**.

Studies published before or shortly after the adoption of REACH anticipated that both benefits for companies and benefits for society and the environment would occur, generally considering that they would take time to materialise and would be hard to quantify. A study published in 2008 (Van Wassenhove, 2008) anticipated benefits in four main areas:

- A stronger tendency to innovate with respect to safer chemicals.
- Improvements in occupational health and environmental effects.
- A common standard within the EU decreasing transaction costs for companies operating in more than one country.
- Improving the reputation of European chemicals.

The 2003 impact assessment of REACH expected environmental and health benefits for the population as a whole, as well as benefits in terms of the availability of information on chemicals and increased transparency and awareness within the industries and their supplier industries. A potential positive effect of REACH was thought to be greater specialisation amongst chemical suppliers and new business models (like chemical

leasing[48]) that may increase safety (COM, 2013). The contribution to firms' operations and their competitiveness, not yet observable after the first registration deadline, could possibly become more visible after the second and third registration deadline (CSES, 2012a). It was anticipated before the adoption of REACH that environmental and health benefits would only begin to materialise from 2018 (COM, 2003). Several other studies also concluded that concrete evidence of those benefits would only be seen in the longer term (COM, 2016a). Based on this timeline, it is difficult to link benefits to a specific registration deadline, and benefits are mostly considered in the literature and by stakeholders as general benefits resulting from the implementation of REACH.

The information gathering for this study has largely focused on direct benefits to companies through the survey, which aimed to verify whether stakeholders had seen some of the benefits mentioned above materialise for their companies. Wider benefits were investigated through the literature review, the survey (which asked companies about their activities to protect health, safety and the environment), and addressed in most interviews.

9.3 Economic benefits for companies

Direct economic benefits for companies as listed above were anticipated to some extent in early impact assessments, however, the materialisation of such benefits has been and is still subject to debate among companies.

In 2012 it was still considered too early to identify a material contribution to firms' operations and their competitiveness, and that REACH had not had, at least at that point in time, made a sizable contribution to increasing consumer confidence for chemical products (CSES, 2012a). More benefits were expected after the second and third registration deadlines; however, most firms were still sceptical of the potential of REACH to provide direct benefits to companies. Potential benefits from the information exchange requirements arising from REACH were overshadowed by the costs and the challenges of supply chain communication; benefits in terms of risk management procedures could not yet be linked to cost reduction related to occupational health and safety or benefits linked to improved knowledge on the uses and properties of chemical substances had not yet translated (and might not fully translate in the future) into business opportunities (CSES, 2012a).

In 2017, "softer" benefits related to REACH were reported (ECHA, 2017a). For instance, there was improved understanding of substances that companies use and better visibility of the supply chain, particularly for downstream users. In addition, the REACH Regulation had also empowered some companies, giving them a stronger position to work with suppliers on impurities in substances of very high concern (SVHCs). However, it was also found that these benefits were lower priority compared to day-to-day business, and the benefits would not outweigh the costs of REACH registration. In addition, SMEs had a more negative view indicating that the process for them had been particularly burdensome with little or no obvious rewards from having been compliant.

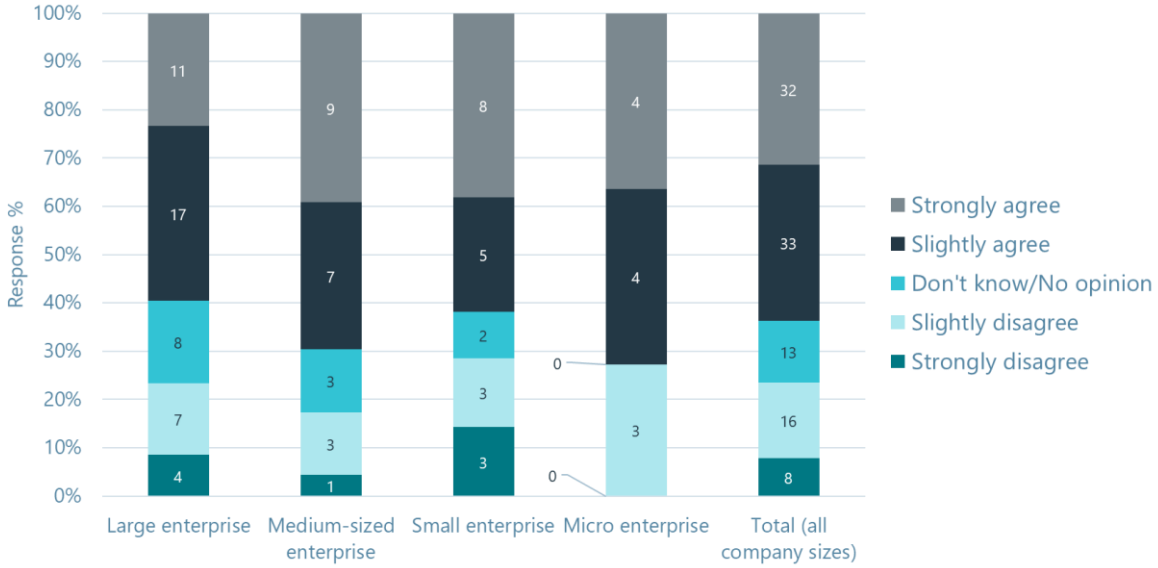
In 2020, the survey, interviews and webinars carried out for this study confirmed that the level of scepticism of companies in relation to economic benefits for companies is still quite high and the general impression is that costs are more significant than benefits. When asked about benefits from registration, interviewees (companies and consortia managers) often said they were limited or overshadowed by costs. In the survey, when asked whether they saw wider benefits from registering substances under REACH, most companies (58%, 142 out of 246) replied that they have not seen benefits and do not expect to see benefits in the future,

[48] Chemical leasing is a business model in which a company does not buy the chemical but purchases the services that chemicals provide. More information on this business model can be found at: https://newsletter.echa.europa.eu/home/-/newsletter/entry/4_15_chemical-leasing-the-way-forward

23% (56 out of 246) only expect benefits to materialise in the future and 19% (48 out of 246) stated that they had already seen benefits from registering substances.

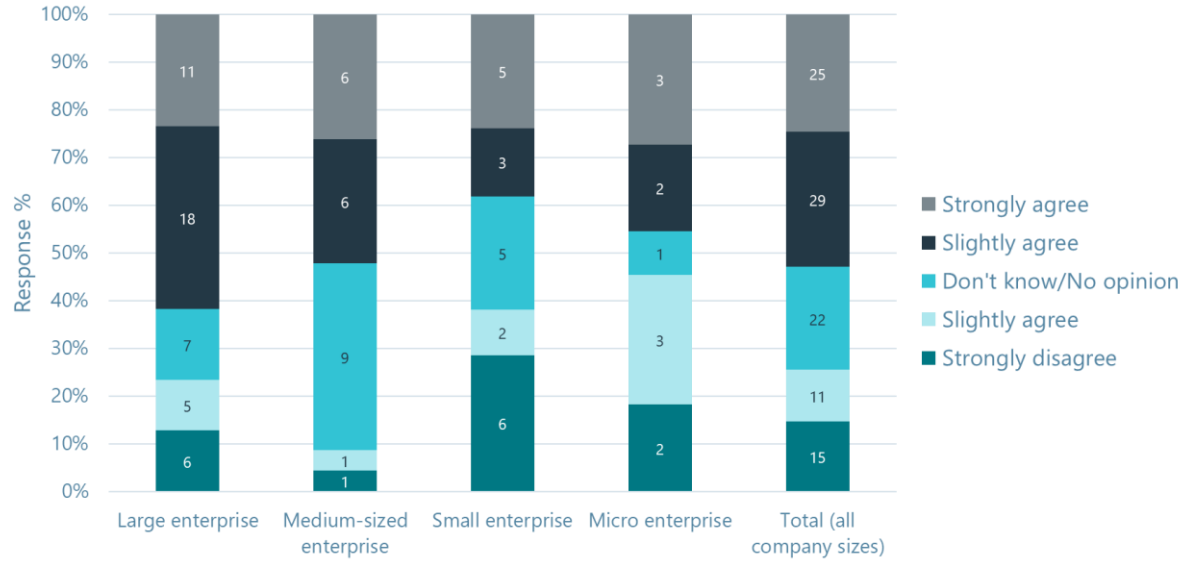
Among the companies that had already seen benefits from registration or expect some in the future[49], 63% (65 out of 103), have reported that REACH registration (all deadlines together) is a competitive advantage to their business, beyond the legal requirement. Figure 9.1 presents these results. The proportion of companies 'strongly agreeing' with this statement was higher for medium, small and micro enterprises compared to large enterprises. In terms of cost reduction, 64% (64 out of 101) of those companies that have seen or expect benefits in the future also indicated having used REACH registration information to comply with other EU legislation and 53% (55 out of 103) to comply with legislation outside the EU. Finally, 52% (54 out of 103) of companies have reported that REACH registration improved the functioning of the EU market via increased transparency, fairness etc. Figure 9.2 presents these results. These results should however be read in light of the fact that 58% (142 out of 246) of companies indicated that they did not see any benefits to REACH registration.

Figure 9.1 What benefits has your company seen - or do you expect - from the REACH registration? **A REACH registration is a competitive advantage to our business – beyond the legal requirement.**



[49] Companies that replied that they have not seen benefits and do not expect to see benefits in the future (142 out of 246) did not reply to this question asking which benefits companies had seen or were expecting. 104 companies (around 42%) indicated that they have seen or expect benefits; not all of them have answered all questions, which explains that totals vary between 101 and 104.

Figure 9.2 What benefits has your company seen - or you expect - from the REACH registration? '**It has improved the functioning of the EU market via increased transparency, fairness, etc.'.**



The survey and interviews also provided other examples of economic benefits that companies had identified, which might be linked to the specific situation of each company and might not be taken as representative for the situations of all companies. During interviews, one large and one micro company indicated that REACH registration brings commercial benefits as it is improving the company's reputation and increasing client's trust in the safety of the product they manufacture. The micro company also mentioned that the registration increased their own confidence as manufacturers regarding the safety and quality of their product. The large company indicated that it changed the way they market and advertise their products. Two other small and micro companies made a similar point in the survey about increasing their credibility and visibility on the market. A consultancy reported that a lot of the companies they work with register for commercial reasons. Some of these companies did not have to register for the 2018 deadline because of the tonnage band but did so because they thought it would give them a competitive advantage by being REACH compliant. One company also mentioned in an interview that the REACH registration led them to rethink their development model and to better forecast the future, taking into account current and potential future regulatory trends to adapt their production. In the survey, it was also reported by two companies that the number of competitors on the market had been reduced following registration deadlines.

9.4 Reducing the use of hazardous chemicals

The REACH baseline study five and ten year updates (Eurostat 2012; European Commission, 2017b) showed evidence of a reduction in the use of hazardous chemicals linked to the first and second registration deadlines (2010 and 2013). The REACH baseline study developed a methodology to assess the nominal risk of a registered substance and the quality of data available to assess the risk. The five- and ten-years updates showed a marked decrease in the nominal risk associated with the registered substances which was largely believed to be due to REACH. Secondly, the results of both updates show a marked increase in the quality of the data, which are available for the chemical assessment of the registered reference substances. Such results are not yet available in connection with the 2018 registration deadline.

Although results from the survey are less clear cut, 46% of respondents did state that they have reduced hazardous chemical use; those respondents were mainly larger companies rather than smaller ones[50].

[50] 59% (28 out of 47) of larger enterprises agreed they reduced hazardous chemical use, compared to 35% (8 out of 23) of medium companies, 38% (8 out of 21) of small companies, and 20% (2 out of 10) of micro companies.

Companies were more divided when asked whether their portfolios contain more substances with lower hazards. Regarding the quality of the available data on substances, nine interviewed stakeholders (out of 22, companies, trade associations, consultants) confirmed that the increased knowledge on substance properties for all substances in companies' portfolios – not only the main ones – and the improvement of classification of substances were benefits for companies and that this is directly attributable to REACH (all registration deadlines). The NGO interviewed also noted that a registration provides the NGO with information about specific chemicals. This information is useful for NGOs, and the NGO reported that they would like to see more information on the lower tonnage bands.

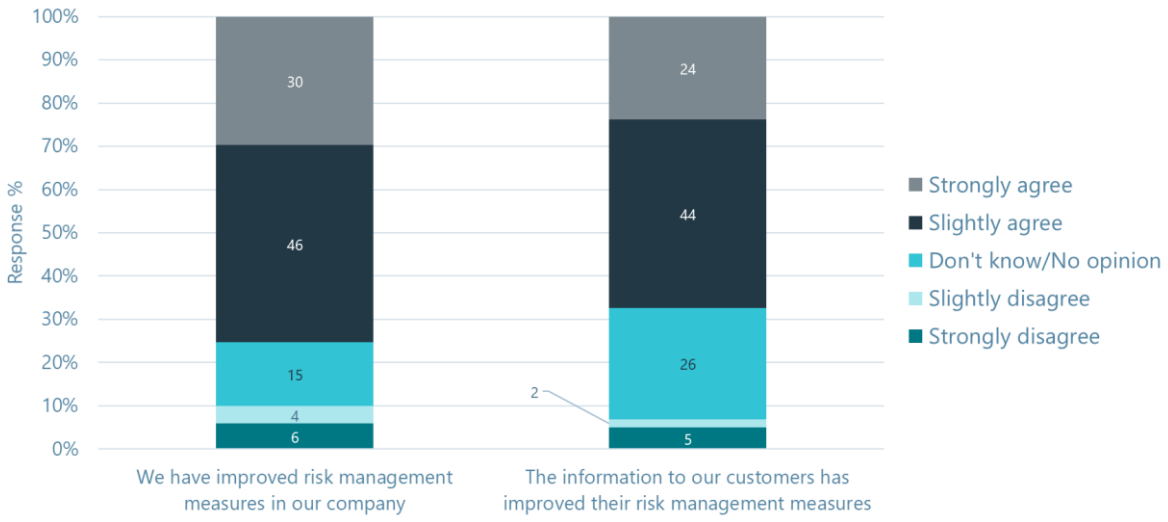
9.5 Improved risk management and information on safe use in companies

Evidence was found that benefits have already materialised, following the three registration deadlines, in terms of improved risk management and occupational safety and dissemination of information on safe use in the supply chain.

In 2016 one report identified benefits in terms of the availability of information on chemicals and increased transparency and awareness within the industries and their supplier industries (COM, 2016a). A survey which assessed the impact and costs for companies to prepare for the 2018 deadline also aimed to identify the main benefits associated with preparing a REACH registration (ECHA, 2018a). That study found that 73% of registrants saw some benefits, with the largest benefit identified across companies of all sizes to be 'more information on substance properties'. Companies then found 'improved information on safety to our customers' to be the second biggest benefit, although it was observed that larger companies derived more benefits from preparing a REACH registration.

According to the survey and interviews carried out for this study, the availability of information on substances and the dissemination of information on safe use through the supply chain was a significant benefit from the REACH registration deadline. Companies participating in the survey have generally acknowledged that improved information in the supply chain had a positive impact on risk management in companies. Among companies that indicated in the survey that they have seen or expect benefits from REACH registration in the future, 69% (69 out of 101) agreed that the information provided to their customers has improved their customers' risk management measures. In addition, 76% (76 out of 101) of those companies indicated that they have improved risk management measures within their company, as a result of the REACH registration. Figure 9.3 presents these results from the survey. As previously mentioned, these results should be read considering that 58% (142 out of 246) of companies indicated that they did not see any benefits to REACH registration. As an example of improve risk management measure, one trade association mentioned in an interview that one of their member companies strengthened training in the company if a chemical was classified as hazardous (carcinogenic or similar) on the basis of the information from REACH, which reportedly worked very well. These findings provide some context to the findings of section 6 on communication obligations. Although communication obligations are perceived as burdensome, especially for SMEs, they are also perceived as the main driver for occupational health and safety benefits in companies. Streamlining and simplifying communication obligations then appear as a potentially beneficial improvement as it would ensure that extended Safety Data Sheets are more effectively used by companies to improve risk management.

Figure 9.3 Expected or current risk management benefits from REACH registration



10. Effects on the EU chemicals market

10.1 Scope of work and key findings

The aim of this chapter is to set out the results of work to identify and evaluate any structural changes resulting from registration under the REACH 2018 registration deadline. The focus is on any changes in prices, supply stability and the availability of chemical substances (withdrawals) in the EU. Differentiation is made between sectors affected by registration obligations, as well as company size and their role under REACH. Specific impacts on SMEs are also considered.

Key findings

- In terms of effects on portfolios and prices, most companies reported absorbing the 2018 REACH registration costs by reducing profit margins. There were only slight impacts from the REACH 2018 registration deadline reported on both profits and operating costs.
- Other, non-REACH business-related events, such as other market dynamics and economic cycles, will also affect product prices, substance withdrawals and other commercial decisions around substances.
- Only limited change has been reported to levels of research and development as a result of the 2018 REACH registration deadline.
- The REACH 2018 registration deadline had no obvious impact on the volume of sales of chemicals in Europe, or on the volume of imports of chemical substances/mixtures/articles. This is borne out by both survey responses and market statistics.

10.2 European chemical industry

The chemical industry is one of the European Union's largest manufacturing sectors with sales of €565 billion in 2018, generating 1.1% of EU gross domestic product (GDP) and representing around 17% of global chemicals sales. Including both EU and non-EU countries, total European chemicals sales were €694 billion in 2018, representing 20.7% of world output[51]. EU production of chemicals has fallen over the last ten years and its share of world markets declined in the last 20 years, with emerging market growth, in particular China, which is now top of the global sales ranking. In 2018, twelve of the top 30 largest chemical-producing countries were in Asia and represented 56.4% of world chemical sales.[52]

More recently, it is reported that investment share in primary production is falling, leading to Europe losing ground in technological capability with a risk posed to European value chains. Protectionism and a lack of growth in other manufacturing industries is resulting in a weaker demand for chemicals. EU chemical industry production has declined since 2018, and EU market share has halved in the past two decades, despite European chemical sales globally ranking second. China continues to grow its chemical industry, with its demand for chemicals also growing[53].

Figure 10.4 presents the evolution of the EU-27 sales levels and structure (home sales, intra-EU sales and foreign sales) and the evolution of the EU share of the global market for chemicals between 2009 and 2019. Since 2009, the highest EU-27 chemicals sales occurred in 2018 at €550 billion, and second highest was in

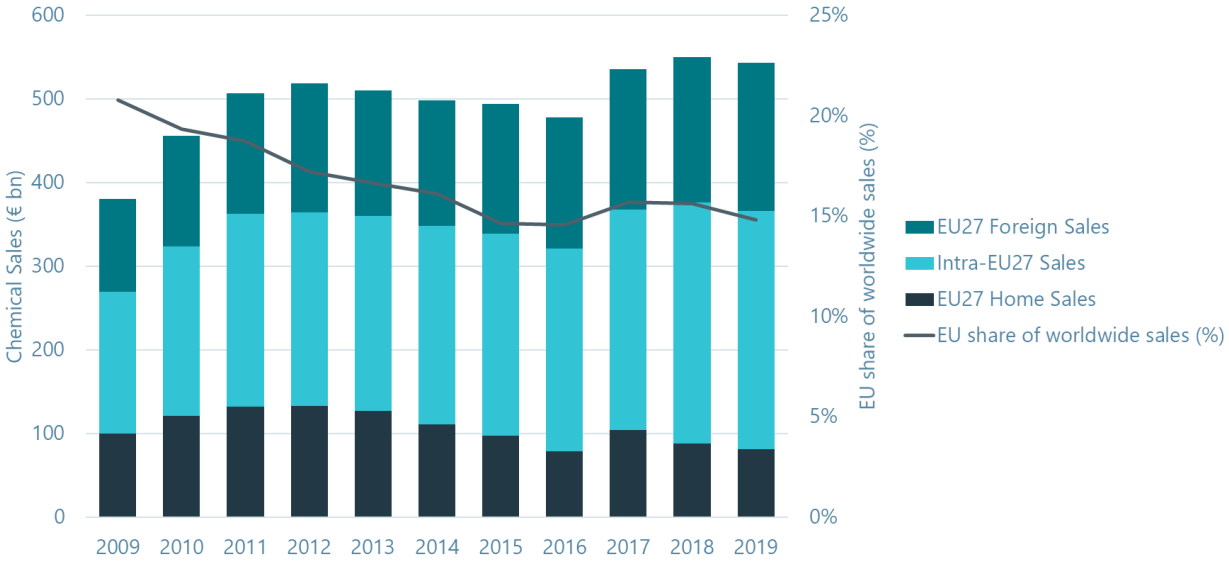
[51] https://www.chemlandscape.cefic.org/wp-content/uploads/pdfs/EU28-23.pdf
[52] https://www.chemlandscape.cefic.org/wp-content/uploads/pdfs/EU28-23.pdf
[53] https://www.chemlandscape.cefic.org/country/eu/

2019 at €543 billion. Figure 10.5 presents EU-27 chemical sales as a proportion of total world chemical sales. Growth in extra-EU27 exports has been continuous from €149.4 in 2014 and reaching €177.5 billion in 2019.[54] Whilst growth is occurring globally in the chemicals market, the EU's share is decreasing, due to the factors discussed above.

It is expected that overall growth in world chemicals sales is predicted to continue, increasing from €3.7 trillion in 2019 to €6.2 trillion in 2030.[55] It is predicted that the EU will lead in speciality chemicals, with an expected continued increase in production value of speciality chemicals, of which many will be 1-10 tonne and 10-100 tonne substances. In 2019, the EU27 and the UK had a speciality chemical production value of €260.9 billion. This is expected to reach €323.8 billion by 2030.[56]

The above highlights that there has been no discernible impact on overall market as a result of the REACH 2018 deadline. Although, data and figures do not provide information on whether REACH costs depressed the level of growth that occurred.

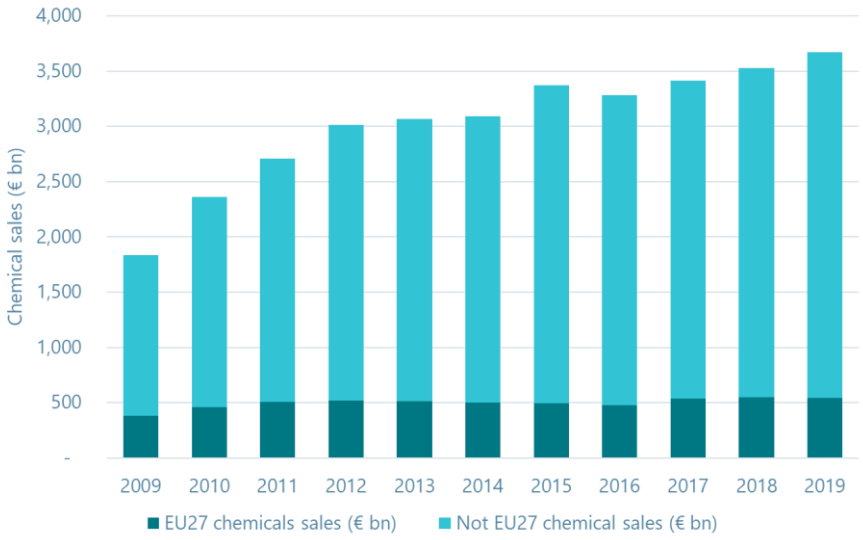
Figure 10.1 EU27 sales and global market share 2009-2019



Source: own elaboration based on CEFIC, 2021 Facts and Figures. https://cefic.org/library-item/data-files-xls-2021-cefic-facts-and-figures

[54] https://cefic.org/library-item/data-files-xls-2021-cefic-facts-and-figures
[55] https://cefic.org/our-industry/a-pillar-of-the-european-economy/facts-and-figures-of-the-european-chemical-industry/
[56] https://cefic.org/our-industry/a-pillar-of-the-european-economy/facts-and-figures-of-the-european-chemical-industry/

Figure 10.2 EU27 chemical sales and global sales 2009-2019



Source: own elaboration based on CEFIC, 2021 Facts and Figures. https://cefic.org/library-item/data-files-xls-2021-cefic-facts-and-figures
EU27 chemical sales + 'Not EU27 chemical sales' = total world chemical sales.

In 2018, the European Union (EU-28) manufacture of chemicals and chemical products included almost 31,000 enterprises and employed almost 1.3 million people[57]. Around 97% of European chemical companies are SMEs,[58] which provide around 39% of employment in the sector[59]. The sector overall generates a value added of around €1.4 billion (2017). In 2017, the EU had a chemical trade surplus of €48.1 billion[60]. The EU manufacturing industry is greatly supported by the EU chemicals industry, with 56% of EU chemicals sold to downstream users.

10.3 Portfolios, prices and product withdrawal

The European Parliament (2013) reported that REACH "might lead to changes in the market structure, in the form of price increases, risk of losing market share vis-a vis for non-EU producers, and withdrawals of some chemicals from the market".

In 2012, it was reported that it was too early to identify the long-term financial impacts on firms from REACH (CSES, 2012a). Compliance costs financially impacted firms; for downstream users, this impact was considered less significant and depended on the product traded. Profit margins were reported to be made smaller for companies in highly competitive markets due to limited capacity to transfer costs to consumers through price increases. In other markets, there may be greater capacity to increase prices and maintain profit margins (CSES, 2012a). In 2012, it was reported that in most cases, total registration costs did not exceed 1% of the total annual turnover of firms (CSES, 2012a).

Regarding the impact on prices of chemicals, the ex-ante impact assessment for REACH (COM, 2003a) anticipated that relative effects of the testing and registration costs of REACH would lead to higher prices of chemicals in certain cases. However, a 2012 interim evaluation (CSES, 2012a) found that REACH had had

[57] Eurostat annual detailed enterprise statistics for industry (NACE). https://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do
[58] Eurostat industry by employment size class (NACE). https://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do. Calculated from EU-28 (2018) figures: Total number of enterprises = 30,931. Total SMEs = 30,065. Total large enterprises = 866. Calculated as 30,065/30,931.
[59] Eurostat industry by employment size class (NACE). https://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do. Calculated from EU-28 (2018) figures: Total persons employed: 1,281,561. Total employed in SMEs = 503,166. Total employed in large enterprises = 778,398. Calculated as 503,116/1,281,561.
[60] https://cefic.org/app/uploads/2019/02/2018-July-Cefic-Economic-Outlook.pdf

some impact on the price of chemicals, but that this was not sizeable. It was reported that the majority of firms (over 50%) tried to absorb the costs resulting from REACH rather than pass costs on to customers. This however depended on the sector in which the firm was involved, with commodity chemicals having less scope to pass on costs than speciality and consumer chemicals.[61] Similarly, there was some evidence of increased prices being paid by EU chemical users as compared to such companies outside of the EU, but this was not considered to be widespread (COM, 2012).

CSES (2012a) reported the withdrawal of substances to not be a widespread phenomenon with limited cases of withdrawal resulting in problems in terms of access by firms to essential raw materials. However, other studies (e.g. COM, 2012; CSES, 2012b) have suggested that withdrawal is a widespread issue due to REACH (the role of registration is not separated out). The present study finds the REACH 2018 registration deadline to have had no impact or a slight negative impact on the availability of raw materials, both in results reported by businesses and non-businesses alike. Overall, most stakeholders (38% of 268) reported no impact, 25% (68 of 268) reported the availability of raw materials to have decreased slightly, and 10% (27) reported a significant decrease. Of these stakeholders, 93 were companies. Some stakeholders were also asked about EU businesses specifically. Here, 38% (6 of 16) consultants, trade associations and other stakeholders reported EU businesses to have experienced a slight decrease in the availability of raw materials. The remaining responses were 'I don't know'.

Accessing raw materials from outside the EU can also be difficult, due to non-EU companies not having sufficient knowledge about REACH. Raw material prices are also driven by market forces, resulting in regulatory costs being absorbed by registrants.

However, as highlighted in the section on direct costs from the registration deadline, data provided by ECHA indicate that the actual number of substances registered for the 2018 deadline was much lower than expected, and also that the costs were higher than expected. It is possible (or even likely) that this has meant withdrawal of some substances from the market, though specific data to demonstrate this are lacking. Another possible reason for this is that the substance tonnages had decreased to below 1 tonne. COM (2012) provide evidence that substances (in particular carcinogenic, mutagenic and reprotoxic chemicals) have been withdrawn from the market/not registered due to their properties as well as the potential costs associated with both registration and with authorisation . Withdrawal may also occur as part of the rationalisation of portfolios. Therefore, the extent to which the withdrawal of substances is due to REACH only, rather than other business-related reasons, must be considered when interpreting results relating to the withdrawal of products from the market.

REACH has certainly had an impact on chemical substance availability for downstream users. Costs of identifying substitutes may be high, and there is uncertainty surrounding the process. In response to withdrawal, the most common approach taken by downstream users is substitution or the changing of EU suppliers. Few firms decide to register the withdrawn substance themselves (CSES, 2012a). Where withdrawn substances have been replaced, there is some evidence that these replacements are of a similar hazard profile (COM, 2012). Additionally, some sectors have found it difficult to substitute or reformulate products for regulatory acceptance (CSES, 2012a; 2012b).

The present study's online survey reported that 44% of 245 respondents saw their profits decrease. Most respondents reported no impact and, of the 44% reporting a decrease, 65% only reported profits to have decreased slightly[62]. For many companies, operating costs increased (55% of 244 reporting an increase), although most only reported operating costs to have increased slightly. No impact on operating costs was reported by 23% of respondents. This suggests that there were only slight impacts from the REACH 2018 registration deadline on both profits and operating costs. For SMEs, 24% (32 of 135) reported that their profits had decreased significantly. This is in comparison to 5% (5 of 110) of larger enterprises reporting the

[61] Note there was some contradiction from the study's participants (CSES, 2012).
[62] Note that the question asked "How did the 2018 REACH registration deadline impact your business or businesses you represent?" and a specific time of when profits decreased cannot be determined.

same. However, 43% (47 of 110) of larger companies reported profits to have decreased slightly. Figure 10.3 presents these results.

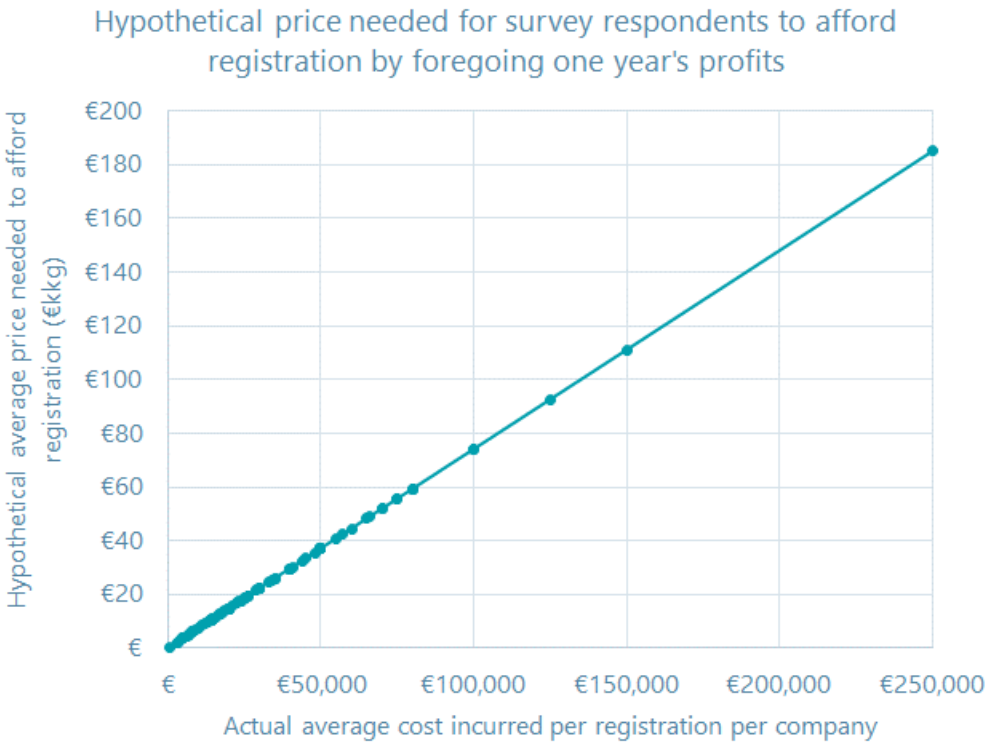
One caveat is that the survey respondents (companies) are all organisations that are currently operational in the chemicals industry; if companies withdrew products from the market and were forced to cease manufacture/import for example, then it is unlikely that they would have responded to the survey. This makes obtaining robust information on substance/company withdrawal from the market problematic.

As highlighted in chapter 4, on costs, the current study suggests that costs of registration, particularly for 1-10t substances, were much higher than predicted. Also, data from ECHA indicate that the number of substances registered in 2018 was much lower than predicted, for the 1-10t range. It is not known whether the higher than predicted costs of registration contributed to the lower numbers of substances registered (with others being withdrawn from the market), or whether it is simply that the previously-estimated numbers of 1-10t substances were too high.

By way of example, taking the average price per registration for 1-10t substances (around €43,700), if it is hypothetically assumed that an average registrant manufactures/imports 9 tonnes per year, and makes an average profit of 15%, that average company would need to achieve a sales price of around €32/kg if they were to forego all profits from that line for one year. Such prices are more likely to be achieved in fine chemicals, rather than commodity chemicals.

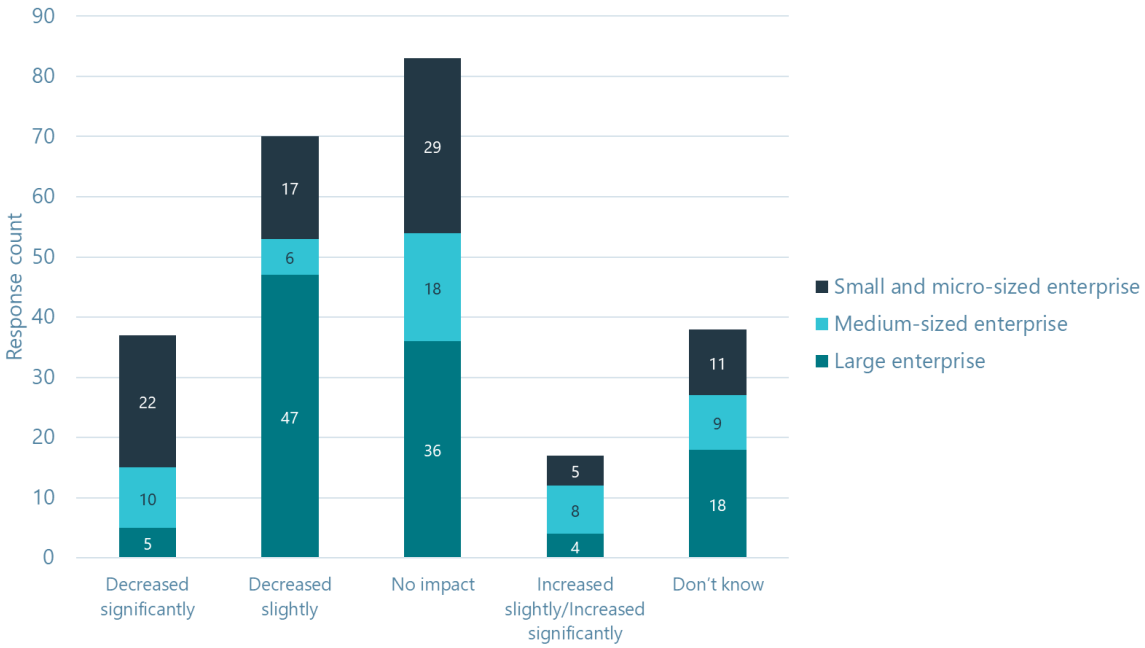
The chart below highlights the data on actual costs of registration from companies responding to the survey, against the price that hypothetically they would need to achieve in order to pay for the costs of registration based on the same assumed sales quantities and profit margins.

Figure 10.3 Hypothetical price needed (€/kg) to afford registration costs



The above is purely illustrative: clearly companies will have had great variability in their tonnages, profit margins and other factors. However, it does highlight the fact that registration is often only likely to have been affordable for substances with higher tonnages, market prices and profitability.

Figure 10.4 Impact on businesses of the 2018 REACH registration deadline: **impacts on profits**



Note: N=245. Results have been grouped and some results have not been reported due to lack of data.

The main actions taken on portfolios and prices were to absorb the 2018 REACH registration costs by reducing profit margins. However, whilst the survey questionnaire explicitly requested information on the impacts on businesses from the 2018 REACH registration deadline, some care should be taken in interpreting causation between these results and the 2018 REACH registration deadline. As highlighted by several interviewees and in previous studies on REACH, these results must be contextualised within the wider economic framework. Other, non-REACH business-related events, such as other market dynamics and economic cycles, will also affect product prices, substance withdrawals and other commercial decisions around substances.

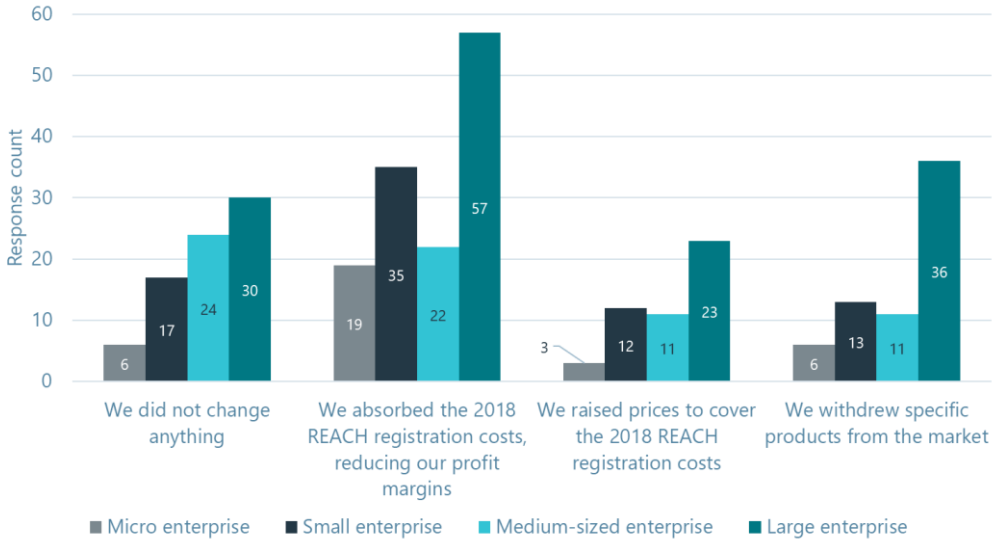
Figure 10.5 presents several key responses to the actions taken on portfolios and prices. Key responses include:

- The main actions taken on portfolios and prices were absorbing the 2018 REACH registration costs, reducing profit margins with 53% (133 of 252) of companies and trade associations selecting this. In general, sectors align around 50% where there were more than 10 responses to the survey, by sector. However, there are some exceptions. For the agriculture, forestry and fishing and mining and quarrying sectors, only 26% of respondents in this sector reported reducing profit margins (5 of 19). In the manufacture of wood sector, 62% (8 of 13) reported reducing profit margins and 67% (4 of 6) of the electricity, gas steam etc. sector reduced profit margins.[63]
- The second most selected action taken was the withdrawal of specific products from the market with 26% of respondents (66) selecting this action. Fewer than 50% of respondents in each sector reported to have withdrawn specific products from the market, with a few exceptions. 55% (6 of 11) of the manufacturing of textiles wearing apparel or leather and related products and 50% (6 of 12) of the construction etc. sector reported to have withdrawn specific products. The manufacture of rubber and plastic products or other non-metallic mineral products sector reported 40% withdrawal (12 of 29).

[63] Note that more than one sector could be selected by respondents.

- Analysing the results by company size where responses reported that they had absorbed costs, reducing profit margins, 70% (19 of 27) of micro-enterprises reported that they had absorbed costs and reduced profit margins. In comparison, 50% (57 of 113) of larger enterprises reported that they had absorbed costs and reduced profit margins.
- 10 respondents from a range of company sizes reported they had changed portfolio composition, moving towards with lower or similar margin products, and 7 respondents from a range of company sizes reported that they had changed portfolio composition with higher margin products.

Figure 10.5 Impact on businesses of the 2018 REACH registration deadline: **actions taken on portfolios and prices**



Most companies interviewed had not passed on the cost of registration to their supply chain, with some indicating that there was substantial pressure on prices from very competitive markets, in particular those for which the majority of competitors are located outside the EU. For some interviewees, changes in prices could not be directly linked to the registration process, as other factors could influence the cost of a substance or a product, such as customer demand, other legislation (e.g. restricted substance lists), etc. Most interviewees had also not experienced withdrawal of products from the market. This confirms previous findings in the literature.

Webinar participants highlighted several elements relating to portfolios, prices and product withdrawal:

- SMEs experience high costs when reaching out to their suppliers and obtaining REACH-relevant information on the substances they import. These costs are usually absorbed internally by the SME (rather than being passed on to customers) due to the competitiveness of the market.
- For companies operating in volatile markets[64], the portfolio of substances (e.g. dyes) used in products can change quickly, posing a significant challenge for companies that have to frequently submit additional registrations for new substances. Therefore, the registration of a substance may not be used for very long before new registration dossiers have to be prepared, and the investment in the registration dossier, which can be quite significant, does not pay off.
- Impacts on profits could be higher than those presented in the survey due to a higher share of registrants being SMEs in 2018, compared to previous registration deadlines. Volumes were

[64] This refers to sectors where raw material prices (such as dyes) are volatile, i.e. they increase and decrease sharply within short periods of time, leading to the need to switch from one product/substance to another.

thus smaller, resulting in fewer opportunities to cover costs incurred, and therefore leading to a greater impact on companies' profits compared to previous deadlines. Although, the process in 2018 was more effective as lessons had been learnt and experience gained by consortia from previous deadlines, and overall requirements for new data should have been lower, the costs could still be substantial, potentially leading to withdrawal of substances in some cases.

- Several cost components from the registration process were "hidden" and will be difficult to identify and quantify and, therefore, it is complex to determine their related overall impact from the REACH registration exercise on the profits of the chemical industry.
- The investment companies make in registrations can be lost when a use is restricted or when a substance is withdrawn from the market following an authorisation requirement.

It was also reported by a trade association that some organisations may be willing to take the risk of not complying with all obligations under REACH registration, as they considered the costs too high, and they would eventually phase out the substance or change their portfolio.

Different types and magnitudes of impacts have been observed between manufacturers and importers: importers with a large portfolio of substances sometimes face difficulties in obtaining REACH-relevant information from their non-EU suppliers on the substances that they import. For instance, they might not be able to obtain the analytical information needed to satisfy the needs for substance ID so they would need to generate that themselves.

Interviewees (trade associations) indicated that companies' decisions to change their product portfolio were mainly driven by changes in the markets and in business opportunities. However, REACH could lead to withdrawal in particular for substances sold into to niche markets where the cost to undertake testing would not be covered by low sales levels.

In the webinars, one participant indicated that, in some sectors, such as dyes for instance, there had been a reduction in companies supplying chemicals on the EU market. However, the participant added that it was difficult to identify the extent to which this had been caused by the 2018 registration deadline alone, as several other factors affect the economy and markets were also relevant. Several interviewed companies and trade associations noted that it is also difficult to assess the impact of the REACH 2018 registration in isolation, on prices of chemicals, for the same reasons.

The online survey requested information on the number of product withdrawals, however limited quantitative information was provided by respondents.

- There were 11 quantitative responses providing estimates of percentage increase in prices for the response "We raised prices to cover 2018 REACH registration costs". These ranged from 2% to 100%. The average (mean) increase in prices was around 25%. This is in line with CSES (2012a) where the majority of firms were reported to have absorbed costs, rather than passing these on to customers.
- There were 32 quantitative responses providing the approximate percentage of the portfolio that was withdrawn in response to "We withdrew specific products from the market". These ranged from less than 1% to 80%. The average (mean) of the portfolio withdrawn was around 18%, the mode 10% and the median around 11%.[65] For those reporting >10% withdrawal, the average (mean) costs per substance registration in the 1-10 tonnage band was €42,269. For the 10-100 tonnage band, the average (mean) was €75,056, which are broadly in line with the average costs across all respondents at 1-10t and somewhat lower than the average for 10-100t.

[65] Average calculated based on survey responses.

- There were 14 quantitative responses providing the approximate percentage of total turnover as a response to "We decided to withdraw from specific markets". These ranged from 3.5% to 50%. The average (mean) of the percentage of total turnover withdrawn was around 22%.[66]

10.4 Research & Development (R&D) and employment

10.4.1 R&D and innovation

The Commission had previously identified the concern that REACH regulation requirements could divert firms' resources from R&D and innovation, as seen by 63% of respondents to a survey forming part of the REACH Interim Evaluation (CSES 2012b and its cited sources). In the same survey, however, 46% of respondents indicated an overall increase in R&D expenditure and other innovative activities.

In REACH, substances used above one tonne a year for product and process orientated research and development (PPORD) can be exempt from the obligation to register for a period of five years. A PPORD exemption request must be submitted to ECHA by companies. Neither the survey nor interviews provided any detailed information on the role of PPORD relating to the costs of the 2018 REACH registration deadline. Total registration costs for PPORD notifications are reported to be the consultancy fees paid to consultancy firms to advise on the process, which vary depending on the number of substances and their complexity. One source reports charging a consultancy fee of between €1,000 to €3,000[67]. ECHA fees are the second cost element and are dependent on the size of the company[68].

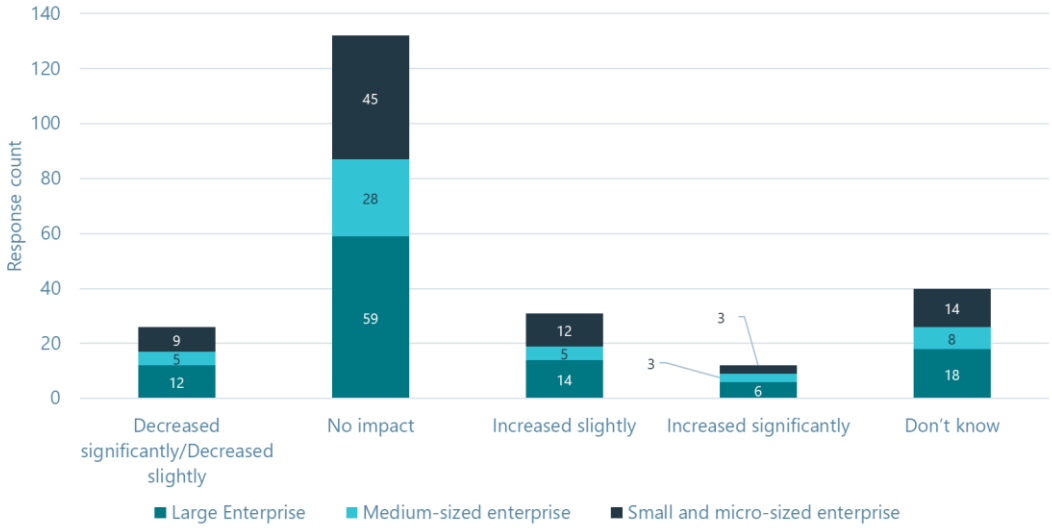
New knowledge was expected to be created from additional testing and from bringing new substances under the scope of the REACH regulation, particularly for the 2013 and 2018 deadlines (CSES, 2012b). However, the CSES (2012b) study did find that 47% of survey respondents indicated that higher testing costs for new substances in the past had been a disincentive for innovation. Information generated for registrations has also been found to inspire the innovative use of existing substances (COM, 2013). The registration of phase-in substances has had a positive impact on substitution. For example, some substances (e.g. expected to be SVHCs) may disappear from the market if not registered[69] and this may foster innovation through their replacement (CSES, 2012b). However, for downstream users, the results of non-registration of such substances may critically impact key inputs for the development of formulations or substances (CSES, 2012b).

Other factors identified in the literature as impacting R&D and innovation include positive innovation results from supply chain collaboration and linkages with downstream users (CSES, 2012b). Stakeholders have also reported that REACH does not provide sufficient protection of intellectual property to promote innovation. The CSES (2012b) study found that, whilst product, process, marketing and innovation was occurring, many companies considered these activities to ensure regulatory compliance and a distraction from normal, planned innovation activities. Despite the additional REACH costs, firms have continued to innovate. A general point is that, due to issues around compliance, related costs and constraints, some non-EU locations are more attractive for undertaking innovative activities, although REACH has not always been single or main driver (CSES, 2012b).

The online survey results of the present study showed that 55% had seen no impact on the investment of businesses in research and development. By company size, this represents 54% (59) of large enterprises, 57% (28) of medium-sized enterprises, 48% (26) small and micro-sized enterprises. Figure 10.6 presents this.

[66] Average calculated based on survey responses.
[67] http://www.cirs-reach.com/REACH/REACH_PPORD_Notification.html
[68] http://www.cirs-reach.com/REACH/REACH_PPORD_Notification.html
69 For example, companies may have decided not to register substances expected to meet the criteria in Article 57 (due to a possible future authorisation requirement) or Annex III (due to increased information requirements for 1-10t substances), even before any regulatory risk management action is taken.

Figure 10.6 Impact on businesses of the 2018 REACH registration deadline: **the investment in research and development**



Note: (N=241). Results have been grouped and some results have not been reported due to lack of data.

Of the responses which reported an impact, most respondents saw a positive impact, with 13% (31 of 241) responding investment of businesses in research and development had increased slightly and 5% (12 of 241) indicating it had increased significantly. However, these results are close to the figures on negative impacts, with 11% (26 of 241) reporting investment had decreased slightly/decreased significantly. This suggests that there has been limited change to research and development as a result of the 2018 REACH registration deadline.

The majority of companies reported no impact on the investment of their business in research and development: 54% (59) of large enterprises, 57% (28) of medium-sized enterprises, 48% (26) small and micro-sized enterprises. For non-EU companies of all sizes (including 'don't know' and 'not applicable' responses) and trade associations, 52% (17 of 33) reported profits to have decreased significantly or slightly, 33% (11 of 33) reported no impact on profits. For R&D, 13% (4 of 32) reported investment in R&D to have decreased significantly or slightly, but the majority reported no impact (17 of 32: 53%) and 25% (8 of 32) reported investment in R&D to have increased slightly or significantly. Note that 23 out of 32 respondents were from large enterprises.

Interviewees reported both positive and negative effects from REACH registration on R&D. It was reported that the registration process had been an incentive for R&D related to alternative methods, QSAR and read-across. Some companies have been able to orient their R&D activities towards substances with a lower impact on health and the environment. However, some other interviewees indicated that their company's staff in charge of research activities had been shifted to regulatory work to comply with the REACH registration process.

10.4.2 Employment

The European Parliament (2013) study reported that conclusions relating to job losses could only be drawn after 2018, with some fearful of a fall-out for SMEs. Overall, the literature provided limited evidence to conclude whether REACH has a positive or negative impact on the capacity of the chemicals market to maintain or generate jobs. The role of registration within this is even less clear.

There has been a recent downward trend in employment in the chemicals sector. However, it is not possible to make a direct link between REACH and these developments as they are driven, mainly, by increasing level of productivity in the sector, a long trend of relocation of production units outside Europe – mainly Asia –

and accentuated by the 2007-2008 financial crisis (CSES, 2012a). There has also been some discussion of the risk of small firms closing by national associations (e.g. Czech Republic, Italy and Austria), but evidence has not been provided (CSES 2012a).

The interviews conducted for this study did not report that the registration process had any effect on employment, while it was more common for larger companies to recruit additional staff to carry out in-house registration process activities. Most SMEs interviewed indicated they had no interest in opening a REACH department due to the number of substances in their portfolios and would prefer to resort to consultants.

10.5 Competitiveness

There was some discussion in the literature of REACH acting as a potential trade barrier against imports and a burden for competitive exports. In 2012, it was considered that the majority of firms (close to 60%) do not consider REACH as relevant in their decision to enter new EU markets. The study found no significant effects on trade from REACH, as the Regulation is not associated with a reduction in administrative costs and ease of exporting (CSES, 2012a).

For imports, the literature reports that in the short-term, margin losses are not significant as most overseas competitors face the same costs to have the right to access the European market (CSES, 2012a). Two scenarios are highlighted as possible with CSES (2012a) arguing that in both instances, European firms will not lose competitiveness on imports:

1. A company decides to leave the European market and thus makes Europe-based manufacturers better off than before, or
2. decides to register its products in Europe, together with its competitors and then contributes to reducing the registration burden.

The present study's survey found there to be no impact on the volume of sales to other EU countries, as well as no impact on the volume of imports of chemical substances/mixtures/articles. The following are key findings from the survey[70]:

- The majority of the manufacture of basic metals etc. sector reported no impact on its volume of sales to other EU countries (80% of 30). The majority of the manufacture of motor vehicles etc. sector, the majority of the manufacture of wood etc. (75% of 12) and the majority of the construction sector (73% of 11) also overall reported no impact on their volumes of sales to other EU countries. For the electricity, gas, steam etc. sector, 40% (2 of 5) reported no impact.[71]
- The REACH 2018 registration deadline had no impact on the volume of sales outside the EU for most companies, with 70% (166 of 239) of responses reporting no impact. 18% responses reported they did not know, and the remaining respondents reported either an increase or decrease in the volume of sales outside the EU.
- There has not been much change concerning the number of competitors in company markets, with 53% (127 of 242) of responses reporting no impact. Some responses from businesses and non-businesses alike, indicated a slight decrease. This corresponds with the information from CEFIC on the EU chemicals industry, which has seen some growth, although not at the same rate as growth globally. However, the impact of the 2018 REACH registration on market growth cannot be determined. The EU's chemical industry has overall grown and is expected to lead in the speciality chemical market which will include many substances in the 1-10 tonne and 10-100 tonne range.

[70] Note figures only includes companies where a company size has been provided.
[71] Note that more than one sector could be selected by respondents.

There was also some suggestion that manufacturers already complying with REACH might have a competitive edge if other world regions decided to adopt similar legislation (CSES, 2012a). The present report's analysis on whether companies utilise the REACH Regulation to comply with other regulations is discussed in the section on benefits.

The same study (CSES, 2012a) found that, whilst efforts were made to absorb costs, EU firms reported that REACH requirements and administration increased the price of their products relative to non-EU competitors. This has a potential longer-term impact on a firm's capacity to compete both within and outside the EU. It was considered by SMEs that they are losing market share due to costs, but mostly due to their decision to withdraw products or reduce production levels. Regarding impact on the single market, the CSES (2012a) study reported concerns for the 2nd and 3rd registration period that *"manufacturers in the low [chemicals] producing EU countries and those dominated by SMEs may lose shares in the EU market as a result of some SMEs withdrawing from certain products to avoid implementation costs"* (CSES, 2012a). As set out in the section on direct costs from the registration deadline, there have been many fewer substances registered at 1-10t than expected, which may be an indication that this concern was borne out in reality.

At a substance level, the literature indicated that the cost of REACH registration has discouraged some companies from competing on certain substances' markets, which has resulted in increased market concentration and prices.

The interviews undertaken in the present study identified several issues, including the issue of substances manufactured in the EU being treated differently than substances in imported articles, which do not need to be registered. It was also indicated by one company interviewed that competitors could consult data from other organisations' Safety Data Sheets, even though they had not been involved in the registration process and did not bear the costs. It was recommended by a trade association that ECHA supports industry in identifying potential 'free riders' that would benefit from the data, block access to the EU market to their competitors, etc., through an early detection system of poorly prepared dossiers.

11. Conclusions

11.1 Overview

This report is provided to support the European Commission in assessing the impacts on economic operators from the REACH 2018 registration deadline. The information gathered in this study relies on an extensive review of the literature, as well as a survey, interviews and webinars involving numerous experts in the field, from industry, trade associations, EU institutions, national authorities, consultancies and NGOs. The report explores a series of topics such as the costs and benefits of the 2018 registration deadline on economic operators; SIEFs and registration consortia; communication obligations for downstream users; use of resources and consultants; and effects on the EU market. A high-level summary of what the study has found follows and further details and specific examples can be consulted in the earlier sections of this report.

11.2 Main findings on impacts from the 2018 registration deadline on economic operators

11.2.1 Costs of the 2018 registration deadline, including costs of updates

This report provides estimates of the costs of registration for the volume ranges 1-10 tonnes and 10-100 tonnes and investigates the various components of registration costs, including fees, costs of dossier preparation, cost of a letter of access, preparation of safety data sheets, costs of training, and costs of legal support.

Around 22,000 registrations were submitted for the 2018 deadline, covering around 10,100 substances in the 1-10t range and there were around 12,800 registrations in the 10-100t range, covering around 4,600 substances. The survey for the current study covered 8% of those registrations and 6% of companies registering 1-10t substances. It covered 11% of registrations and 3% of companies registering 10-100t substances. Therefore, resulting estimates of costs (shown below) are considered to be reasonably representative of the wider registration costs.

The average costs of registration per substance and per company were collated through survey responses. For the 1-10 tonnage band, the average costs per registration was around €44,000 and the average costs per substance registered was around €95,000, while for the 10-100 tonnage band, the average costs per registration (per company) was around €101,000 and the average costs per substance registered was around €280,000. Based on the above cost estimates from the survey results and on data on the actual numbers of substances/registrations from ECHA, total costs of registration were estimated as €1,290 million for the 10-100t range and €960 million for the 1-10t range, giving €2,250 million in total

The study investigated several components of the costs of registration, such as the costs of preparing a dossier and the costs of undertaking tests. Based on survey responses, the costs of preparing a registration dossier (including drafting, finalising a technical registration dossier and submitting it, including administrative data and producing summaries for REACH annexes) was high for both the 1-10t substances (average of €18,000) and 10-100t substances (average of €39,000); this is a key finding as most registrants will need to prepare the registration dossier.

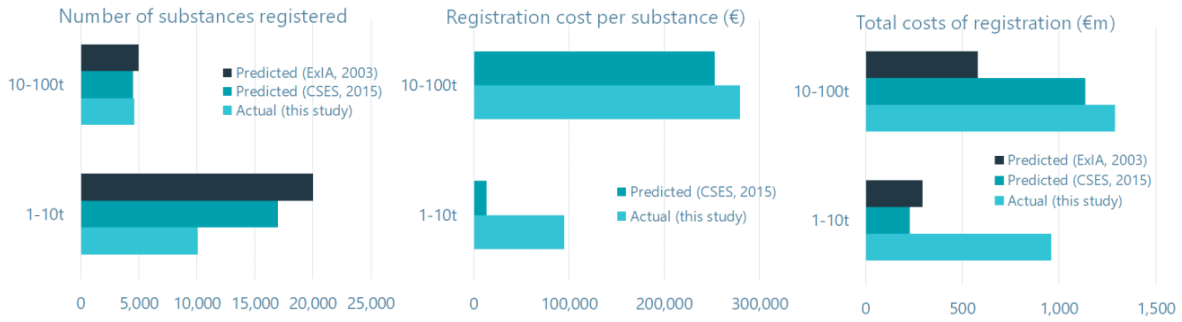
In addition, there were substantial costs of undertaking tests to obtain the necessary information for submission. The costs of tests for all of the endpoints under REACH Annex VII (1-10t substances) are around €60-€70,000; the costs of testing for 10-100t substances is much higher, particularly for toxicological and ecotoxicological tests. However, note that not all these tests were necessary, not all companies had to undertake those tests, and some companies obtained the results by paying for a letter of access. Testing was

reported as particularly expensive for complex substances such as UVCBs compared to basic chemicals. The costs of changes to company systems and of legal support was also reported as significant in some cases; however, there was only a small number of responses on this cost component.

Compared to the ex-ante estimate, total EU costs of registration (see above) were similar to those predicted for the 10-100t substances. However, for the 1-10t substances total EU costs are estimated to have been over seven times that predicted, despite only half the number of substances being registered compared to the prediction.

In terms of the higher-than-expected costs for 1-10t substances, companies stated that the main cost drivers were accessing data, additional testing and external support. The costs of preparing the registration dossier were a substantial proportion of costs. The results suggest that significantly more testing was undertaken than was expected, contributing to the higher costs than those predicted.

The three charts below highlight some of the key conclusions on the costs of registration and a comparison with the previous ex-ante estimates. The charts reflect that the actual number of substances registered at 10-100t was in line with expectations before the 2018 deadline; however, the number registered at 1-10t was a bit more than half of the number predicted.



REACH requires that registration dossiers be reviewed on a regular basis and **updated** as new information becomes available. Companies interviewed indicated that they often wait for ECHA to request an update to be made, e.g. through compliance checks, evaluations or dossiers being considered incomplete; otherwise, the main reasons why companies did not update registrations was because it was not perceived as required or because there was no new information available.

In terms of costs of updating registrations, companies most frequently incurred costs in the range €1,000 to €10,000 for all tonnage bands, although costs were lower for lower tonnage-band substances. The costs of updates do not appear to be related to the size of a company and the costs to update were, overall, considered affordable by SMEs. Testing costs and the Letter of Access were reported as the main drivers to the costs of updates.

A key challenge with updating registrations reported by companies relates to the frequent changes to IUCLID software and information requirements. IUCLID version upgrades and changes by ECHA were frequently reported to have been an issue in updating dossiers, as well as changes being made to the guidelines which then change the requirements for companies. Overall, encoding information in IUCLID was reported as a main task outsourced by companies to consultants, reflecting the complexity perceived by businesses.

Other issues in updating registrations include problems related to data-sharing, cost sharing and communication, which were encountered by about half of respondents to the survey. Companies also faced difficulties in complying with deadlines for updates that were close to the 2018 registration deadline, given the limited capacity of laboratories, which were reportedly overwhelmed with requests for analysis.

11.2.2 SIEF and registration consortia

The approximate costs associated with joint registration for the 1-10 tonnage band vary between less than €1,000 to more than €20,000, with a substantial share of respondents having had costs between €1,000 and €10,000. For the 10-100 tonnage band over a third of respondents reported costs of above €20,000.

A range of pricing policies have been used by SIEF and consortia. Feedback highlighted that splitting the cost based on company size (i.e. smaller sized companies would incur a lower cost than larger companies involved in the consortium) and production quantities (i.e. the higher the production of the substance, the higher the cost to participate in the consortium) made the costs to participate in a consortium both more proportionate and affordable.

Many registrants faced issues regarding disputes over pricing policies, cost sharing, prices of data or unexpected costs for SIEFs. In addition, it was often difficult to provide information to registrants (and difficult for registrants to obtain information) on the split of the Letter of Access costs between members of a SIEF and/or consortium. Overall, more problems with SIEFs than with consortia were reported for the REACH 2018 deadline. For example, regarding challenges with communication or transparency, it can be observed that many more respondents agreed with the fact that there were more challenges with communication or transparency of decision making for SIEFs compared to consortia. However, this was not the case for affordability (where more problems were reported for consortia); overall this study found costs of be less affordable for consortia than for SIEFs for the 2018 REACH registration deadline. This conclusion is surprising, given that participation in consortia is voluntary, while participation in SIEFs was mandatory. There were mixed views on whether the Implementing Regulation (EU) 2016/9 on joint submission of data has been successful or not. Most respondents thought that the regulation brought some improvements related to the transparency and fairness of costs, with organisations feeling more comfortable inquiring about costs and raising questions about the split of costs. Some reported that, on several occasions, the regulation balanced the power between lead registrants (i.e. data owners) and co-registrants and, thanks to the regulation, several legal actions have been avoided. However, other companies reported that these improvements were not significant and that issues related to data sharing and joint registration raised for the previous registration deadlines (as mentioned in the 2018 REACH review) remained.

11.2.3 Communication obligations for downstream users

Article 31 of REACH covers communication obligations between downstream users and suppliers to ensure that relevant information is passed through the supply chain. In this context, manufacturers and importers of substances must provide their customers with a safety data sheet (SDS). Results show that REACH has led to an increase in costs of managing information exchange along the supply chain, and the costs of preparing these SDS (and extended versions, eSDS) are considered a more substantial burden for smaller companies.

Key challenges in communication in the supply chain included, among others: complex data requirements, low awareness of some small downstream users, or non-EU manufacturers, etc. In particular, eSDS (and in particular exposure scenarios) were often considered lengthy, complex and too technical for the audience they are addressed to (users, workers). Companies suggested streamlining eSDS and simplifying exposure scenarios to improve communication in the supply chain.

11.2.4 Resources and consultants

This study explored how registrants have adapted to REACH over the last registration deadline and whether they had adequately qualified staff in-house to deal with REACH or contracted consultants. For the 2018 registration deadline, compared to the previous deadlines, companies were less likely to have a dedicated REACH unit/manager within their organisation and more likely to outsource some or all of the registration activities to consultants. Smaller companies were more likely to outsource registration activities to consultants and laboratory facilities.

Key reasons to outsource registration activities included limited internal human resources as well as the lack of both technical and regulatory expertise in-house, in particular for those companies registering chemicals for the first time. The main tasks outsourced cover the overall preparation of the dossiers and encoding in IUCLID, SIEF/consortia management and technical support (e.g. monitoring technical studies).

Overall, the quality of consultants was considered to be satisfactory, but the costs of services provided by external consultants were considered high by a majority of respondents, although these costs will depend on the type of consultancy.

11.2.5 Benefits to companies from the 2018 registration deadline

The information gathering for this study has largely focused on direct benefits to companies through the survey; other wider benefits to workers, consumers, society and the environment have been investigated in the literature.

The literature reports that benefits have already materialised, following the three registration deadlines, in terms of improved risk management and occupational safety and dissemination of information on safe use in the supply chain. However, surveyed companies generally found it difficult to identify direct benefits *to companies* from REACH registration. Those that did highlighted that REACH registration could be considered as a competitive advantage and that it increased the transparency of the market.

Companies considered the availability of information on substances and the dissemination of information on safe use through the supply chain as a significant benefit from REACH registration, as it has had a positive effect on risk management practices in companies. Thereby, increased information on substances seems to encourage companies to reduce the use of hazardous chemicals, although results are less clear cut on this issue.

11.2.6 Effects on the EU market

The overall growth in world chemicals sales is predicted to continue, increasing from €3.7 trillion in 2019 to €6.2 trillion in 2030. The EU leads in speciality chemicals, with an expected continued increase in production value of speciality chemicals, of which many will be 1-10 tonne and 10-100 tonne substances: in 2019, the EU27 and the UK had a speciality chemical production value of €260.9 billion, which is expected to reach €323.8 billion by 2030. However, the EU's share of world markets has declined in the last 20 years, with emerging market growth, in particular China, which is now top of the global sales ranking. Analysis of EU-level data does not demonstrate a discernible impact on the overall market as a result of the REACH 2018 deadline, to date. However, the available data does not allow interpretation of whether REACH costs may have depressed the level of growth that occurred.

The underlying reasons for the lower-than-expected number of 1-10t substances registered (a bit more than half that predicted) is unknown. However, the costs of registration, per substance, were much higher than expected, which may well have led to fewer substances being supported through REACH registration. It is worth noting, however, that these estimates of costs and numbers of substances expected to be registered for the 2018 deadline were considered to be one of the most uncertain parts of the ex-ante cost estimates in the original impact assessment.

There were only slight impacts from the REACH 2018 registration deadline reported on both profits and operating costs. For those companies which had taken an action on their product portfolios and/or prices, most reported absorbing the 2018 REACH registration costs by reducing profit margins, and therefore, have not passed on the cost of registration to their supply chain: for some companies, this, in turn, resulted in substantial pressure on prices from very competitive markets, in particular those for which the majority of competitors are located outside the EU Other, non-REACH business-related events, such as other market dynamics and economic cycles, will also affect product prices, substance withdrawals and other commercial

decisions around substances and these may have been important over the period of 2018 REACH registration.

Only limited change has been reported to levels of research and development as a result of the 2018 REACH registration deadline.

11.3 Possible uptake of findings in the current policy context

11.3.1 Next steps for registered substances under REACH

The registration of chemical substances is only the first step of a series of processes set out in REACH to assess and manage the risks from chemicals being placed on the EU market. Following registration, ECHA publishes non-confidential information included in the registration dossiers on its website, which can be freely accessed by citizens who wish to be informed of potential risks of chemicals being placed on the market. Published information will cover, for example, the identity of the substance, the outcomes of studies on intrinsic properties and hazard profiles, levels where no adverse effects are expected for human health and the environment, classification and labelling, and any guidance on safe use of the substance.

ECHA is responsible for checking the compliance of registrations with the requirements set out under REACH. The quality of selected registration dossiers and testing proposals is being evaluated by ECHA and Member States. Based on such evaluation, registrants may be asked to provide further information on a substance. By the end of 2020, 19.2% of registration dossiers in the 10-100 tonnage band were checked for compliance and 13.8% of registration dossiers in the 1-10 tonnage band [72].

Based on this evaluation, substances may be proposed as candidates for further regulatory processes. Substances subject to harmonised classification and labelling or identified as a Substance of Very High Concern and then placed on the Candidate List may trigger additional regulatory risk management such as Authorisation (through recommendations for the Authorisation List and applications for Authorisation) or Restriction (e.g. limit or ban). Therefore, a good understanding of the costs and benefits in the first step of registration (as well as the drivers for those and potential hurdles) is critical to assessing the wider impacts from REACH incurred by economic operators.

11.3.2 The wider policy context

The European Green Deal[73] published in 2019 announced the elaboration of a Chemicals Strategy for Sustainability with the aim to achieve better health and environmental protection along with increased global competitiveness. In 2020, the European Commission presented this Chemicals Strategy for Sustainability[74], setting out areas where it wants to make greater progress, along with concrete objectives and actions. Such areas cover, inter alia: the promotion of safe and sustainable-by-design chemicals; achieving non-toxic material cycles; protection against the most harmful chemicals; addressing risks from endocrine disruptors, mixtures and PFAS; and the coordination and simplification of actions across the EU's chemical legislation.

Ample evidence on the performance of existing legislation has been gathered by the European Commission, including the REACH review (2018) and the Fitness Check on the most relevant chemicals legislation (2017) amongst others. Along with these ex-post studies, the present report informs the European Commission in a series of impact assessment processes to further improve chemicals legislation, by building on existing evidence and the feedback from the participation of and consultation with stakeholders. It is expected that

[72] https://echa.europa.eu/progress-in-dossier-evaluation
[73] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[74] https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

the outcome and findings of the present report can feed into several actions to be undertaken by the European Commission in the future. For example:

- **Further extending the duty of registration under REACH to substances not under scope, e.g. certain polymers of concern.**

  In 2019, a study was published by the European Commission to support an impact assessment of covering certain polymers by REACH registration; this provided a detailed cost-benefit analysis of the registration requirements that could be used. For such ex-ante studies, where stakeholders are asked to extrapolate future costs and/or benefits of a possible intervention, there is typically a significant lack of data from consultation, resulting in significant uncertainty around certain data points. Therefore, existing information on costs and benefits from registration for substances other than polymers can provide a strong basis for future assessments. Findings from the present study could serve to further fine-tune the assumptions, calculations and estimates made in a future impact assessment on possible changes to REACH, concerning polymers but also other possible amendments, such as the inclusion of a mixture assessment factor, or extension of protections for professional workers, for example.

  Key findings and lessons learnt from existing registration processes can feed into the elaboration of new processes for substances not yet under scope, e.g. polymers, in order to ensure the effectiveness and efficiency of such new processes. Some of the above findings pin-point areas with potential to reduce inefficiencies, unnecessary costs or complexity.

- **Improving the availability of data on chemicals by updating information requirements**. In coming years, the European Commission will assess how to best introduce information requirements under REACH on the overall environmental footprint of chemicals (including on emissions of greenhouses gases). In addition, the Chemicals Strategy for Sustainability indicates that the current requirements for low and medium tonnages do not fully enable the identification of substances with critical hazard properties (including effects on the nervous and immune systems). It also states that information requirements may be updated, irrespective of the tonnage band, to better identify carcinogenic substances manufactured or imported in the EU. Finally, the Commission is also considering the introduction of explicit requirements to take into account the impact of mixtures, e.g. by adding (a) mixture assessment factor(s) in the chemical safety assessment of substances. The present report, along with previous evaluations carried out on REACH, enable the baseline costs from current requirements under REACH to be understood. This understanding can be further complemented to present the cumulative impacts from new or updated information requirements, such as those mentioned above. In addition, key findings from the report can help anticipate the challenges and opportunities for industry (and across supply chains) and investigate characteristics or factors which have or have not worked.

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Appendix A
Workshop report

Workshop report

European Commission, DG GROW

Study on the impacts of the REACH 2018 registration deadline on economic operators

Workshop report

Wood – November 2020

Report for

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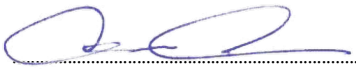

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Document revisions

No.	Details	Date
1	Workshop report	17/11/2020

Contents

1. Introduction

1.1 Background

This document provides a summary of the content and outcomes of two online webinars that took place on 14 and 21 October 2020 for the study on the impacts of the REACH 2018 Registration deadline. The study is being led by Wood, Milieu and PFA, as contractors to the European Commission (DG GROW).

The overarching objective of this study is to assess and quantify the impacts on economic operators of the REACH 2018 registration deadline. The study will investigate cost impacts, e.g. direct costs from registrations, costs of updates, extended safety data sheets, as well as wider impacts from the 2018 registration deadline, including impacts on competitiveness, innovation and structure of the industry. The overall study has the following objectives:

- **Task 1:** Develop a methodology to assess the impacts from the REACH 2018 deadline.
- **Task 2:** Identify and review all relevant existing information and gather new data.
- **Task 3:** Analyse that data and provide conclusions.
- **Task 4:** Discuss preliminary results in an ad-hoc workshop.
- **Task 5:** Present the final study results.

The scope of this study is as follows:

- **Legislation and timing**: The study considers impacts occurring from the latest (2018) REACH registration exercise only.
- **Analysis:** The consultation and the analysis focused on impacts (costs and benefits) to economic operators (i.e. businesses). Economic operators include manufacturers from the chemical industry, importers, only representatives (ORs) as well as downstream industries affected by the 2018 registration requirements.
- **Geography:** The study scope is the EU27 and the UK.

1.2 Purpose of the online workshops

Given the COVID 19 situation at the time, the workshop was held as two separate online webinars on 14 and 21 October 2020. The workshops both lasted 2 hours. The objectives of the online workshops were to:

- **Present, test and validate findings** from the online survey inviting reflections, feedback and corrections and ensure all available data has been used.
- **Highlight outstanding gaps/barriers in** knowledge (e.g. missing stakeholder groups, unreliable data, outlier findings, weaker coverage of specific objectives outlined in the Terms of Reference).
- **Enrich existing data** (qualitative and quantitative) based on participants' reflections and experiences. This was addressed via break out groups with a smaller number of people, with direct experience of these issues.
- Understand and explore **changes over time, lessons learned, and policy implications, including challenges for SMEs in particular.**

1.3 Workshop participants

73 stakeholders attended the webinar on 14 October 2020, and 40 attended the webinar on 21 October. Stakeholders included economic operators, trade associations and public authorities.

1.4 Description of breakout session themes

As a means of focussing the workshop discussion over the two webinars, a number of topics were developed which were organised as follows:

Online workshop 1:

- Direct costs of the 2018 registration exercise and resourcing.
- Participation in SIEFs and consortia.
- Benefits from the 2018 registration exercise.

Online workshop 2:

- Effects on chemicals markets: structural changes in the market, supply of chemicals and product withdrawal, changes in prices, innovation, R&D, trade, competition, benefits for the industry as a whole.
- Communication obligations within the supply chain and downstream users.

2. Key points from online workshop 1

2.1 Plenary session

2.1.1 Project and workshop overview

The workshop started with an overview of the project background and the relevant legal framework, presented by Otto Linher from the European Commission, DG GROW. The structure and objectives of the online workshop were also presented.

Following the opening session, during the plenary, Wood presented a description of the project context, a description of the project scope and key elements of the consultation. The presentation included an overview of findings from the online survey and interviews from the study. Topics covered included:

- Direct costs of registration.
- Resourcing and consultants.
- Participation in SIEFs and consortia.
- Benefits from the 2018 registration.

A summary of the general findings presented to participants in workshop 1 for each topic are summarised in the sections below.

2.1.2 Direct costs of the registration exercise

The direct costs of the registration exercise in 2018 were quantified and the different components of registration costs estimated. There is differentiation between the two tonnage volume ranges (1-10 tonne and 10-100 tonne). General findings for this specific objective include:

- The average approximate costs of registration per substance varied from €5,000 to more than €75,000 for substances in the 1-10 tonne range, and €20,000 to more than €200,000 for the 10-100 tonne range. A small minority of respondents found these to be lower than €5000.
- Most respondents who registered substances in the 1-10 tonne range estimated the approximate costs of a letter of access to be between €5,001 and €25,000 (51%), 16% of respondents indicated costs less than €5,000, 10% between €25,001 and €50,000 and 3% above €50,000. For the 10-100 tonne range, 28% indicated costs between €5,001 and €25,000, 29% indicated costs between €25,001 and €50,000 and 16% above €50,000. Some respondents also indicated 'Don't know'.
- For laboratory test/ studies, 20% of respondents that registered in the 1-10 tonnage band and 24% for the 10-100 tonnage band reported that laboratory tests/ studies were needed for all of the information requirements. 71% of respondents in the 1-10 tonnage band and 81% of respondents in the 10-100 tonnage band required laboratory tests/ studies for at least some information requirements.
- The feedback indicated that the costs of testing were particularly expensive for complex substances, such as UVCBs; grouping substances in order to carry out read-across was also identified as a substantial source of costs.

- The main drivers of costs were similar in both tonnage bands and included costs of accessing existing data and costs of additional testing and/or generating new data. Other drivers of costs were that companies often could not rely on read-across for their dossier and that data was often of poor quality and required additional work.

2.1.3 Resources and consultants

Information on the resources spent on adapting to REACH, including the availability of adequately qualified persons both in-house and externally was requested. This included obtaining information on the use of consultants. General findings for this specific objective include:

- More than half of respondents outsourced some or all of the activities under registration to consultants and/or technical specialists. Results show that the share of companies that were able to carry out registration activities in-house slightly decreased since 2010.
- Larger enterprises were more likely to use internal resources for registration work compared to SMEs. Feedback indicated that it was difficult for SMEs to fulfil registration requirements without the external support from consultants.
- About half of the respondents reported that it was not easy to hire internal staff to meet the 2018 registration requirements.
- Consultants mainly focused on handling the submission of data via IUCLID and the management of SIEF and consortia, e.g. the representation of companies, financial management, cost sharing, etc. Consultants also provided technical support, such as monitoring, technical studies and interacting with laboratories.
- The main reasons for outsourcing were the absence of in-house knowledge on the REACH registration process and the lack of internal staff capacity. The absence of in-house technical knowledge and expertise to cover risk management and risk assessments etc., were mainly outsourced.
- In general, participants found the service provided by external consultants to be of good quality. It was reported that consultants had built up knowledge with industry over time, and they had gained in both understanding and efficiency in the registration process since 2010.
- It was reported that the availability of qualified consultants improved in 2018, compared to the previous deadlines, especially for management and coordination activities such as in SIEF or consortia. On the other hand, there was a lack of consultants and laboratories with in-depth technical and scientific knowledge on certain specific substances. Similarly, for complex substances, the number of laboratories able to carry out testing was limited.
- Costs of services by consultants were generally considered as high; however, it was less expensive to hire consultants than to establish a REACH department in-house, especially for SMEs.

2.1.4 Participation in SIEFs and consortia

Information on the pricing policies of SIEF as well as their affordability, and the transparency, fairness and communication practices in relation to the expected benefits from Implementing Regulation 2016/9. General findings for this specific objective include:

- Excluding responses of 'Don't know' and 'Not applicable', for costs associated with joint registration, most respondents indicated costs between €1,000 and €10,000 for the 1-10 tonnage band, with much lower numbers reporting costs in other ranges specified (see the charts in the presentation in Appendix B). For the 10-100 tonnage band, the ranges with the

highest number of responses were the €1,000 to €10,000 and the "more than €20,000" ranges, where the number of responses was around the same, with much lower responses in the "less than €1,000" and €10,000 to €20,000 ranges.

- Over 20% of respondents claimed that they faced significant problems or challenges with SIEFs but which were resolved while an additional 10% of respondents faced issues that were not resolved. Key issues raised for SIEFs were challenges with communication or transparency of decision making; disputes with pricing policies; cost sharing, the price of data or unexpected costs; and participation requiring too much time. Key issues encountered within consortia were similar, and in addition costs were considered unaffordable in several instances.
- Results were divided on how participating in consortia changed since 2016: most respondents found that the Implementing Regulation on data sharing brought about improvements related to the transparency and fairness of costs but several others noted that issues related to data sharing and joint registration raised for the previous deadlines remained similar. It was added that the Implementing Regulation was very broad and not fully understood by industry, especially by SMEs, and that it required a substantial amount of work to implement and adopt procedures.

2.1.5 Benefits from the 2018 registration process

Information was gathered on whether there were any positive impacts for business from the 2018 REACH registration process and the nature of any benefits. General findings for this specific objective include:

- 19% of respondents noted that they had already seen benefits from registering substances; another 23% of respondents said they had not seen any benefit yet, but expected benefits to materialise in the future. The remaining 58% did not expect to see benefits in the future. This feedback was similar regardless of company size.
- However, when asked about specific improvements, some respondents identified benefits (see below).

For those respondents that did identify benefits, the main benefits included:

- Improved risk management measures in their company. Results were divided on whether companies changed their suppliers to those with better risk management measures.
- Results were also divided on whether research and development had increased because of REACH registration.
- More than half of companies confirmed having used REACH registration information to comply with other EU legislation and around half reported using this information to comply with legislation outside the EU (mainly for larger companies.)

2.2 Break-out session 1

These sections present summaries of the breakout group discussions and reflections on these topics from the plenary session. Each topic was discussed by two different breakout groups, hosted by a facilitator and rapporteur.

2.2.1 Discussion points

Table 1 presents the discussion points that the break-out groups were asked to consider.

Table 1 Discussion points on the direct costs of registration and resourcing/consultants

Direct costs of the registration exercise in 2018
What are your views on the results around direct costs of registration (2018) considering levels of cost and cost drivers, and were these significantly different from your own and why?
We are looking for estimates of the following costs – are you aware of data sources that cover these components: • Cost of quantitative structure relationship models (QSARs) and read across studies for 1-10 / 10-100 tonnage substances. • Cost of CSR/CSA • Cost of training for your company: have these costs represented a burden?
Do you think there were disproportionate costs/impacts for SMEs? If yes, could you provide examples of these and describe the implications and suggestions on how these could be reduced in the future?
What were the main lessons learnt from REACH 2018 registration? Do you have any suggestions on ways to make registration more cost-effective in the future?
Do you have any suggestions on how to reduce costs related to updates in the future?
Resourcing and consultants
What were your own experiences of using consultants and do you have ideas on how to make best use of consultants in the future?
What are your views on how COVID-19 has affected updates? Has there been any impact on resources, and has it led to reduced activity in updating?
How do your expected resources needed for the maintenance and updates of registration compare to those needed for the original registration?

2.2.2 Key points made

Direct costs of the registration exercise in 2018

Views on results from the online survey

- Participants generally agreed that costs for registration for their companies were very similar to those found in the online survey.
- Key points made by workshop participants on the direct costs of registration included:
  - It would be useful to include an indication of the administrative cost as a percentage of the total cost of registration.
  - The results from the online survey did not reflect how the registration costs affect the price of a substance; presenting such an indicator of the share of the overall price of a substance

that corresponds to registration costs would be a good indicator, providing another perspective about registration costs in the study. This comment was made by a trade association.

- It would be beneficial to contact consortia to get ranges of total costs per type of substances (i.e. simple to complex).

Variation in cost

- It was mentioned that registration costs per substance can vary significantly: as costs are divided among the SIEF members; the average costs of registration per substance will depend on the number of companies that are registering each substance. Therefore, the average figures presented may not be representative of costs for individual operators. The range of substances that companies have registered vary from very simple to very complex – in term of registration dossier. Therefore, it is certain that substances are particularly expensive to register, whereas others are not.
- One participant indicated that, in some cases, costs do not relate to individual substances, but are incurred e.g. for testing, when read-across is applied to a group of substances. Similarly, some SIEF/consortia cover multiple, similar substances for registration and the costs (e.g. consortium management, certain parts of CSAs) may be shared across several similar substances, making it difficult to allocate costs to a specific substance.

Resources and consultants

Expected resources needed for the maintenance and updates of registration compare to those needed for the initial registration

- The complexity in the regulatory framework has increased dramatically over the past 10 years; therefore, it was considered difficult to keep an updated understanding of how the regulation works and to obtain the appropriate resources internally. In this context, complying with REACH requirements in the future may necessitate increasingly relying on external resources. This point was made by an employee of an economic operator.
- The recent publication of the Implementing Act on dossier updates[1] and, possibly, the (then expected) new chemicals strategy for sustainability, will result in a more complicated and resource-intensive registration process, especially for low tonnage bands, leading to less efficiency in costs. This point was made by an employee of an economic operator.
- One participant stated that, in several cases, they could not register all of the substances they import, and, therefore, they had to select those to be registered. This point was made by an employee of an economic operator.
- The content and quality of information for registration purchased through a LoA is often not known in advance. If the quality of the information is poor, and additional work is required following evaluation, this can lead to additional costs being imposed. This point was made by an employee of an economic operator.
- The number of full-time equivalents (FTEs) that they employ covering registration under REACH has remained the same as before the 2018 registration deadline, even though the deadline has passed, as staff are needed to continue to cover updates, new registrations (as business needs change) and to react to ECHA's evaluations. This point was made by an employee of an economic operator.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32020R1435

2.3 Break-out session 2

2.3.1 Discussion points

Table 2 presents the discussion points that the break-out groups were asked to consider.

Table 2 Discussion points on the benefits from the 2018 registration for economic operators

Benefits from the 2018 registration for economic operators
What benefits have you observed from the 2018 REACH Registration specifically?
Can you distinguish the benefits of the 2018 registration from the benefits of REACH registration in general?

2.3.2 Key points made

Benefits from the 2018 registration for economic operators

Benefits from the 2018 REACH registration

- It was noted that the Commission Implementing Regulation introduced greater flexibility and transparency on data sharing and LoA; however, this only represented a small improvement.
- The main benefits are related to better communication in the supply chain as safety data sheets have improved significantly and have become fully part of the communication process. Registrants have reportedly become more active in communicating to and engaging with their supply chain, which improved the management of risks from chemicals; this view was supported by several participants. This point was made by an employee of an economic operator.
- Furthermore, it was noted that the REACH registration process draws attention to safety data sheets, and, therefore, customers are increasingly aware of their existence and use. Consultants also played an important role in that regard, in terms of providing better safety data sheets, and, in turn, better safety information.
- On the other hand, some economic operators indicated that it is still too early to observe benefits from the 2018 registration process, and that benefits will become more apparent in the longer term.
- Furthermore, another participant also claimed that, despite there being no visible benefits for (some) economic operators, there are environmental and health benefits as well as information benefits for regulators.

Points for improvement on REACH registration

- It was noted that the guidance for REACH registration changed between registration deadlines. For example, one participant mentioned the change in approach to read-across, which meant that the approaches previously applied in the 2013 registration deadline were no longer valid and they required additional resources to implement changes. The participant also mentioned that such changes also led to possible lack of coherence with legislation in other parts of the world which has been based on REACH

- Two operators mentioned that there were no clear benefits from registration to their business and that it was key for their downstream users to know that a substance is registered (i.e. through the registration number) and that the actual content of the registration or SDS was less important to them.

2.4 Break-out session 3

2.4.1 Discussion points

Table 3 presents the discussion points that the break-out groups were asked to consider.

Table 3 Discussion points on participation in SIEFs and consortia

Participation in SIEFs and consortia
If you have participated in SIEFs and consortia in the previous registration deadline, what are your views on the evolution of the operation of SIEFs and consortia? Were there fewer/more challenges this time?
Have you seen any improvements coming from the application of the Implementing Regulation 2016/9 on data-sharing? If so, please explain which improvements.

2.4.2 Key points made

Participation in SIEFs and consortia

Issues with SIEFs

- A participant noted that, despite being particularly complex to manage, SIEF cannot be further regulated as they fall under the principle of 'freedom of contract', i.e. organisations can form contracts without government restrictions. A couple of participants noted that this lack of regulation and enforcement in SIEF decreases their effectiveness. They concluded that, for the 2018 registration deadline, some companies would rather buy a Letter of Access as it was considered more efficient than carrying out the tests themselves.
- One participant shared an example of a SIEF managed by a non-EU company through their Only Representative, for which there were issues of unfairness, that, in turn, led to delays.
- One economic operator indicated that SIEFs work well when led by a third-party organisation; however, this, in turn, increases the costs
- Furthermore, with regards to the Cefic (European Chemical Industry Council) programme which commits to dossier updates, the Read-Across Assessment Framework (RAAF) rules are quite stringent, meaning that, where Read Across was thought sufficient in the past, testing would be required, increasing costs and making it difficult to comply with the deadline.
- A lead registrant noted that SIEF were useful in the registration process and disagreed with others' interventions that SIEF had not been effective. Nevertheless, the participant acknowledged that SIEF led to additional administrative burden from dealing with a large number of requests, in addition to carrying out their own registration activities.

Cost sharing

- A consultant mentioned that large companies usually have the necessary expertise for registration, which small companies benefit from by being part of the same SIEF or consortium. This expertise from larger companies is, however, not necessarily covered by the costs of an LoA.
- An economic operator noted that it was difficult for them to obtain detailed information on the split of the LoA costs between members of a SIEF and/or consortium, confirming the survey results: this was particularly the case for administrative costs, which they thought to be higher than testing costs.
- An operator stated that, in their experience, the process of cost sharing had generally been fair to companies involved, although disputes can arise.
- A member of a trade association indicated that cost sharing was applied in several ways, depending on the specific consortium, which makes it difficult to provide general views on the process of sharing costs among members and on possible issues encountered. The participant further stated that the perception from consortia members on cost sharing depended on their level of involvement in the preparation of the registration dossier. It was confirmed, however, that in some instances, prices were considered unfair.

3. Key points from the online workshop 2

3.1 Plenary session

3.1.1 Project and workshop overview

The workshop started off with an overview of the project background presented by Otto Linher from the European Commission, DG GROW. The structure and objectives of the online workshop were also presented.

Following the opening session, during the plenary Wood presented a description of the project context, a description of the project scope and key elements of the consultation. The presentation included an overview of findings from the online survey and interviews from the study. Topics covered included:

- Effects on chemicals markets: structural changes in the market, supply of chemicals and product withdrawal, changes in prices, innovation, R&D, trade, competition, benefits for the industry as a whole
- Communication obligations within the supply chain/downstream users: challenges, concerns and cost drivers from communication obligations under REACH for downstream users; challenges and cost relating to eSDS.

A summary of the general findings presented to participants in workshop 2 for each topic is provided in the sections below.

3.1.2 Impacts on EU chemicals market

Information was gathered on structural changes such as change in price, supply and chemical substance availability in the EU as a result from the REACH 2018 registration deadline. General findings for this specific objective include:

- Overall, about 45% of organisations responding to the survey reported that profits had decreased but a third of respondents reported no impact on their profits. Of those facing a substantial decrease in profits, smaller companies seemed to be the most affected, while larger companies seemed more likely to have faced only a slight decrease in profits. Only a few respondents experienced increased profits due to the 2018 registration deadline. Some interviewees indicated that changes in prices could not be directly linked to the registration process, as other factors could influence the cost of a substance or a product, such as customer demand, other legislation (e.g. restricted substance lists), etc.
- Over half of respondents indicated that registration had had no impact on investments in research and development. However, it was also reported that the registration process had been, for some, an incentive for R&D related to alternative methods, QSAR and read-across. Some companies have been able to orient their R&D activities towards substances with a lower impact on health and the environment. Nevertheless, some interviewees indicated that their staff in charge of research activities had been shifted to regulatory work to comply with the REACH registration process.
- Over half of respondents absorbed the costs of registration by reducing profit margins. Other actions taken on their portfolios or prices as a consequence of the 2018 registration deadline were withdrawing specific products from the market (26%) and raising prices to cover the registration costs (19%).
- It was reported that substances manufactured or placed on the EU market were treated differently than substances in imported articles, which do not need to be registered.

- The issue of free-riders was also raised in relation to competition – i.e. as competitors can access data from other organisations' SDS without paying for the cost of registration.

3.1.3 Communication obligations

Information was gathered on communication obligations under REACH, such as safety data sheets, and the associated cost drivers. General findings for this specific objective include:

- Most respondents felt that communication obligations did not represent a significant cost in the REACH 2018 registration process. For those who did, cost drivers included complicated data requirements, understanding the requirements, poor communication from others in the supply chain, or simply the setting up of new ways of working with the supply chain.
- Respondents provided very wide ranges of costs of preparing SDS (between €200 to €50,000).
- Respondents identified a series of challenges linked to eSDS. First, eSDS were generally considered too long. Stakeholders frequently reported that the information contained in the registration dossier was often inadequate to develop a useful Safety Data Sheet, as this information was too long and too complex. As a result, SDS were often considered as complicated or confusing, even for technical staff. As a result, it was noted that, often, the SDS, on top of being labour-intensive to prepare, were not sufficiently used.
- Hence, the majority of respondents felt that SDS could be improved, e.g. by making them available in all languages, by using automated translation, or by resorting to simplified exposure scenarios.

3.2 Break-out session 1

These sections present summaries of the breakout group discussions and reflections on these topics from the plenary session. Each topic was discussed by two different breakout groups, hosted by a facilitator and rapporteur.

3.2.1 Discussion points

Table 4 presents the discussion points that the break-out groups were asked to consider.

Table 4 Discussion points on effects on the chemicals market

Effects on chemicals markets
What were, according to you, the key changes on the EU chemicals market, driven by the 2018 registration? Consider differences between smaller and larger companies. • Profits in the chemical industry • Structural changes such as withdrawals of products, change in portfolios, withdrawal of company from certain markets, etc. • Prices of substances and products • Research, development and innovation
In your opinion, what are the main impacts on trade and competition on markets? The issue of free riding came up in the survey, what is in your opinion the extent of the issue, and what could be done?

3.2.2 Key points made

Effects on chemicals markets

Impacts on profits and markets

- An economic operator expressed that several cost components from the registration process were "hidden" and that such hidden costs will be difficult to identify and quantify and, therefore, it is complex to determine their related overall impact from the REACH registration exercise on the profits of the chemical industry.
- One participant indicated that, in some sectors, such as dyes for instance, there had been a reduction in companies supplying chemicals on the EU market. However, the participant added that it was difficult to identify the extent to which this had been caused by the 2018 registration deadline alone, as several other factors affect the economy and markets. It was noted it is also difficult to assess the impact of the REACH 2018 registration in isolation, on prices of chemicals, for the same reasons.
- Another point mentioned was that different types and magnitudes of impacts have been observed between manufacturers and importers: importers with a large portfolio of substances sometimes face difficulties in obtaining REACH-relevant information from their non-EU suppliers on the substances that they import. For instance, they might not be able to obtain the analytical information needed to satisfy the needs for substance ID so they would need to generate that themselves.
- Reaching out to the supplier and obtaining information represent a high cost for SMEs, which is usually absorbed by them internally (rather than being passed on to customers) due to the competitiveness of the market.
- For companies operating in volatile markets, for example in the textile market, the portfolio of substances (e.g. dyes) used in products can change quickly, posing a significant challenge for companies who have to frequently submit additional registrations for new substances. Therefore, the registration of a substance is not used for very long before new registration dossiers have to be prepared, and the investment in the registration dossier, which can be quite significant does, not pay off.
- One economic operator expressed that impacts on profits could be higher than what was presented in the survey.: a higher share of registrants were SMEs in 2018, compared to previous registration deadlines, and volumes were thus smaller, resulting in fewer opportunities to cover costs incurred, and therefore leading to a greater impact on companies' profits compared to previous deadlines. However, there were also lessons learnt from previous deadlines, as consortia that had been involved before had experience in how to deal with registration, which made the process more effective in 2018.
- A key point made was that the investment companies make in registrations can be lost when a use is restricted or when a substance is withdrawn from the market following an authorisation requirement.

Presentation of costs

- It was mentioned that there should be more granularity in the way results for small companies are presented in the study. It is difficult to determine the impacts from the registration deadline on SMEs in general, as these impacts will depend on their sector, activity and the competition they face. Companies that operate in niche markets may not benefit from the support from a consortium and will bear more costs by themselves and experience greater impacts on their profits than other registrants.

3.3 Break-out session 2

3.3.1 Discussion points

Table 5 presents the discussion points that the break-out groups were asked to consider.

Table 5 Discussion points on communication obligations

Communication obligations
Why do you think the range of costs to prepare SDS provided by respondents was so wide (i.e. between EUR 200 to EUR 50,000)? • What are the main factors driving the low/high costs of SDS?
How would you improve SDS? • Do you agree with the suggestions made? • Do you have any other suggestions that we have not covered?

3.3.2 Key points made

Communication obligations

Range of costs for SDS

- Many points were made by participants to explain the variability in costs to prepare SDSs. It was reported that the time and cost to prepare an SDS highly depended on the number of products in a portfolio. It was mentioned that the low cost of €200 (presented from the survey results) is likely the cost to prepare a single SDS, and higher costs represent the cost to prepare SDS for a portfolio of substances.
- Costs of preparing an SDS also vary a lot depending on whether a mixture contains several components and on the number of languages into which the SDS needs to be translated.
- An economic operator commented that the costs of the SDS were not significant for large companies, whereas these are more substantial for micro and small companies.

Suggested improvements for SDS

- An economic operator mentioned that eSDS are generally too long (e.g. sometimes hundreds of pages) and contain too much information, meaning that even specialised staff struggle to understand the content, which, in turn, can be counter-productive as they are generally not read. As such, they should be simplified, in particular regarding worker safety instructions. As they are, they represent a really high cost for SMEs while not being sufficiently used. In addition, SDSs received from suppliers from outside the EU sometimes provide very little information or miss relevant information. An example of how to make this more efficient was observed in the Netherlands, where workplace 'instruction cards' are made available to workers which summarise the main hazards and the safety instructions in a very practical way for a specific activity or task.
- Several participants disagreed with the suggestion (from the survey) that the SDS should be provided within the LoA. It was noted that SDS and eSDS were specific to the companies' uses and substances, and therefore, there would be a risk that products are placed on the market

without verifying the applicability of the SDS beforehand, leading, in turn, to liability issues. This view was supported by other participants noting that, in some sectors, companies use different mixtures involving a given substance, and therefore, it would not possible to resort to a single SDS. It was suggested that trade associations or consortia could provide guidelines, templates and support on how to draft eSDS, while the companies themselves would actually draft them, thereby increasing the consistency and harmonisation of eSDS.

- A participant mentioned that there is confusion in the supply chain in terms of what customers can or cannot legitimately ask for – for instance customers get confused and ask for registration numbers for mixtures. An example was raised of one company telling a customer not to purchase from a competitor because they did not have a registration number, even though such a registration number was not needed for a mixture.

Translation of SDS

- Participants discussed the relevance of the translation of the exposure scenarios into other languages, which is a requirement from public authorities: this was considered as a high cost while not bringing substantial added value to users. One participant added that translation was one of the main cost drivers in preparing their SDSs.
- On the other hand, one participant noted that translation was very important to users, in particular as workers do not always understand English.
- ECHA added that although the translation of annexes from the registration dossier are cumbersome and costly, it is a legal obligation to translate them as they are part of the registration dossier. The body of the SDS, on the other hand, should only be translated when useful.

Exposure scenarios

- It was noted by several participants that simplified exposure scenarios should be considered to avoid complexity and make documents readable. One participant added that internal staff also found it difficult to understand exposure scenarios. Participants noted that, in addition to general guidance, a defined template could be developed in the regulation by ECHA. It was also suggested that other working groups could help prepare the templates for exposure scenarios.

4. Closing remarks

4.1 Feedback from breakout groups

Following the breakout groups, the participants reconvened in the plenary session and the project team provided brief feedback. The breakout group sessions were useful to the study team in gaining valuable feedback on personal experiences and views on the costs of the 2018 REACH registration and helped to build on the preliminary findings from the literature review, online survey and interviews. The workshop discussions also provided insights into the important factors at play on the impacts of the 2018 REACH registration process.

4.2 Next steps

The team summarised the next steps towards the finalisation of the study, which are as follows:

- Carry out **remaining interviews** in November and December with trade associations (e.g. downstream users), NGOs, ECHA and its Board of Appeal and Directors' Contact Group, SIEF and consortia managers, as well as additional companies that could help.
- Develop **a series of case studies**, to allow for in-depth understanding of certain topics.
- **Triangulate the information** obtained from all sources, comparing perceptions (from interviews), observations (from the survey) and documentation (written evidence from the literature), using transversal analysis and expert judgement. The project team will review the feedback received and cross-reference responses collected from various engagement methods in order to validate, assess their quality, and identify any possible trends and patterns or highlight inconsistencies.

The notes from the workshop, summarised in this report, will be used by the study team in preparing the final report for this study, due early 2020.

Appendix A
Workshop agenda

Date: Wednesday 14 and Wednesday 21 October 2020

Meeting at: Online

Subject / purpose:

Two webinars for the study to provide insights on '*the impacts of the REACH 2018 Registration Deadline.*'

Online workshop 1 – 14 October 2020

CET	Start – end minute	Session
9:00	0 - 5	Opening & objectives of the webinar
9:05	5 - 25	Overview of findings (so far) of the study 'Impacts from the 2018 REACH registration deadline on economic operators' – outcome from the research and online survey with ca. 300 responses on: • Direct costs of registration, including costs of update • Resourcing and consultants • Participation in SIEFs and consortia • Benefits from the 2018 registration Introduction to break-out sessions and reminder on structure of rest of the day
9:25	25 - 30	Time to split in one of the two break-out sessions
9:30	30 - 50	Break-out sessions: • **Direct costs of 2018 registration** (including update) & **resourcing**, **consultants** o Main drivers in costs of registration (incl. costs and types of training sought, etc.) o Availability of adequately qualified persons to deal with REACH within and outside companies, including SMEs' constraints in acquiring qualified staff or consultants o Any disproportionate impacts/costs for SMEs? o Lessons learnt and ways to make registration more cost-effective in the future
9:50	50 - 65	o **Benefits from the 2018 registration** for economic operators o Possible increase/improvement in knowledge of hazard profile within the company, as well as knowledge of chemical use/ exposure levels,

CET	Start – end minute	Session
		possible lower disease rates in the workplace, any cost savings?
10:05	65-85	• **Participation in SIEFs and consortia** ○ Price policies of SIEF, including on transparency, fairness, communication practices ○ Affordability of SIEF price policies per type, size, sub-sector, business model, location. ○ Impacts on operators from the cost-sharing disputes and solutions found
10:25	85 - 95	Time to join the plenary (& grab a coffee!)
10:35	95 - 110	Feedback from the break-out sessions & key take-aways
10:50	110 - 115	Next steps to finalise the project
10:55	115 - 120	Closure

Online workshop 2 – 21 October 2020

CET	Start – end minute	Session
9:00	0 - 5	Opening & objectives of the webinar
9:05	5 - 30	Overview of findings (so far) of the study 'Impacts from the 2018 REACH registration deadline on economic operators' – outcome from the research and online survey with ca. 300 responses on: Effects on the chemical markets: supply of chemicals innovation, R&D, trade, competition, benefits for the industry as a whole Communication obligations with the supply chain / downstream users Introduction to break-out sessions
9:30	30 - 35	Time to split in one of the two break-out sessions
9:35	35 - 60	Break-out sessions: Effects on chemicals markets: structural changes in the market, supply of chemicals and product withdrawal, changes in prices, innovation, R&D, trade, competition, benefits for the industry as a whole
10:00	60 - 85	Communication obligations within the supply chain / downstream users Challenges, concerns and cost drivers from communication obligations under REACH for downstream users; challenges and cost relating to eSDS.

CET	Start – end minute	Session
10:25	85 - 95	Time to join the plenary (& grab a coffee!)
10:35	95 - 110	Feedback from the break-out sessions & key take-aways
10:50	110 - 115	Next steps to finalise the project
10:55	115 - 120	Closure

Appendix B
List of sectors

The table below provides the list of sectors covered in the study as far as possible, along with their NACE Rev. 2 classification on Eurostat. The questionnaire survey uses the same list – but amalgamates several of the individual NACE codes to ease the process of responding.

Sub-sectors covered (corresponding NACE code)
Agriculture, forestry and fishing (A)
Mining and quarrying (B)
Manufacture of food products (C10)
Manufacture of beverages (C11)
Manufacture of tobacco products (C12)
Manufacture of textiles (C13)
Manufacture of wearing apparel (C14)
Manufacture of leather and related products (C15)
Manufacture of wood and of products of wood and cork except furniture (C16)
Manufacture of paper and paper products (C17)
Printing and reproduction of recorded media (C18)
Manufacture of coke and refined petroleum products (C19)
Manufacture of basic chemicals, fertilisers, plastics and synthetic rubber in primary forms (C20.1)
Manufacture of pesticides and other agrochemical products (C20.2)
Manufacture of paints, varnishes and similar coatings, printing ink and mastics (C20.3)
Manufacture of soap and detergents, cleaning preparations, perfumes and toilet preparations (C20.4)
Manufacture of other chemical products (C20.5)
Manufacture of man-made fibres (C20.6)
Manufacture of basic pharmaceutical products and pharmaceutical preparations (C21)
Manufacture of rubber and plastic products (C22)
Manufacture of other non-metallic mineral products (C23)
Manufacture of basic metals (C24)
Manufacture of fabricated metal products, except machinery and equipment (C25)
Manufacture of computer, electronic and optical products (C26)
Manufacture of electrical equipment (C27)
Manufacture of machinery and equipment (C28)
Manufacture of motor vehicles, trailers and semi-trailers (C29)
Manufacture of other transport equipment (C30)
Manufacture of furniture (C31)
Manufacture of games and toys (C32.4)
Manufacture of medical and dental instruments and supplies (C32.5)
Other manufacturing (excluding manufacturing of toys or medical and dental instruments) (C32)
Electricity, gas, steam and air conditioning supply (D)
Water supply; sewerage; waste management and remediation activities (E)
Construction (F)
Wholesale and retail trade (G)
Transporting and storage (H)
Professional, scientific and technical activities (M)
Other (to be specified by respondent or interviewee)